UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

REPORT OF THE PRESIDING OFFICER

ON

PROPOSED TRADE REGULATION RULE

FOR THE
HEARING AID INDUSTRY
[16 C.F.R. Part 440]
[Public Record 215-44]

This report, required by Section 1.13(f) of the Commission's Rules of Practice, contains the Presiding Officer's summary of the public record and initial findings and conclusions with regard to those issues designated by the Presiding Officer and such other findings and conclusions as he sees fit. The report has not been reviewed or adopted by the Bureau of Consumer Protection or the Commission. The Commission's final determination in this rule-making proceeding will be based upon the record taken as a whole, including this report by the Presiding Officer, the report and recommendations prepared by the staff under Section 1.13(g) of the Rules of Practice, and comments upon these reports received during the 60-day period after the staff report has been placed on the public record.

G. Martin Shepherd
Presiding Officer

August 1, 1977

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SUMMARY, FINDINGS, AND CONCLUSIONS

G. Martin Shepherd, Presiding Officer.

PART I. INTRODUCTION

A. Preliminary matters. This proceeding commenced with publication of the Initial Notice in the Federal Register on June 24, 1975.[1] The notice included the full text of the proposed rule, reference to the legal authority under which the rule was proposed,[2] a statement describing with particularity the reason for the rule, an invitation to all interested parties to propose disputed issues of fact which they considered material and necessary to resolve, and an invitation to all interested parties to submit written comments on the proposed rule. Augmenting the text of the rule and statement of reason therefor, the Initial Notice contained (1) 30 in-depth questions particularly relevant to the basis for the rule and (2) an invitation to comment thereon.[3]

After publication of the Initial Notice, G. Martin Shepherd was designated as the Presiding Officer by the Special Assistant Director for Rulemaking, Bureau of Consumer Protection, William D. Dixon, and a public record for the rulemaking proceeding was established. Attached to this report as Appendix III is an outline of the format of the record. The basic format was intended to separate information and documents submitted on the basis

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1 40 Fed. Reg. 26646. Copies were mailed to interested parties known to the staff.

2 15 U.S.C. 41, et seq.

3 The Initial Notice conformed in all respects to provisions of § 1.11 of the Commission's Procedures and Rules of Practice (Rules of Practice) (16 C.F.R. § 1.11). A copy of the Initial Notice is attached as Appendix I.

of source and type of material. For instance, comments received from consumers, industry members, government sources, and technical and scientific sources are in separate sections. Comments received are separated from official notices, petitions, motions, and responses thereto. The transcript of the hearings and hearing exhibits are separated from written comments, and other types of materials are grouped under appropriate headings. Indefinite or incomplete information and minor clerical errors caused a relatively small number of submissions to be categorized improperly, but all written comments have been reviewed and taken into consideration. Each section of the record has its own pagination starting with page "1."

Citations to the record in the text or footnotes of this report will be with the following abbreviations:

R - Written record consisting of written comments and material submitted pursuant to Initial and Final Notices, material placed on the record by the Presiding Officer or by the Commission Staff, and rebuttal submissions. Citations will be to section and page (i.e., R-3-1401).

Some citations may be to document numbers. These will show the section of the record in which the document may be found and the number of that document. For example, "R-10-D101-15" would indicate a reference to page 15 of document number 101 found in Section 10 of the record.

Tr.- Transcript of the informal hearings.

HX - Exhibits presented and directed to be placed in the record at the informal hearings other than those attached to witnesses' statements and incorporated into the record as part of such statements.

By Notice in the Federal Register of August 19, 1975, the Commission extended the period for filing "proposed issues of specific fact" concerning the rule from August 25, 1975, to September 24, 1975.[4]

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[4] 40 Fed. Reg. 36145--copy attached as Appendix IV.

The Presiding Officer's Final Notice was published in the Federal Register on December 30, 1975.[5] It contained the information described in Section 1.12 of the Commission's Rules of Practice including the dates and places for the public hearings on the proposed rule. It established a termination date of February 27, 1976, for the receipt of written comment on the proposed rule. Pursuant to Section 1.13(d)(1) of the Rules of Practice, the Presiding Officer designated 35 issues for consideration in accordance with Section 1.13(d)(5) and (6). The issues were designated after consideration of the early written comments and the nine submissions from interested parties (including two from the staff) proposing disputed issues of fact.[6] Three petitions for the addition, deletion, or modification of those issues were filed.[7]

The Commission considered and denied the petitions and appellants were so notified by letter from the Secretary dated March 8, 1976.[8] This left the Presiding Officer's designated issues intact and none were modified or added during the proceeding.

Pursuant to authority of Section 1.13(d)(5)(ii) of the Rules of Practice, the Presiding Officer announced, by memorandum of March 5, 1976, the designation of six groups of interested parties. R-1-D53. The groups designated as having members with the same or similar interests in this proceeding were: (1) Manufacturers, (2) Retail Dealers, (3) Audiologists, (4) Medical Profession, (5) Senior Citizens-Consumers, and (6) Other Consumers. The memorandum was forwarded to Legal and Public Records for inclusion in the Record on March 5, 1976, and copies were mailed to those who had advised that they desired to participate as "interested persons" at the hearings. The memorandum advised those desiring to participate that they were required to select their group representative (for the purpose of examination of witnesses) and that the Presiding Officer had communicated with certain interested persons who had indicated "(1) substantial agreement of their group members, (2) a capability, and (3) a willingness to be designated as Group Representatives for the purpose of examination, including cross-examination." Therefore, the following interested persons were recognized by the Presiding Officer as Group Representatives:

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5 40 Fed. Reg. 59746. A copy of the Final Notice is attached as Appendix II.

6 R-2-D1-9.

7 R-1-D49-51.

8 R-1-D70.

Group 1--Manufacturers--Thomas V. Vakerics, Esq., of the law firm of O'Connor & Hannan, which represents the Hearing Aid Industry Conference (a national hearing aid manufacturers' trade association). (Other membership of Group 1 were also named.)

Group 2--Retail Dealers--Timothy J. Waters, Esq., of the law firm of Peabody, Rivlin & Lambert, which represents the National Hearing Aid Society (a national retail dealers' association).

Group 3--Audiologists--Larry B. Cornish, Esq., Director, Federal Affairs Division, American Speech & Hearing Association. (Prior to the hearings Mr. Cornish resigned and was replaced by Richard J. Dowling, Esq., of the same Association.)

Group 4--Medical Profession--Harry W. McCurdy, M.D., F.A.C.S., Executive Director, American Council of Otolaryngology.

Group 5--Elderly Consumers--David H. Marlin, Esq., Director, Legal Research and Services for the Elderly, National Council of Senior Citizens, Inc. (Other legal counsel associated with NCSC were named later to represent this Group at the hearings in Chicago and San Francisco.)

Group 6--Other Consumers--Glenn A. Goldberg, Esq., Executive Director, The National Center for Law and the Deaf.

Two of the groups did not actually participate in the hearings except on the brief occasions when they presented witnesses. For instance, the medical profession never had a representative present to examine witnesses, and a consumers' group representative, Glenn A. Goldberg, Esq., relinqished his status to the National Council of Senior Citizens (David H. Marlin, Esq.) which, in fact, represented the consumers' interests throughout the proceeding. R-1-883-84. Requests for financial compensation for costs of participation in this proceeding were received from five parties who actually took part or desired to participate. Such applications were given attention as required by Section 1.17 of the Rules of Practice. Four applicants were consumer groups and one, the National Hearing Aid Society, is the industry's national retail dealers' association.

Funds were granted to the National Council of Senior Citizens to represent consumers at the hearings and examine witnesses at the three hearing sites, to investigate and report on consumer experiences, to present expert and consumer witnesses, and to submit final comments.[9] The attorneys appearing on behalf of

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[9] Application, R-1-349-67. Approval, R-1-406-09, 569. Supplemental application, R-1-573-79. Supplemental approval, R-1-895-97.

NCSC at the various locations represented the consumers' interests in a most creditable manner.

An application from the California Citizens Action Group was under consideration but was withdrawn by that group.[10] Applications of two consumers' groups were denied.[11]

Although compensation was granted to the dealers' association, the National Hearing Aid Society, receipt thereof was made contingent on future contributions from its members to help finance participation. This resulted in the association receiving no compensatory funds.[12]

An informal "off the record" prehearing conference was held on April 5, 1976, and all group representatives attended. Its primary purpose was to discuss basic procedural matters and explore the manner in which the hearings would be conducted under the new "hybrid rulemaking" procedures set forth by the Magnuson-Moss amendments to the FTC Act and by the Commission's new Rules of Practice. The Presiding Officer promised to conduct as informal a proceeding as the participants and the law would allow, but he reserved the right to maintain flexibility to deal with problems as they arose. All were cautioned to accord all witnesses respectful treatment and, for the most part, all witnesses were treated quite courteously. Many subjects were discussed at the conference which do not require discussion here, but it appeared that the conference was worthwhile.

B. Informal public hearings. The informal public hearings commenced in Washington, D.C. on April 12, 1976, and continued at that location for 5 weeks to May 15 (27 days including two Saturdays). The second site was Chicago where hearings were conducted from June 7, 1976, until June 29 (18 days including one Saturday). The third and last site was San Francisco where hearings opened on August 2, 1976, and terminated on August 18 (13 days). Thus, there were actually 58 days of public hearings in

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10 Application, R-1-964-82. Withdrawn, R-1-1024.

11 Application of Consumer Association of Kentucky, Inc., R-1-403-05. Denied, R-1-808-09. See also application of New York League for the Hard of Hearing, R-1-984-1021. Denied, R-1-1091-92.

12 Application, R-1-1093-1106. Request for more information, R-1-1107-08. Supplemental information, R-1-1109-30. Conditional grant, R-1-1134-37. See also additional correspondence relating to the application, consideration thereof, and advice from NHAS that it was ineligible to receive funds in view of the conditions attached to the grant, R-1-D314-18.

which approximately 203 witnesses were heard. The transcript of testimony includes 12,018 pages. Four physical exhibits and 234 hearing exhibits (many with other documents attached) were placed on the record. The entire record includes over 60,000 pages.

All witnesses who requested to be heard and who satisfied the requirements of the Final Notice for the submission in advance of either a fully prepared statement or a "detailed and comprehensive outline"[13] were heard except for two who had schedule conflicts and several who, for reasons of their own, cancelled their scheduled appearance. One noncontroversial consumer witness who was scheduled to appear could not wait when the hearings were running an hour late.[14]

One controversial witness was unable to testify and be examined in Chicago due to a misunderstanding as to how early he would appear and the necessity of his return to Detroit on an early flight. This witness, Edward J. Hardick, Ph.D., Associate Professor, Department of Audiology, Wayne State University, had submitted extensive comments supporting the rule and probably would have been subjected to extensive cross-examination.[15]

Efforts to finance and reschedule Dr. Hardick failed but, as an alternative to cross-examination he voluntarily agreed to respond to written interrogatories which were invited-- but none were forthcoming. Dr. Hardick's submissions remain on the record as written comments.[16] Although Dr. Hardick's submissions supportive of the rule were extensive and provoked controversy, neither his testimony nor complete examination thereof could possibly even approach being outcome determinative of any issue. The evidence and expert opinions he offered were, for the most part, merely corroborative of that which a large number of audiologists had previously offered and about which they had been examined and re-examined.

To avoid what the group representative for the manufacturers viewed as potential difficulty,[17] he was permitted generous blocks of time in which to schedule his group's witnesses. The same

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13 See 40 Fed. Reg. 59747, Appendix II of this report.

14 Tr. 6353-56. See statement of A. M. Oppenheimer at R-10-4859.

15 For on the record discussion of this matter, see Tr. 6356-65, 6396-97.

16 R-10-5564-66, 6400-38; R-5-D120, R-8-D697-774, D779-784.

17 See request by HAIC, R-1-447-48.

privileges were granted to the group representative for the dealers. For the most part, this arrangement worked well and was executed in apparent good faith (Tr. 5) but a few problems (not worthy of mention here) arose which led to tighter control of the scheduling process at the third hearing site.

One problem, which has presented itself in other Magnuson-Moss proceedings,[18] concerns the contacting of witnesses after they have filed their requests to appear but prior to their appearances. Industry counsel maintain they have every right to request extensive responses from such persons in order to prepare for examination. Apparently, there are no prohibitions against such contacts.

Early in this proceeding witnesses began advising the staff that they had received letters from the attorney for the Hearing Aid Industry Conference requesting that they produce a multiplicity of documents on a multiplicity of subjects concerning issues related to the proposed rule.[19] Any attempt to respond to such a request would have been quite burdensome and, in most cases, burdensome in the extreme. Tr. 95-96. Many witnesses were quite concerned and perplexed by the requests and sought advice. Their reactions ranged from being humorous about it to being quite distraught. Dr. Darrel E. Rose stated he was "not offended" by these things and it "didn't frighten" him because he has a "legal staff to protect" him. He did not feel harassed. Tr. 478-79.

However, some other witnesses not having ready access to legal advice sought such advice from the staff and/or private counsel. For instance, according to Commission counsel, some believed there was some legal process attached to the request. Tr. 99, 300. One witness reported seeking a lawyer's advice because she thought the letter was a "precursor to a subpoena." She felt intimidated and harassed.[20] One unnamed witness was reported to have become "absolutely . . . unglued by the receipt of that letter."[21] Another witness felt she "had to reply to it" or "there would be other methods pursued." She was "very upset"

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18 See, e.g., Report of the Presiding Officer in re: Trade Regulation Rule for Proprietary Vocational and Home Study Schools. Public Record 215-38, at 6-8.

19 See, e.g., HX-7T which is a copy of a letter and attachment typical of the 20 letters the attorney said he had forwarded. See also Tr. 95-101, 543-45 where the matter was discussed.

20 Bonnie Smith, Tr. 294, 296.

21 Id. at 301.

by the letter.[22] The letters of request could certainly lead many nonlegal minds to be extremely concerned.

Reacting to this problem, the Presiding Officer directed that anyone seeking information from potential witnesses must make it abundantly clear on the face of the written request that the request is for a "voluntary" response and that the individual need not reply.[23] Subsequent written contacts with witnesses conformed to those instructions according to the attorney involved. Nevertheless, requests for information from witnesses need not be limited to written communications and, in fact, were not in this proceeding. Other contacts were made by telephone[24] and such contacts are, at best, difficult to appraise for compliance.

Of course, there are numerous other problems witnesses may face, but another worthy of mention occurred in this proceeding when William E. Lentz, Ph.D., Director, Hearing Clinic, Colorado State University, was advised by Jack Glasgow, Chairman, Board of Hearing Aid Dealers, Department of Regulatory Agencies, Denver, Colorado, that the Board had authorized him to convey to Dr. Lentz "its displeasure at your public testimony, and its regret that it will be unable to utilize your services in the future." Of course, Dr. Lentz's testimony was critical of hearing aid dealers and applicants for licenses to sell hearing aids (whom he had tested for the Board).[25] While we do not have all of the facts in this case, those facts on the record cast a serious shadow of doubt upon the reason for and wisdom of the Board's action.

The point of this discussion is that there have been instances where witnesses have felt intimidated, harassed, or, at the least, burdened by those with opposing views. Fear of harassment or retaliation for testimony is nothing new to the field of law, but it should be reduced to a minimum in proceedings of this nature. Such tactics will burden and discourage witnesses--if not drive them off. It may be that the Commission will want to consider such problems and possible remedial action as it gains experience in Magnuson-Moss proceedings.

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22 Gretchen Syfert, individual witness, Tr. 5209-10.

23 For on the record discussion, see Tr. 95-99.

24 See letter of Apr. 9, 1976, from Joan Z. Bernstein, Acting Director, Bureau of Consumer Protection, to Thomas V. Vakerics, Esq., discussing contacts with witnesses, R-1-806-07, and his response of Apr. 24, 1976, R-1-825-26.

25 For correspondence relating to this matter see R-1-1486-94; R-1-D294-95, D305-06.

Examinations of witnesses appearing at the hearings were conducted by all group representatives present and indicating a desire to do so. No other persons present requested to participate in examination during the course of the hearings. Because the rule proposed was very broad, it was necessary to designate several broad issues (in the Final Notice) upon which examinations would be permitted. Also, many of the designated issues which were more narrowly drawn unavoidably opened up vast areas of relevant inquiry, especially where scientific and highly technical facts were involved. For a full and true disclosure of the enormous number of relevant facts related to the 35 designated issues, not to mention the multiplicity of subissues and side issues, broad license for examination became necessary.

Under such circumstances, it would have been extremely time-consuming to have required counsel to adhere to the practice of stating justification (orally or in writing) for each of their questions or lines of inquiry as provided for under Section 1.13(d)(5)(i) of the Rules of Practice. The forum could have been converted into an endless series of debates between the Presiding Officer and counsel, and little questioning could have been accomplished within any reasonable time. It would have become a forum for error and alleged error while the Presiding Officer ruled on the spot as to the (1) relevancy of particular questions to particular designated issues, (2) whether examination was necessary or rebuttal submissions or additional oral presentations would suffice, or (3) whether a particular presentation was required for the resolution of a designated issue, etc. Counsel would have been severely tested and restricted as they sought to justify their positions, and the Presiding Officer would have been hard put (at least in this proceeding) to exactly categorize each question as justified or unjustified, relevant or not relevant, etc. The logical and comprehensible flow of examination would have been destroyed.

No Presiding Officer would have been so wise and skillful as to call each shot at the target correctly in the heat of battle. One would need the wisdom of King Solomon to be right every time but, alas, he was not scheduled to preside. Subsequent review of the transcript would have been a logician's nightmare as the reviewer waded through masses of arguments. Therefore, the Presiding Officer chose to modify the more idealistic concepts of limiting examination solely to designated issues because those concepts just would not work well in this setting.

Counsel obviously <u>preferred</u> the Presiding Officer's compromise modification which extended considerable freedom to counsel in their scope of examinations in exchange for reasonable restrictions on each one's time for examination. But it cannot be reported that all counsel <u>settled</u> for the compromise. Some did, but some did not. The transcript is redundant with objections from industry counsel because they were limited as to the time

allowed for examination--although time allotted to them was generous as compared to the time allotted other counsel. In many cases, if the schedule had allowed, the Presiding Officer would have permitted more time for examination. However, it can be reported that the time limitations for examination did not seriously prejudice any party on this record as a whole. It should be noted that there was a substantial amount of apparent posturing for the record by counsel on this "time" issue in the Presiding Officer's opinion.

Where industry counsel were sorely tried for time to examine a witness, they were always free to submit their unasked questions for inclusion into the record for review in accordance with Section 1.13(d)(4) of the Rules of Practice, but this opportunity was taken advantage of only on a few occasions[26] and rejected on others.[27] Of course, all counsel were cautioned repeatedly by the Presiding Officer, at the prehearing conference, in the opening statement (Tr. 7) and throughout the hearings, to pose their most important questions first to avoid running out of time before major points were covered. All were advised to plan and execute examinations so that points and issues within their statutory rights were covered first. Tr. 7. Nevertheless, industry counsel often complained bitterly when their time expired even though their examinations were not always well directed at designated issues.

The most important fact to note in regard to time limitations for cross-examinations, and objections thereto, in this proceeding is that the testimony involved was almost always quite repetitious and came from experts who usually contributed evidence of a cumulative and corroborative nature. There were no "key" witnesses in this proceeding. It is not necessary to indefinitely pursue the same types of experts, one after another, in order to gain a reasonably accurate picture of the basic truth of the matters under discussion, especially when opposing counsel are always permitted to question experts within the scope of their expertise and are not limited to the scope of direct testimony--and they were not so limited in this proceeding.

During the early stages of the hearings, we experimented with various approaches to determine the most beneficial and fair order for direct and cross-examination. It was originally thought that

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26 See Tr. 6612-15 and HX-95. On one occasion counsel submitted a list containing both questions asked and not asked. The Presiding Officer returned the list for corrections, but it was never resubmitted in proper form. Tr. 9417, 9490.

27 See, e.g., Tr. 5921-22.

the customary order of direct examination first, and cross last, would be most suitable. However, counsel soon asked that they be permitted to confer and agree to allocate the time and order for examinations amongst themselves. This tact was briefly tested but did not seem to function satisfactorily. As the hearings progressed, it became obvious that industry counsel could be expected to complain that they were not permitted sufficient time for examination, whether direct or cross, regardless of the system used.

In response, the Presiding Officer determined to adhere more closely to the statutory requirements and permit cross-examination first. Then, shorter periods were allowed for direct examination with another final opportunity for cross. This soon evolved into a system where the Presiding Officer allocated time for direct and/or cross-examination based on his own sense of where it was needed the most under the particular circumstances and in view of the particular testimony. This "playing-it-by-ear" turned out to be the best and fairest approach for this proceeding. No particular rule of thumb dictated who received a certain set amount of time for a particular type of examination, but major emphasis was always placed on the statutory rights for cross-examination. Nevertheless, the value of direct examination was usually recognized, at least to a limited degree, for purposes of clarification, qualification, and even some rehabilitation when necessary, appropriate, and justifiable.

Determinations as to who should have the most time for examinations were often complicated by the fact that many witnesses testified to various propositions (both in support of and against the rule) which seemed to call for legitimate cross-examination from all interested groups. Thus, it was not unusual for a group representative to use this time to engage in both direct and cross-examination of the same witness.

Under the system employed, counsel were relatively free to pursue examination of the issues they believed important regardless of whether the issues were designated. While this led to tangential questions, the digressions were seldom serious, and witnesses were permitted to respond if and as they saw fit.

Most witnesses answered all reasonable questions asked of them in a forthright manner. This is not to say that some preferred not to answer some questions or evade others. Two witnesses refused to answer questions posed by adverse counsel. One expert witness became upset by the manner in which she was

being questioned by both the group representative for manufacturers and the alternate group representative for hearing aid dealers[28] and refused to answer several questions from them.[29]

Another witness flatly refused to answer any questions from the group representative for consumers. This witness was Curt C. Clinkscales, III, National Director of the National Alliance of Senior Citizens--a relatively new organization which has been the subject of some skepticism and criticism. Tr. 10632.[30]

Mr. Clinkscales is not aligned philosophically, politically, or otherwise with the well established National Council of Senior Citizens (Tr. 10638) which received compensation from the Commission to participate in this proceeding to represent consumers. Mr. Clinkscales stated rather vague and ill-defined reasons for refusing to answer questions from the NCSC attorneys. He alleged that NCSC did not "constitute a valid consumer senior citizen input but a paid-for-a-purpose input." He further stated that he refused "to be a party to any sort of a put-up job." Tr. 10632-33. He also felt it was unfair for him to have to respond to questions from an attorney for an organization which he freely and publicly castigated.[31]

In both cases, the witnesses were advised (1) that they were free not to respond, (2) that their testimony would remain on the record, and (3) that the fact that they did not respond to examination would be considered in weighing their testimony. Tr. 6952-53, 10632. This approach was entirely consistent with the Presiding Officer's interpretation of the basic intent of the Magnuson-Moss amendments--namely, to permit volunteer witnesses to say anything they wish to say, orally or in writing, and not be legally bound to respond except in most exceptional (and outcome determinative) circumstances. In neither of the above two cases was the testimony anywhere near being outcome determinative to any important issue in this proceeding.

There will always be a multitude of built in difficulties in scheduling witnesses, especially when a large number are involved. Careful advance planning is essential to avoid many problems. In

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28 Vega H. Weimar, Tr. 6529-34, 6538-39.

29 Counsel for dealers placed on the record questions he would have asked Ms. Weimar, Tr. 6612-15.

30 Jack Anderson, "Watchdogging for the Elderly," The Washington Post, Aug. 1, 1976, HX-170. See also on the record discussion, Tr. 10671-78.

31 For part of the on the record discussion, see Tr. 10632-38.

this proceeding, the staff and the Presiding Officer exerted every reasonable effort to plan for and accommodate those desiring to appear and, for the most part, the plans were well made and executed. When difficulties arise, it will always be easy, in hindsight, to criticize the planners. Since industry counsel were permitted to partake in such planning in this proceeding, they too could be criticized for some results, but no harsh criticisms are necessary or appropriate in this report.

Generally, witnesses filed appropriate and timely requests to appear with sufficient outlines or full statements of expected testimony along with exhibits to be introduced. However, there were many exceptions--all of which were handled with emphasis on exerting every effort toward qualifying each witness rather than insisting upon the literal terms of the Final Notice.

Group representatives were constantly cautioned from the first day of hearings not to construe the Presiding Officer's leniency in such matters as a precedent (Tr. 5) but requests to appear and advance outlines of testimony continued to be tardy and too often inadequate. Therefore, it was often necessary to request additional information from potential witnesses. Since we were dealing with close time limits, a new law, and new procedures which caused at least some misunderstandings on the part of less careful readers, the Presiding Officer kept the gates open for all willing witnesses to enter and contribute their input to the record.

The staff was astute in assuring that its witnesses satisfied the advance requirements, but many other sponsored and unsponsored witnesses had difficulty meeting deadlines with proper statements. As a result, the opportunity for counsel to properly prepare in advance for examinations of witnesses was not always presented. Improvements in meeting advance notice requirements were evident as the proceeding progressed and as the Presiding Officer became less lenient,[32] but problems of this nature can be expected to be common to Magnuson-Moss rulemaking proceedings unless full written statements from witnesses are required well in advance. The Presiding Officer's leniency in qualifying witnesses did not seriously prejudice any interested party in this proceeding.

The deadline for witnesses to submit their outlines or statements of anticipated testimony was set for 3 weeks in advance of the date for the hearings to start at each of the three locations. During the 3 weeks interim periods the staff and Presiding Officer had to review all advance statements, determine whether they were adequate, seek clarifications where they were inadequate, determine how much time the testimony of each witness

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32 See Presiding Officer's memorandum of June 3, 1976, R-1-959-60.

would probably require, estimate the appropriate time for examination of each witness, and then fit the witness into the schedule where it was personally convenient to the witness and as fair as possible to all interested parties. In such situations, everyone's problems come into play and this, naturally, results in at least some minor miscalculations as one attempts to estimate future needs. Many early (but less than perfect) estimates were compensated for at the time of the hearings by allowing more than the originally allocated time for examinations. Most of these problems were solved by juggling time but, of course, there were times when the crystal ball was too cloudy and it was impossible to compensate by squeezing 2 minutes out of one to fully satisfy everyone. Nevertheless, on the record as a whole, nobody was denied fundamental due process because of scheduling problems.

In summary, the noble efforts to avoid undue delay and accommodate all witnesses, and, at the same time, do all of this in the fairest possible manner under all of the varied circumstances, seemed to pay off by balancing out the equities for all concerned. These efforts, coupled with the freedom granted to counsel to pursue their examinations as they thought best, resulted in what the Presiding Officer believes to be a more complete record than it might otherwise have been, and a record that shows all were treated fairly.

The usual rules of evidence applicable to litigated proceedings did not apply to this proceeding. Tr. 7. While counsel were asked to avoid leading questions, they were seldom asked to rephrase such questions. Much time was saved by avoiding continuous and unproductive arguments over matters of this nature. Those who objected to others using leading questions were as guilty of the practice as anyone. R-1-1051. Leading questions often get to the point without taking extra time to lay a "proper" foundation, and they can otherwise elicit meaningful response from experts who are not too likely to be led where they are unwilling to go. In informal proceedings such as this, strict adherence to rules of evidence is unnecessary.

Objections from counsel were permitted but served little constructive purpose. Objections from some counsel often seemed to be used more for the purpose of cautioning one's witness rather than protecting the witness against improper questioning. Objections were sometimes useful and provided guidance to the Presiding Officer for better conduct of the proceeding, but they were usually more disruptive than productive. Constant and quarrelsome objections required the Presiding Officer to preclude further objections on a few occasions in order to save time and prevent further inappropriate disruptions.

Witnesses were not protected from hard questions, but counsel were not permitted to unfairly surprise them, badger them, or treat them belligerently, see, e.g., Tr. 6890-6903. Fortunately, there

were only a few instances where intervention of the Presiding Officer was deemed necessary to assure proper regard for witnesses. Generally, examination was pursued courteously for the proper purpose of exploring the basis for and reasoning behind the conclusions reached or statements made by the long line of experts.

From the beginning of this proceeding it was the Presiding Officer's fervent hope and intent to conduct an informal hearing in a relatively informal and amicable manner. The Congress and the Commission seemed to envision Magnuson-Moss rulemaking as an essentially informal procedure but with certain limited rights for cross-examination and discovery, when necessary, by interested parties. Nevertheless, when industry counsel are bent on converting an informal procedure into a trial, it becomes necessary to cope with their efforts. When industry counsel are intent on attacking the Statute, the Rules of Practice, the proposed rule, and the conduct of the proceeding, it becomes necessary to cope with those efforts too. Under these circumstances, the Presiding Officer's job becomes less pleasant--but more challenging.

From the first few minutes of the hearings, it appeared that some would prefer to transform the hearing from a quasi-legislative fact-finding forum into an adversary proceeding.[33]

The Magnuson-Moss amendments require that final rules be supported by "substantial evidence" on the record as a whole. It is clearly staff's burden and duty to develop that record by introducing evidence believed (1) to support the rule and (2) to disclose the true facts. Some will disagree as to what are the true facts. Of course, industry members and others opposed to the rule can be expected to introduce evidence in opposition, while those favoring the rule can be expected to introduce evidence supporting the rule. Therefore, staff must walk the sometimes fine line between the two extremes and find and introduce the true facts.[34]

In most TRR proceedings, there will be those who do not agree with all that is said and done. Disagreements arise and tempers are strained. There will soon appear to be advocates on various sides of various issues and some of those advocates will contest (probably strongly) whether staff is developing true facts or false evidence. Allegations of bad faith may follow.

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33 The manufacturers' group representative, Thomas V. Vakerics, Esq., requested that the proceedings be suspended until the Commission could respond to his petition to appoint an Administrative Law Judge to preside, Tr. 8-11.

34 The Presiding Officer believes that staff performed all of their many duties in an admirable manner.

And so it was with this proceeding. As those opposed to the rule accused staff of being biased advocates, and as staff was forced to defend its integrity, it became difficult to differentiate this "informal" proceeding from a trial.[35]

The atmosphere of advocacy became unequivocal as industry representatives pressed for more formal procedures and charged other participants (including the Presiding Officer) with improper and biased conduct. Charges and counter-charges between counsel were not atypical occurrences, and far too much time was consumed during the hearings (and on the record) as counsel sought to place their views on the record. To prevent unnecessary, repetitous, and unwarranted discussions of "housekeeping" and other problems from cluttering the transcript, the Presiding Officer chose to force some such exchanges "off the record." But as the conduct of certain of the industry representatives became somewhat more aggressive and, in the Presiding Officer's opinion, less acceptable for the orderly conduct of the proceeding, he determined to allow the record to more accurately reflect the whole of future colloquies. However, he also instructed all counsel to limit extraneous discussions on the transcript and, instead, to present their views in writing for the record--an instruction not always followed without reminders, and, then, often reluctantly.

Counsels' propensity to engage in colloquies on the record can probably be traced to the Presiding Officer's permissiveness during the first few weeks of the hearings. During that period, he purposely permitted rather free expressions of views because all participants were "first-timers" in dealing with the new law and new Rules of Practice for this new version of hybrid rulemaking. Given this new procedure with "limited" rights for examination and other modifications and adaptations of formal procedures, there was abundant room for different interpretations and misinterpretations. Because of this the Presiding Officer wanted all to have opportunity to air their thoughts and make their contributions. But, as the proceeding commenced, it became obvious that such freedom of expression was leading to too much repetitious and needless haggling and had reached the point of diminishing returns.

As the second stage of the hearings commenced in Chicago, it appeared to the Presiding Officer that the group representative for manufacturers and the alternate group representative for dealers were overenthusiastic in their efforts to protect their clients' interests. While the Presiding Officer does not seriously

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35 We need to ask the question, "When should a member of the staff say nothing or take exception when others malign his motives or character, and make various derogatory accusations, etc.?"

question their motives or sincerity, their conduct during the first day in the Chicago hearings indicated that they were going to test the Presiding Officer's resolve to enforce his previous instructions concerning conduct of counsel, as well as test his ability to control the participants.

The type of conduct in question is not that which stands out so vividly on the transcript but, rather, it is more nearly one of attitude, behavior, appearance, tone, and general demeanor--all of which, taken together, amounts to a failure to fully maintain appropriate decorum. It is easier to control counsel's conduct than it is to control their attitude.

As the second day of the Chicago hearings began (Tr. 5724-29), the Presiding Officer advised all counsel that there would be a tightening of the reins in order to produce a less cluttered transcript. Objections would still be permitted but they should not be abused. They should not be made without good reason, and the basis therefor should be stated succinctly. Objections should not be used as an excuse for extensive free wheeling criticism of the conduct of the proceeding. Such comments were to be put in writing for the record rather than on the transcript. Counsel were also advised not to speak out unless they had first been recognized by the Presiding Officer. There had been too many attempts to engage in free and argumentive exchanges.

There is no need to detail the episodes of less than unobtrusive conduct of counsel here at this time, and it should be made clear that the Presiding Officer did not conclude that obstreperous tendencies crossed the line that he would consider separates one from being momentarily out of order as opposed to being blatantly contemptuous.

In advising counsel of the more formal conduct to be required, the Presiding Officer also invited all counsel to submit their written suggestions as to how the conduct of the hearings could be improved. Those comments are on the record. R-1-1026-1050. They were helpful in assisting the Presiding Officer to reconsider his policies, but they did not offer much that had not been previously considered--nor were the alternatives suggested considered to be substantial improvements. However, they did confirm that the conduct of some industry counsel had become cause for concern and that more drastic modifications should be considered. Such modifications or other actions by the Presiding Officer did not appear to be necessary as the proceedings progressed.

Fortunately, as the hearings closed in the Windy City, the Presiding Officer was able to state, "We are concluding on a far better note than when we opened here and that was no trick of fate, no accident." Tr. 9366. Although the following hearings in San Francisco were certainly not devoid of contention, disruptive incidents were relatively minor and only momentary. As the hearings finally closed, the Presiding Officer was able to state,

"I am very glad to say that an improvement has been noted . . . but I have learned a lesson that those who sit in similar chairs must learn. When leniency is mistaken as a sign of weakness, one can no longer afford to be lenient."

Certainly, all of the lawyers who participated in the proceeding lived up to their primary duty to protect their clients' interests and, in that regard, all are deserving of high praise. They all represented their clients with vigor and sincerity. Tr. 12,015.

C. Motions. During the course of this proceeding, there were approximately 75 documents in the nature of motions, petitions, or requests filed and entered in Section 1 of the record. Many contained several propositions and all required serious consideration. None were believed to be merely dilatory in purpose but many, if granted, would have led to long delays. Certainly, no complete discussion of the motions and answers thereto is appropriate or necessary here. The motions and responses are all on the record and the Presiding Officer will stand on the responses of record. (Many other documents, which were not in the nature of a motion or petition, were entered in Section 1 of the record because they related to procedural problems or other administrative matters.)

It is uncertain as to which and how many of those motions, petitions, or requests will be the bases for appeals, but there is a strong possiblility of future appeals to the Courts as business interests muster their forces to test the Magnuson-Moss system for rulemaking.

It was evident from the early stages of this proceeding that vigilant efforts would be made by industry counsel to contest the basic statute, the Rules of Practice, and the entire conduct of the proceeding by the staff, the Presiding Officer, and the Commission itself. Virtually every shred of evidence, every act, and every ruling in this proceeding (which was not in industry's favor) was the subject of objections, motions to strike, or otherwise denounced. There is much more that could be said here, but it will suffice to note that industry counsel have expended considerable efforts to build their record to provide numerous bases for appeals.

1. Status of the Presiding Officer. There are certain categories of motions deserving of relatively brief comment at this time. One involves the Commission's basic decision that a member of the staff of the Bureau of Consumer Protection would be appointed by the Special Assistant Director for Rulemaking

who is also a member of the staff in that Bureau) to be the Presiding Officer "responsible for the orderly conduct of the rulemaking proceeding."[36] Neither the Special Assistant Director for Rulemaking nor the individual appointed as Presiding Officer had any part in the proceeding prior to the appointment. They had no direct or indirect interest in the gathering of evidence or drafting of the proposed rule, nor were they subordinate to the Assistant Director who directed the staff attorneys assigned to the project. Nevertheless, the fact that all staff members were under the direction of the Bureau Director was and will be an issue.

On April 9, 1976, counsel for the Hearing Aid Industry Conference filed with the Office of the Secretary a motion, addressed to the Commission, to (1) disqualify the Presiding Officer and appoint an Administrative Law Judge for this proceeding and (2) suspend the hearing until an Administrative Law Judge could be appointed. Of course, the motion was quite untimely, being filed on the Friday prior to the Monday on which hearings were to commence. Also, it was misdirected to the Commission since the Rules of Practice clearly do not provide for interlocutory appeals of this nature.[37] Accordingly, the HAIC motion was transmitted to the Presiding Officer for disposition pursuant to Section 1.13(c)(1) of the Rules of Pracice and, thus, became the first order of business at the hearings. Tr. 8-11.

The main thrust of the memorandum in support of the motion[38] was that the Presiding Officer was an attorney on the staff of the Bureau of Consumer Protection and, as such, could not be independent (or even appear to be independent) of the "inevitable pressures to conform to Bureau policy."[39] Of course, the motion was denied[40] primarily because there could be no doubt that the Commission was fully aware of the fact that the Presiding Officer was on the rolls of the Bureau of Consumer Protection. This same

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36 See § 1.13(c), Rules of Practice.

37 See § 1.13(c)(2)(i).

38 R-1-601-10 (attachments run to p. 712).

39 Id. at 609.

40 Tr. 8-11 and by letter of Apr. 19, 1976, R-1-713-14.

problem has arisen in other Magnuson-Moss rulemaking proceedings and can be expected to be raised in the future.[41]

It is clear that the Commission never intended for the Presiding Officer to be a judge. He was intended to be more like an administrative officer who controls and conducts an informal rulemaking proceeding in an orderly manner without undue costs or delays, but in such manner as to be fair to all parties as they seek to express their views. His primary mission is to establish a record in what was intended to be, essentially, a quasi-legislative fact-finding proceeding. While the Presiding Officer is still a member of the staff, he has a different status from that of staff attorneys and a different role to play. Since he prepares his own report to the Commission and since he has no vested interest in the preparation of or justification for the proposed rule, there is no reason why he cannot be objective and fair to all parties. While he remains accountable to the Bureau and the Commission for the conduct of an orderly hearing, it is totally unfair to conclude from this that he cannot, will not, or did not perform his essential functions in the fashion intended and directed by the Commission.

2. Requests for more particularity. One of the more important series of motions began with petitions from several parties requesting that staff be required to submit a detailed statement as to the factual assumptions on which the proposed rule is based. In addition to explicit details of the factual assumptions, requests were made for detailed statements of the legal theories, policy considerations, etc. These motions customarily listed various categories of detailed information considered by the petitioners to be essential in order to satisfy the "notice" requirements of the statute and of due process.

Of course, the statute states that "the Commission shall . . . publish a notice of proposed rulemaking stating with particularity the reason for the rule . . . ."[42] The Rules of Practice repeat that requirement and direct that the statement of the reason for the rule shall be in the Initial Notice.[43] (The Rules of

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41 Other allegations in the memorandum in support of the subject HAIC motion included: (1) the Presiding Officer failed to properly apply the provisions of the Magnuson-Moss Act and the Commission's Rules of Practice and (2) the Presiding Officer had demonstrated bias by denying a series of HAIC motions, etc. See also HAIC motion to certify the question to the Commission (R-1-902-05) and response denying it (R-1-906).

42 § 18(b)(1), FTC Act.

43 See § 1.11, Rules of Practice.

Practice also require a Final Notice[44] and direct the Presiding Officer to publish it.)[45] Thus, these motions raised the question of whether the Initial Notice stated with sufficient "particularity" the "reason for the rule."

One of the first such motions requested a ". . . clear and concise Bill of Particulars specifically setting forth those acts or practices which the Commission feels that the hearing aid industry, and Maico [Hearing Instruments, Inc.] in particular, have allegedly engaged in so as to support the necessity for these hearings," etc.[46] The principle motions were submitted by the two major industry associations.[47] The HAIC motion (R-1-67-87), in effect asked for far more detailed information than the Commission would be required to present at any stage of the proceeding up to and including the final promulgation of the rule.[48]

The Initial Notice did set forth a "STATEMENT OF REASON FOR THE PROPOSED RULE."[49] It can be argued that the statement under

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44 § 1.12, Rules of Practice.

45 § 1.13(c)(1), Rules of Practice.

46 Letter of Sept. 10, 1975, from Thomas C. Kayser, Esq., R-1-24-27. Response at R-1-28-31.

47 NHAS motion, R-1-55-66; response at R-1-100-02. NHAS motion to certify, R-1-112-16; response at R-1-117. HAIC motion, R-1-67-87; response at R-1-103-06. HAIC motion to certify, R-1-130-38; response at R-1-163-64.

48 In partial response the Presiding Officer stated in letter of Oct. 28, 1975:

* * *

> With respect to your request that Commission counsel set forth a concise statement of each alleged violation as to each manufacturer, separately numbered, describing the act or practice being challenged, etc., it would appear that you consider this rulemaking proceeding to be a multi-party adjudicatory proceeding to be conducted primarily under procedures used for litigated cases. In my opinion, this tends to misconstrue the intent of the Statute but, evidently, it is the Statute you disagree with, as well as the Commission's Rules of Procedure, and the administration of both. * * * R-1-105.

49 See Appendix I at 26651.

that particular heading did not, by itself, satisfy the requirement that the reason for the rule be set forth "with particularity." However, if this were to be considered a defect, then such defect was certainly cured by all that preceded and succeeded that statement in the very same context in the very same Initial Notice. Those who have complained about insufficient notice have never even acknowledged that the "STATEMENT OF REASON . . ." is surrounded by the explicit provisions of the proposed rule itself and 30 in-depth questions which essentially explore into the reasons and basis for the rule.

In various forms, the motions for more "particularity" continued throughout the proceeding. For instance, by motion of June 17, 1976. R-1-1144-62. NHAS renewed its motion of September 24, 1975. R-1-57-66. In response, the Presiding Officer replied, in part:

* * *

> It is still my position that the Initial Notice satisfied the statute (Section 18(b)(1) of the Federal Trade Commission Act) and the Commission's Rules of Practice (Section 1.11(c)) insofar as it states the "Reason for the Rule" with sufficient particularity to afford interested persons an ample basis for making relevant comments and otherwise participating to the fullest extent in all stages of this proceeding. As previously noted in my letter of October 17, 1975, the Initial Notice is composed of the terms of the Proposed Rule, the Statement of Reason for the Rule, and an Invitation to Comment which contains an extensive array of questions designed to focus attention on the issues of fact, law, policy, or discretion involved. The Initial Notice should be read as a whole and, when it is so read, it will be found to satisfy the requirements of the statute and Rules of Practices.
>
> Again, it must be recognized that the staff is not required by the statute or Rules of Practice to place its entire case on the record at the very outset of this rulemaking proceeding. That is being accomplished during the proceeding. Nevertheless, to further inform interested parties of the information and data it intends to rely upon as a basis for the Rule; the staff did enter considerable information in the Public Record at an early date, and such was the basic information staff intended to rely upon. Of course, much information has been placed on the record by the staff and all other interested parties

and, of course, staff will rely upon much of that information (as is contemplated by the law under which we are working). In this regard, submissions made or sponsored by the staff have been, in large part, merely expansions on the basic information originally referred to in my letter of October 17, 1975. Such procedure is also comtemplated by law.

It should be noted that, in addition to the Initial Notice, the Final Notice contained an extensive list of Designated Issues which were designed to further focus on the important issues in this proceeding and afford further guidance and particularity. Also, during the course of the hearings, there has been ample opportunity to examine and cross-examine witnesses on their presentations and on all manner of issues. There will also be opportunity after the hearings to submit written rebuttal. Again, I believe you have had fair notice, and there will still be even further opportunity to reply after the Presiding Officer's Report and the staff's analysis of the record with recommendations have both been placed on the record. Surely, all of this provides the basic fairness the statute demands. R-1-1163-64.

* * *

As these petitions for more particularity accumulated, it became more evident that there was really less need for the detailed information the petitioners were demanding. As is evident from the response received to the invitation to suggest issues to be designated as material and necessary to resolve,[50] there were many who had a firm grasp of the problems triggered by the proposed rule.

Upon reading the very comprehensive written comments so expertly prepared for, and submitted on behalf of, NHAS and HAIC,[51] one will better realize how completely familiar with the issues and theories the manufacturers, dealers, and their counsel were from the beginning. No doubt, experience gained from the many previous proceedings, hearings, studies, and reports (concerning the industry, its practices, and its problems) contributed to the industry's ability to comprehend exactly what was

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50 See the entire § 2 of this record.

51 See NHAS, R-3-3455-3838 and HAIC, R-3-3839-3996.

involved. The proposed and enacted laws of nearly all of the states in recent years have certainly left little doubt as to the issues and theories. Congressional inquiries, HEW actions, the many extensive reports by consumer interest groups, and the many FTC actions have all served to keep this industry well apprised. The point is that the proposed rule came as no surprise--nor were the provisions unheard of previously. Nevertheless, the Initial Notice still can stand on its own.

3. Discovery. Under ordinary circumstances in a Magnuson-Moss rulemaking proceeding, there should be no need for the use of compulsory process[52] or requests for disclosure under the Freedom of Information Act.[53] This is so because the staff is expected to place on the rulemaking record, as soon as possible after the Initial Notice is published, all available documentary evidence it possesses and on which it intends to rely as a basis for the rule. In addition, staff should make publicly available at the earliest possible date all documents containing information relevant to the rule that would be accessible under the FOIA.[54] Having done this, requests for disclosure will be automatically satisfied.

Soon after the Initial Notice was published in this proceeding the Presiding Officer requested the staff to follow the above noted procedures.[55] Accordingly, staff's first submissions were entered into the rulemaking record by memorandum of August 14, 1975, addressed to the Commission's Division of Legal and Public Records. In that same memorandum, the staff stated:

* * *

> In addition, the staff has decided to make available for public inspection copies of various categories of documents, in order

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52 Compulsory process is covered by the Rules of Practice, § 1.13(d)(6).

53 5 U.S.C. § 552 et seq., and § 4.11 of Rules of Practice, (hereinafter referred to as FOIA).

54 This procedure was not required by the new Rules of Practice, but is in accord with pre-Magnuson-Moss Commission policy.

55 It should be noted that this was only the second trade regulation rule proceeding, (under the Magnuson-Moss amendments and the new Rules of Practice) to have matured to this stage. Therefore, staff had not fully anticipated the Presiding Officer's request and was not immediately prepared to place on the record all of the requested information.

to anticipate, facilitate and comply with any request for access which may be made in the future under the Freedom of Information Act, 5 U.S.C. 552, as amended. These documents . . . include all relevant documents relating to the hearing aid industry that are in the files of the staff attorneys who conducted the investigation of the hearing aid industry which resulted in the Proposed Trade Regulation Rule for the Hearing Aid Industry, 16 C.F.R. 440 with the following exceptions:

1. Documents contained in the files of the following past Commission actions against hearing aid industry members: The Telex Corporation, 79 F.T.C. 61 (1971); Mather Hearing Aid Distributors, Inc., 78 F.T.C. 709 (1971); and Mountain States Hearing Service, Inc., 77 F.T.C. 640 (1970). These are closed matters which contain materials which were not used by staff in connection with the development of the proposed rule. Any requests for access to any of the documents in any of these files that are not already available to the public in Room 130 of the FTC building should be directed to the office of the Secretary pursuant to § 4.11 of the FTC Rules of Practice.

2. The Special Reports of various hearing aid industry members which were placed on the public record as part of the FTC's Advertising Substantiation Program. These are available for inspection in Room 130 of the FTC building.

3. Documents and portions of documents not accessible under the Freedom of Information Act. These include:

a. Documents and the portions of documents constituting internal memoranda, exempt under 5 U.S.C. § 552(b)(5).

b. The identities of consumers and of those to whom the staff has gone for advice, exempt under 5 U.S.C. § 552(b)(6).

c. Certain commercial or financial information that is privileged or confidential, exempt under 5 U.S.C. § 552 (b)(4).

d. Documents and portions of documents constituting investigatory files compiled

for law enforcement purposes, exempt under 5 U.S.C. § 552 (b)(7).

e. Internal memoranda related solely to the internal personnel rules and practices of an agency, exempt under 5 U.S.C. § 552 (b)(2).

4. Publications readily available to the general public, the duplication of which for these purposes would be wasteful. These publications are listed in Attachment I.

5. Copies of documents that are already in the record of this rulemaking proceeding.[56]

The staff assured the Presiding Officer that all relevant materials in the staff's files on August 14, 1975, that were to be relied upon as a basis for the rule or that were accessible under the FOIA were placed either in Section 8 of the rulemaking record or on the FOIA public record as accessible information on that date.[57] Subsequently, the staff collected additional materials and, as soon as they could be processed, they were either introduced into Section 8 of the rulemaking record or made available under FOIA. Some documents which staff had originally made available under FOIA were subsequently introduced into Section 8 of the rulemaking record. Also, some documents previously made available under FOIA were later introduced by the staff as part of certain rebuttal statements and, therefore, were placed in Section 13 of the rulemaking record.

As requests for discovery were received, the petitioners were advised that all relevant and accessible factual materials

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[56] See memorandum of Aug. 14, 1975, in rulemaking record binder 215-44-1-1-1.

[57] Section 8 of the rulemaking record was designated, "Commission Staff Submissions," and was set aside for the staff to introduce evidence to be relied upon to support the rule. The FOIA public record was kept separate from the rulemaking record.

had already been made available to the public,[58] but this was not the end of requests for additional discovery.[59]

By letter of December 12, 1975, HAIC appealed to the Commission the Secretary's denial of access to additional materials under FOIA. After careful review of all undisclosed materials, a few more documents or portions of documents, were made available and HAIC was so advised by the Secretary's letter of January 28, 1976. R-1-1801-04. That same letter advised that, "Requests for production of information believed to be essential, and comments regarding the sufficiency of the rulemaking record, should be brought forward in that forum."

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58 I.e., see R-1-544-45, 791.

59 Among the various motions in the nature of requests for discovery were the following: (1) NHAS petition to expunge documents or produce witnesses, R-1-454-65, response at R-1-475-76; (2) NHAS request to staff to respond to 78 detailed interrogatories and produce documents, R-1-544-45; (3) NHAS motion to compel staff to reply to interrogatories and produce documents, R-1-841-75, response at R-1-876-77; (4) NHAS motion for more particularity as to factual assumptions, R-1-1144-62, response at R-1-1163-64; (5) NHAS motion to compel production of documents, etc., R-1-1166-74, response at R-1-1175-76; (6) NHAS motion to compel production of documents, R-1-1180-1200, response at 1201-02; (7) HAIC request for access to all Commission records including portions of documents deleted from material previously made available under FOIA, R-1-166-82; (8) HAIC request for staff to respond to 78 detailed interrogatories and identify all documents relied upon as the basis for each and every part of the rule, R-1-421-44, staff's response at R-1-475-46; (9) HAIC motion to compel staff to respond to interrogatories and produce documents, R-1-477-516, response at R-1-517-18; (10) HAIC motion to certify #9 supra to Commission, R-1-722-70, response at R-1-771-72; (11) HAIC request for "full access" to witnesses obtained by National Council of Senior Citizens, R-1-580-81, response at R-1-806-07; (12) HAIC motion to compel staff to produce documents, R-1-773-804, response at R-1-805; (13) HAIC request for access to information regarding complaints, R-1-915-16, response at R-1-923; (14) HAIC motion to require production of documents, R-1-1223-63, response at R-1-1264-65; (15) HAIC motion to certify #13 supra to Commission, R-1-1321-22, response at R-1-1323; (16) HAIC motion to compel production of documents, R-1-1411-28, response at R-1-1429; and (17) ASHA motion to compel production of documents from HAIC, R-1-1443-57, response at R-1-1458. This list does not include all motions or petitions in the nature of requests for discovery.

Accordingly, HAIC petitioned the Presiding Officer on April 6, 1976, to require extensive disclosures. R-1-773-804. After considering the request, the staff's response to the request under FOIA, (R-1-791) the Commission's response to the request under FOIA, (R-1-801-04) and the past and expected accumulations of information on the record, the Presiding Officer concluded that HAIC had received all information it was entitled to receive under the law, and all that was needed to protect its rights in this proceeding.

Not only was the request unreasonable in scope, but further disclosure was not required for a full and true disclosure with respect to the designated issues.[60]

In summmary, all nonexempt materials were originally publicly available (except for a few items which were made available after the Commission's review) and the Commission had declined to exercise its discretion to release certain exempt information. Thus, the question was raised as to whether the Magnuson-Moss amendments carved out some exception to the exemptions of FOIA. It is conceivable that information exempt under the FOIA would nevertheless be necesary to establishing a complete rulemaking record and affording due process to all parties. But no bona fide showing of such need was made in this proceeding, and no bona fide showing of need was made under Section 1.13(d)(6) of the Rules of Practice.

From the foregoing, it can be concluded that much ado was made over the alleged lack of notice and alleged failure to disclose material information in this proceeding. In fact, a bountiful supply of material information was made available to the public at a reasonably early date in the proceedings. The proposed rule was spelled out in the Initial Notice with a statement of reason for the rule and 30 in-depth questions relating to the reasons and bases for the rule. The Final Notice designated 35 important issues of fact for consideration--many of which were similar to the questions set out in the Initial Notice. Expert counsel for interested parties had viewed the notices and were well aware of the issues as they so capably demonstrated throughout the proceeding. Nevertheless, requests for more and more discovery continued to occupy much time and effort for all concerned. And, in the final analysis, none of it really seemed to be necessary to a proper consideration of the proposed rule.

Through it all, efforts of the Presiding Officer to distinguish between a trial and this hybrid rulemaking proceeding seemed not to be noticed. But if counsel for the "defense" attempt to insist on converting a Magnuson-Moss rulemaking proceeding into a trial, it will be difficult at times to discern the differences.

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60 See Presiding Officer's response at R-1-895.

Thus, responses by the Presiding Officer such as the following seem to have had relatively little impact on the determined recipients:

* * *

> In my opinion, most of the questions posed to the Commission's staff . . . demonstrate that you have a firm comprehension of the staff's contentions and, therefore, it appears that you should have no real problem working from that vantage point in preparing and submitting presentations during the hearings.
>
> As for the request for detailed statements of the basis for each contention and identification of each document upon which the staff intends to rely in support of each contention, staff has already placed many such documents on the written record, and we can expect much more evidence, information, and testimony to be submitted during the course of the hearing by all interested parties. The time for staff to parse the record in detail comes at a later stage in the proceeding.
>
> In accordance with the manner in which the Commission's Rules of Practice are drawn, we are still in the information gathering stages of this proceeding. Eventually, the hearings will be concluded and then, after 30 days, the record will be closed as to further submissions of information. Subsequently, the Presiding Officer's report and the staff's report will be placed on the Record. By then, interested persons will have had ample time to review the entire record and may then make their comments in light of the record as a whole and the reports submitted by the Presiding Officer and staff. Therefore, you and other interested parties will be accorded full opportunity (1) to know what positions are taken, what contentions are made, and what is relied upon as a basis for such positions and contentions, and (2) to make your comments concerning the same. Thus, it appears that you will have the last word on the record before the matter goes to the Commission for consideration.

In view of the foregoing, I believe that you will have received due process . . . . R-1-517-18.

4. Oath. Some will consider the several motions to require testimony to be under oath a minor matter while some consider it the key to determining whether comments and testimony are trustworthy, reliable, and probative. Counsel for HAIC evidently felt strongly that all written and oral submissions should be under affidavit or oath--or striken altogether from the record. The proposition was incorporated into four motions.[61]

Evidently HAIC eventually saw the wisdom of not striking from the record all written comments not sworn to, but in the latter two motions cited[62] requested that all oral testimony be under oath. All of these motions were denied.

Succinctly stated, among the reasons the Presiding Officer felt it unnecessary and undesirable to require witnesses to testify under oath were the following: (1) Commission custom has not been to require oaths in informal rulemaking proceedings (under § 553 of Title 5, U.S.C.) and, unless a compelling need arises or the Commission indicates a desire to do so, uniformity in Magnuson-Moss proceedings is preferable; (2) requiring oaths would be another step toward converting a basically informal forum into a formal adjudicatory proceeding; (3) the first motion requesting formalization by oaths for oral testimony and affidavits for written comments came much too late for uniform treatment of both written and oral comments; (4) requiring written comments to be sworn to would, in this (or any) proceeding, increase the burden on those submitting comments and increase costs for all concerned; (5) if oaths for oral testimony were required, the question would probably be raised as to the comparative value of the written comments not under affidavit; (6) requiring oaths might create for some a more forbidding atmosphere and result in a chilling effect for those who might prefer not to testify for fear that antagonists might, through misunderstanding or design, attempt to misconstrue and misinterpret the truth they have attempted to speak;[63] (7) it was soon obvious that there would be no need to rely on the honesty of any one person or any small

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61 See R-1-67-77, response at R-1-103-06; see also R-1-130-38, response at R-1-163-64; see also R-1-715-18, response at R-1-719-21; see also R-1-898-900, response at R-1-901.

62 Id.

63 The reader of this record will soon understand that antagonistic feelings are prevalent and comments are too often misconstrued, taken out of context, misinterpreted, or misunderstood.

group of witnesses in this proceeding to determine the truth of any material issue because there would be a multitude of persons providing written comments and oral testimony on all issues--thus, in the aggregate, that evidence which is trustworthy, reliable, and of probative value could be detected; (8) men tend to believe that their biases are based on truth (as they see it) and oaths do not usually alter their opinions--therefore, we must sift fact from fiction and seek that testimony built upon the most solid foundation; etc. R-1-719-21.

5. Participation by Commission Counsel. Brief mention may be appropriate of the motion by HAIC to preclude Commission Counsel from participation in the examination of witnesses and the presentation of rebuttal submissions.[64] The arguments were that the rules of practice do not provide for staff's participation and, even if participation is permissible, staff should be excluded due to failure to comply in a timely manner with the notice requirements. R-1-586.

Of course such formality as notice is unnecessary when the fact that staff will participate is obvious to all. Such notice has never been required in any rulemaking proceeding. In fact, the Presiding Officer did not require HAIC to fully comply with the notice requirements since its interest was obvious.

Staff is not an "interested party" in the same sense as are other interested parties. As counsel for the Commission, staff's role is so implicit in the statutory scheme and the Rules of Practice that there is no valid question as to whether staff will be an active participant in all phases of the proceeding. Staff's role is unique, and it's participation is indispensable and essential in any TRR proceeding. Staff plays various roles as a party in interest and this includes matters where ministerial functions are concerned. In view of these considerations, no notice that staff desired to participate was required by the Presiding Officer who, regardless of the foregoing, has authority to exercise discretion as to who will be permitted to participate.

In passing, it might be mentioned that if the Presiding Officer had excluded participation (in this early Magnuson-Moss proceeding) due to "failure to comply in a timely manner with the notice requirements" as HAIC urged, (R-1-586) then we would have not heard from a large number of witnesses sponsored by HAIC and others. The inconsistent logic demonstrated by this HAIC motion was not atypical of many arguments made in this proceeding.

6. Objections to rebuttal submissions. When the hearings closed on August 18, 1976, the Presiding Officer announced that

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64 R-1-585-93, response at R-1-593a.

the deadline for written rebuttal submissions would be October 22, 1976. Tr. 12,015. More specific instructions concerning the format and content for rebuttal submissions were mailed to all group representatives on September 14, 1976. R-1-1367-68.

Rebuttal submissions from group representatives were filed in a timely manner and all were placed in Section 13 of the record. The staff made 78 submissions totaling 2106 pages. All other submissions amounted to another 2152 pages for a total of 4258 pages.

Attorneys for the National Hearing Aid Society and Hearing Aid Industry Conference soon advised that they desired to file motions to strike much of the rebuttal offered by others and they were informed they could do so. Accordingly, NHAS filed its extensive "Consolidated Motion" on November 24, 1976. R-1-1495-1524. Time was extended for HAIC to file its motion R-1-1558, which was received on December 29, 1976, adding over 1000 more pages to Section 1 of the record with documents in the nature of surrebuttal. R-1-D281. HAIC's attempt to submit surrebuttal documents (long after the deadline for rebuttal) was rejected.

Both of these motions contained extensive objections and arguments relating to rebuttal submissions made by all parties supporting the rule, but their principal thrust was against the staff's rebuttal submissions. Of course, this required staff to review and respond individually to all objections in both motions.[65]

The Presiding Officer reviewed all relevant documents and responded to the motions (by two letters of February 11, 1977) (R-1-D292 and D293) denying the motions for the most part but, in part, making several minor corrections or clarifications on the record.[66] In responding to the NHAS motion, the Presiding Officer stated, in part; "I have . . . concluded that there were no instances of violations by any party of my instructions which would require excision from the record [of rebuttal submissions]." R-1-D292.

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65 For staff's response to the NHAS motion, see Memorandum of Dec. 20, 1976, (31 pages) R-1-1527-57. For staff's response to the HAIC motion, see Memorandum of Jan. 25, 1977, (50 pages) R-1-D290.

66 See corrections noted in three attachments to the Presiding Officer's letter of Feb. 11, 1977, to Timothy J. Waters, Esq., R-1-D292.

In responding to the HAIC motion, the Presiding Officer stated in part:

* * *

> . . . Of course, your motion raises issues not covered in the response to Mr. Waters, the most important of which is your asserted right to submit surrebuttal.
>
> In my opinion, your submission of surrebuttal at this late date, long after the record has been closed to rebuttal submissions constitutes yet another attempt on your part to fashion your own procedures in direct controvention of the presiding officer's instructions. R-1-D293.

* * *

Subsequently, HAIC petitioned the Presiding Officer to certify the ruling denying surrebuttal to the Commission. In response, the Presiding Officer stated, in part:

* * *

> The crux of the arguments you have presented is whether ". . . fundamental due process and fairness require that a party to be regulated by any Commission 'rulemaking' activities should have the opportunity to make final rebuttal submissions in response to all evidence placed in the rulemaking record, not simply to evidence placed in the record prior to the time rebuttal submissions are made by all interested parties." (Emphasis added.)
>
> As you agree in your conclusion (pages 10-11 of your motion), "Neither the Magnuson-Moss Act nor the FTC Rules of Practice specify the timing or extent of rebuttal." Therefore, we may logically conclude that the presiding officer has discretion to set appropriate limitations as to the allowable time for, and permissible extent of post-hearing rebuttal submissions.

* * *

> Your motion was placed on the record along with all attached documents (including the surrebuttal documents) for the limited purpose of serving as evidence of the motion itself but I excluded all surrebuttal statements contained in or attached to that motion insofar as they might be used as evidence on the record for any other purpose.
>
> Under the circumstances you are free to request review of your motion in a separate section of your final comments to the Commission but you should not cite anything in your motion (or attachments) as evidence on the rulemaking record for any other purpose unless and until the Commission extends such opportunity.
>
> Your arguments for the superior right to submit final surrebuttal to any and all evidence submitted during the post-hearing rebuttal period by those who support the proposed rule portrays an inaccurate view of who has predominant interest in a Magnuson-Moss rulemaking proceeding. Dealers and manufacturers are not the only parties having vital interests in Magnuson-Moss rulemaking proceedings. Nor are they the only ones subject to regulation under this proposed rule. There are many conflicting interests and none are necessarily paramount to others. Many parties and groups will be directly affected by the outcome whether or not a rule is promulgated (i.e., medical doctors, manufacturers, dealers, audiologists, consumers, etc.)[67]

As was predictable, subsequent to HAIC's claim for the right of those who would be regulated by the rule to have the ultimate right of rebuttal, the American Speech and Hearing Association claimed the same right under the same theory because its members would also be regulated by the rule.[68] Of course, ASHA represents a large segment of the "hearing aid delivery team," most of whom support most of the provisions of the rule.[69] Audiologists would also be regulated by the rule. If all of those to be regulated

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[67] Letter of Mar. 7, 1977, to Thomas V. Vakerics, Esq., R-1-D309.

[68] Letter of Mar. 8, 1977, R-1-D312.

[69] See ¶ 5 of this record generally.

by the rule are to be given rights to "ultimate rebuttal," there could, indeed, be no end to rebuttal and surrebuttal in this proceeding because the various interested parties could go on responding to each other ad infinitum or, at least, until one wore the others out. Such a procedure could not be tolerated.

The other theory apparently advanced as a basis for the "ultimate right" for rebuttal centers on those who support the rule as opposed to those who are against the rule. Such a distinction would present logical difficulties in this proceeding. Not only could audiologists argue that they support the rule, but some can (and did) argue that they oppose the rule in whole or in part. The same is true of industry members since some do support the rule in whole or in part. In fact, even the staff might make a valid argument that it opposes the rule, in part. Also, one might ask at this juncture, "What happens to the consumers' interests in a fight like this?" Some consumers support the rule and some oppose it. Are consumers not to be given rights for "ultimate rebuttal" individually or through their representative? Obviously, the suggested distinctions are not well placed in this proceeding.

In this proceeding, it seemed fair to follow the usual method used for previous rulemaking proceedings and permit all to make final rebuttal comments at the same time. The Commission can appraise the record as it stands at that point and determine whether further proceedings are necessary.

Almost all parties submitted new evidence in their rebuttal, but the most difficult decisions the Presiding Officer had to make involved certain studies or surveys which definitely included considerable amounts of new evidence which the submitting parties will definitely rely upon (to one degree or another) in their final comments.

As a procedural matter the most difficult new evidence to allow into the record was embodied in a study (submitted by the staff) recently completed by Patricia Powers, M.S.W., Department of Sociology, Utah State University, entitled A Report on Results of Interviews with Utah Hearing Aid Owners. R-13-945-1032. This document reported on a "pilot study . . . to assess the satisfaction of Utah consumers with hearing aids." R-13-966. The Presiding Officer was first advised of the then incomplete study when Ms. Powers filed her advance statement of testimony. R-10-6514. Nothing more was heard of the matter until Ms. Powers appeared as a witness almost 1 month later. At that time, the Presiding Officer cautioned her to "avoid that subject" since we had "no previous information concerning it. Tr. 9836.

In fact, at the hearing, Ms. Powers simply mentioned that her interviews with Utah consumers were about half completed and that she had been advised she could not submit late comments on that portion which had been finished. Tr. 9848. Nevertheless,

several attorneys did ask Ms. Powers many questions relating to her ongoing study in Utah. Then, subsequent to the hearings, Ms. Powers forwarded to the staff and the Presiding Officer (1) various correspondence relating to the Utah study and (2) a copy of the actual report. The report and material relating thereto were placed in Section 14 of the record as "Excluded Evidence" since the period for submitting written comments had long since expired.[70]

In concluding that Ms. Powers' report and related comments could come in as legitimate rebuttal, the Presiding Officer took into consideration all circumstances including the nature of all other rebuttal submissions which contained considerable amounts of "new" evidence. However, none of the new or other evidence offered as rebuttal (including Ms. Powers' report) could possibly be outcome determinative of any designated issue.

Other rebuttal submissions that presented similar problems associated with permitting considerable amounts of new evidence in as rebuttal without the need for further hearings included (but were not limited to (1) a 17 page report (with almost 900 pages of supporting documents) on a survey (conducted on behalf of NHAS) of consumer complaints recorded by various governmental and other agencies (R-13-2714-3588); (2) two statements from two marketing experts (not previously heard from) expressing opinions (on behalf of HAIC) regarding certain economic considerations applicable to the rule; (R-13-D93 and D94); and (3) considerable new evidence with comments submitted by ASHA. R-13-147. All were allowed into the record.

In summary, many interested parties submitted new evidence which appeared to be legitimate rebuttal and which would be useful to the Commission in supplementing previously acquired evidence. However, none of the rebuttal required extension of the proceeding.

Although the question of reconciling the new evidence (submitted as rebuttal) with the massive record as a whole does not appear to present any great difficulty in this proceeding, the same problem will doubtlessly arise in other Magnuson-Moss rulemaking proceedings and could create more serious problems. Unfortunately, there are few absolute and specific guidelines as to what constitutes fair and acceptable rebuttal evidence, so, apparently, each Presiding Officer in each proceeding will have to make individual determinations on a case-by-case basis as to whether rebuttal submissions are acceptable and/or whether some rebuttal demands further extension of the proceedings.

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[70] See HX-222, letter of Oct. 5, 1976, where Ms. Powers was advised of the disposition of her submissions and reasons therefor.

D. Nature of this report. The Rules of Practice require the Presiding Officer to prepare only a "summary of the record, both written and oral, relating to the issues designated" by him,[71] and to make "initial factual findings and conclusions as to these issues."[72] In addition, it will be helpful to discuss some sub-issues, side issues, and other issues in connection with any discussion (even a summary discussion) of the designated issues in this proceeding. Also, the Rules of Practice permit the Presiding Officer to make such other findings as he sees fit--and that authority will be used, but sparingly.

In this report an effort has been made to avoid extended discussions on questions of law or policy, and no effort has been made to make a complete analysis of the record or to redraft the proposed rule. Such matters, for the most part, have been left for the staff.

The findings and conclusions set forth in this report are based on the record as a whole after review of the contents of each section of the record of this proceeding. The Presiding Officer heard every witness and has considered their demeanor as they testified as well as the rebuttal submissions allegedly pertinent to their testimony and/or credibility. The summary, findings, and conclusions include reference to only a microcosm of the possible hundreds of other examples of, and citations for, the various propositions considered.

Written comments submitted by certain associations are in large part capsulizations of the multiplex of communications submitted by the members of the groups they represent. Therefore, it is appropriate to utilize the well-prepared HAIC comments[73] as a microcosm of comments from most manufacturers. Likewise, the expertly drafted NHAS comments[74] will be employed as basically representative of comments by most dealers. Comments from members of both of those groups were almost universally opposed to all parts of the rule.

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71 See designated issues in Final Notice, Appendix II.

72 See § 1.13(f).

73 HAIC, R-3-3839-3996; see also Section 3 of record generally.

74 NHAS, R-3-3455-3838; see also Section 3 of record generally.

To the contrary, the many audiologists submitting written comments were almost universally in favor of most parts of the rule and, therefore, it will be appropriate to use ASHA's extensive statement in support of Dr. Kenneth O. Johnson's testimony[75] as basically representative of most of the comments submitted by audiologists. While the record shows that audiologists sometimes disagree with each other on various issues, it also indicates that they generally hold and express their own individual views which are based on their own knowledge, biases, and experiences. Nevertheless, audiologists usually come out in substantial accord on the ultimate material issues.

In the Presiding Officer's opinion, as a general proposition the comments and testimony of audiologists on this record are the least biased, most trustworthy, and most credible. Comparatively speaking, the Presiding Officer believes that most of the testimony by, and on behalf of, audiologists was based on firmer facts than most other, and is usually entitled to greater weight than most other. The audiologists generally spoke in the most straightforward and objective manner and usually based their conclusions on more specific data rather than on generalities. It may also be noted that they knowingly testified against their own interests regarding key issues (i.e., audiologists profess to be the most competent and knowledgeable regarding the testing of hearing and the selection of the most appropriate amplification for hearing loss, but they were also the ones who testified that even their best scientific procedures and skills were not always reliable indicators of whether an individual would receive significant benefit from use of a recommended hearing aid). Also, it should be noted that audiologists are aware that they too will be regulated by any promulgated rule. Yet, they seem to accept this potential regulation of their own practices as proper and in the public interest. Accordingly, this report places due weight and reliance on such evidence. (Regarding such considerations, see Addendum at Appendix V.)

Any motions, petitions, or requests of any nature appearing on this record not previously or hereby specifically ruled upon, either directly or by the necessary effect of the conclusions in this report, are hereby denied.

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75 Statement in support of testimony by Kenneth O. Johnson, Ph.D., Executive Secretary, American Speech and Hearing Association, R-10-1587-2921. This statement is hereinafter referred to or cited as "ASHA" or as "ASHA comment."

PART II. SCOPE AND NATURE OF THE PROBLEMS

A. General. A great deal of testimony and written comment in the rulemaking record of this proceeding was devoted to a portrayal of the hard-of-hearing individual and the various methods used to improve impaired hearing.[1] The record contains numerous recitals of the roles of various providers of hearing health care including manufacturers, physicians, audiologists, and hearing aid dealers.[2] The tests, equipment, and procedures used in the examination and evaluation of hearing losses are also extensively described,[3] and as might be expected, there is a considerable amount of material dealing with the characteristics of hearing aids and the utility of these devices in improving the hearing ability of those persons who have suffered hearing loss.[4] As this evidence is repeated time and again throughout the record, it is appropriate to address these subjects in summary form at the commencement of this report, for a knowledge of these matters is essential to an understanding of the various issues raised in this proceeding.

B. Characteristics of the hard-of-hearing.

1. The numbers. According to a 1971 Health Interview Survey conducted by the National Center for Health Statistics through the Bureau of Census, there are 14 1/2 million people in the United States who have hearing impairments.[5] This exceeds the 9 1/2 million with visual impairments and constitutes over one-fourth of the 51 million impairments in the

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1 See, e.g., comment of Hearing Aid Industry Conference (HAIC) R-3-3839-81; comment of American Speech and Hearing Association (ASHA) R-10-1609-40, (this comment is in the form of a prepared statement by Kenneth O. Johnson, Ph.D., Executive Secretary of ASHA); comment of National Hearing Aid Society (NHAS) R-3-3503-20.

2 Id., HAIC at 3860-68, 3881-90; id., ASHA; id., NHAS at 3521-41.

3 See, e.g., ASHA, R-10-1609-13; HAIC, R-3-3881-88; and D. Rose, Audiological Assessment, Prentice-Hall, Inc., 1971, R-8-Exh. D.

4 K. W. Berger, "History and Development of Hearing Aids," in Amplification for the Hearing-Impaired, Grune & Stratton, Inc., 1975, R-8-Exh. B-1.

5 Economic Problems in the Hearing Aid Industry; Hearings before the Subcommittee on Government Regulation of the Senate Select Committee on Small Business, 94th Cong., 1st Sess. 98 (1975), statement by Edward B. Perrin, Director, National Center for Health Statistics, Department of Health, Education and Welfare.

country.[6] The survey did not include people residing in institutions where the prevalence of chronic conditions is thought to be much higher than in the general population.[7] For example, a 1973 survey by the Division of Health Resources Utilization Statistics showed that the prevalence of hearing impairments in nursing homes was approximately five times what it was in the general population.[8]

A recent survey conducted by the National Association of the Deaf in cooperation with the Deafness Research Training Center estimates that 174 out of every 1000 persons over 65, or approximately 5,000,000 older persons, have significant hearing impairments.[9] Citing the difficulty of obtaining precise statistics, Arthur Fleming, Commissioner, Administration on Aging in the Department of Health, Education and Welfare estimated in his testimony that this figure would rise to 7,000,000 if those over age 60 were included. Tr. 608.

The Health Interview Survey also showed that slightly less than one-half of the 14.5 million hearing-impaired persons had bilateral hearing losses and 2.5 million had losses so serious that they could best hear and understand only shouted speech. A significant number of this 2.5 million had losses of hearing at birth or lost their hearing at an early age.[10]

Dr. Philip Lawrence, in his testimony before a Senate Subcommittee, said that surveys conducted by his agency showed that the prevalence of hearing impairment was higher among males, members of the white race, and persons living outside of metropolitan areas. The prevalence was lower among the better educated, those who had higher family incomes, and among residents of the Northeast region.[11]

Although hearing impairment is recognized as one of the most prevalent handicaps, it is also one that has received relatively little attention--at least until recent years. This is

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6 Id.

7 Id. at 99.

8 Id. at 98.

9 J. Schein and M. Delk, The Deaf Population of the United States, Silver Spring, Maryland (1974), R-8-Exh. A-29.

10 Economic Problems in the Hearing Aid Industry, Note 5, supra (Statement of Dr. Phillip Lawrence, Deputy Director, National Center of Health Statistics, at 93-94).

11 Id. at 92.

illustrated by the statement that of the estimated "10 million hard-of-hearing," fully 75% have not received medical attention or evaluation to determine if their hearing could be improved.[12] Using the total of 14 1/2 million hearing-impaired, a spokesman for HAIC estimated that only 2.5 to 3 million wear hearing aids today.[13] Whichever totals are used, the figures are impressive in that they show the overwhelming majority of the hard of hearing are not receiving assistance.

2. Personality. Hearing impairment is a serious disability. It is thought to be more debilitating than other types of sensory losses for it has significant effects on personality, speech production, and language development.[14] As Helen Keller is reported to have said:

> I am just as deaf as I am blind. The problems of deafness are deeper and more complex, if not more important, than those of blindness. Deafness is a much worse misfortune. For it means the loss of the most vital stimulus--the sound of the voice that brings language, sets thoughts astir, and keeps us in the intellectual company of man.[15]

Some children are born with hearing defects but such defects may also be the result of illness or accident. An undetected hearing impairment can seriously prejudice the development of the communicative skills of the child and in fact can distort his whole personality. Even though intelligent, he may give the appearance of being dull, retarded, or inattentive, and lazy. This handicap may also be characterized by a refusal to participate in group activities.[16]

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12 David Barnow, a former President of HAIC, Tr. 1631.

13 John Kojis, President, Maico Hearing Instrument Company, Tr. 1970.

14 Final Report to the Secretary on Hearing Aid Health Care, (Prepared by the Department of Health, Education and Welfare Interdepartmental Task Force on Hearing Aids, July, 1975), (Final HEW Task Force Report), R-8-D494-13.

15 Id. at 11.

16 Edith Corliss, Facts About Hearing and Hearing Aids, A Consumer's Guide, NBS Consumer Information Series 4, Ed: James E. Payne, (National Bureau of Standards, U.S. Department of Commerce, November, 1971) R-8-D222-9; Laszio Stein, Director, David T. Siegel Institute of Communicative Disorders, Tr. 8971-73.

Adults who suffer a sudden hearing loss are prompted to do something about it. But most hearing losses are gradual and cumulative and individuals are inclined to conceal these losses for as long as they can. It is a characteristic of the psychology of the aging hearing-impaired to refuse to recognize that there is a handicap because to admit it is tantamount to admitting that they are growing older and are no longer fully capable of coping with the world. The adult may blame others for his difficulty, limit social contacts with others, and become alienated from neighbors, employers, and fellow workers. Family relations may be strained to be followed by a gradual withdrawal of the hearing-impaired person from both family and society. Reluctance to seek assistance or to wear a hearing aid is common.[17] Rather, the individual seeks to conceal his loss from others. If the individual does not realize that he has a hearing impairment, equally difficult communication problems may occur. He may not be able to detect verbal intonations making the speech he hears seem flat and denoting a lack of interest on the part of the speaker. Inability to hear may provoke others to shout which may serve as an irritant to both parties causing them to reduce communications to essentials.[18] The reluctance of the individual to admit hearing loss is fully documented in the record.[19] The record also shows that those who have suffered a hearing loss and who do seek help are constantly looking for a cure or the hearing aid that will not only be invisible but that also will restore the hearing they have lost. Such a search will not be successful.[20]

3. Causes and effect of hearing loss. There are two types of hearing losses. The first is conductive loss which is caused

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17 Richard Fechheimer, Senior Vice-President, Grey-North Advertising, Inc., Tr. 6965; David Barnow, Note 12, supra at 1626; John B. Davis, Executive Secretary, Illinois Association of the Deaf, Tr. 8544.

18 HAIC, Note 1, supra at 3855-56, citing W. G. Gardner, Auditory Impairment and Information Processing for the Elderly, Tulane University School of Social Work, (Ann Arbor, Michigan: Xerox University Microfilms, 1975).

19 HAIC, Note 1, supra at 3857-58; Barnow, Note 12, supra at 1629-30.

20 Mary Burke, Hearing Clinic, Northwestern University, Tr. 6409-13; Ray Stallons, audiologist on behalf of the National Hearing Aid Society, Tr. 7868-69; Mary Ruth Whitman, audiologist, Illinois Department of Public Health, Tr. 8585.

by a blockage in the passage of air or impairment of the mechanical movement in the outer or middle ear. The second is sensorineural or nerve loss which results from damage to the nerve mechanisms in the inner ear. These mechanisms convert the energy produced by the movement of the fluid in the inner ear into nerve impulses which pass along the fibers of the auditory nerve to the brain. Sensorineural losses are sometimes divided into two classifications with "sensory" used to describe an impairment of the systems in the inner ear which convert the mechanical energy into electrical energy. The "neural" pathologies are those which interfere with the transmission of the electrical energy through the acoustic nerve system to the cortex. A person may suffer from both conductive and sensorineural loss in the same ear.[21]

External ear conductive losses may result from a complete blockage of the ear canal. This may be caused by an excessive build up of wax, foreign bodies, infections, and congenital malformations of the external ear and canal.[22]

Middle ear problems may be the result of perforation of the ear drum, infection, interruptions of the ossicular chain as a result of congenital malformations, injury to the head or ear, or to a disease known as ostosclerosis in which bony deposits form between the stapes bone and the oval window so that the lever action of the bones is restricted.[23] Medical and surgical treatment is usually effective in the treatment of these types of conductive losses.[24]

Sensorineural losses may result from hereditary defects, viral illnesses with attendant high fever, reactions to certain drugs such as quinine and some of the antibiotics, and an inner ear disease called Meniere's Syndrome which may also cause head noises, nausea, and dizziness. Other hearing losses of this type may be caused by tumors which interfere with the nerve impulses traveling along the auditory nerve. The aging process which leads to hearing loss is called presbycusis, which is characterized by a gradual decline in hearing

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21 Corliss, Note 16, supra at R-8-D222-6-7; L. L. Price, "Pure-Tone Audiometry," in Audiological Assessment, Prentice-Hall, Inc., 1971, R-8-Exh. D-190-91.

22 Corliss, Note 16, supra at 6-7; Price, Note 21, supra at 191.

23 Id.

24 Id., Price at 195.

ability especially for high pitched sounds.[25] Sensorineural losses may also result from noise. An intensive very loud sound such as that resulting from an explosion may cause immediate and irreversible partial or total hearing loss. Constant but less intense sounds may cause a gradual loss of hearing over a period of time.[26]

A conductive hearing loss is characterized by a diminishment in the loudness and intensity of sounds rather than in the quality of the sound heard. Sensorineural loss may result in a deterioration of the quality of the sound--there may be a continuous hissing or ringing and speakers may seem to be slurring their words or mumbling. High pitched sounds are usually the first to deteriorate.[27]

C. Providers of hearing health care. Throughout this report reference is made to the various providers of hearing health care. Some of these providers compete with members of their own class and some compete with members of the other classes. A brief description of their functions and roles without an attempt to evaluate the effectiveness of their performances is set forth in this part of the report.

1. Physicians. Medical doctors specializing in diseases of the ear and throat are known as otolaryngologists. The term otolaryngology is also used as a short form for the medical speciality devoted to the study of the diseases of the ear, nose, and throat which is technically known as otorhinolaryngology. An otologist is a medical doctor who specializes in problems of the ear.[28] All of these doctors are collectively described as ear specialists but in this report they will be referred to by the term otologists for purposes of clarity and better identification. Otologists strongly believe that entry into the hearing care system should be through the medical component since loss

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25 Corliss, Note 16, supra at 7; Price, Note 21, supra at 195-96.

26 Corliss, Note 16, supra at 7; Price, Note 21, supra at 196; Paying Through the Ear, A Report on Hearing Health Care Problems, Public Citizen's Retired Professional Action Group, (Preliminary Draft, 1973), R-8-D421-VIII-1 (hereinafter the RPAG Report).

27 Corliss, Note 16, supra at 8.

28 J. Delk, Comprehensive Dictionary of Audiology, Hearing Aid Journal, 1975, p. 116. HAIC, Note 1, supra at 3881-82.

of hearing is a symptom of disease.[29] Audiologists also agree that entry into the system should be by way of the otologist and that the latter group have a definite role to play in the treatment and rehabilitative process.[30]

Hearing aid dealers as a matter of policy believe that entry into the system should be through the otologist and that first time users of hearing aids ought to have a medical examination before being fitted.[31] In addition, the National Hearing Aid Society (NHAS) has suggested that the hearing aid dealer or salesman promptly refer to an otologist those patients who demonstrate any of the following seven symptoms: (1) visible congenital or traumatic deformity of the ear; (2) history of or active drainage from the ear within the previous 90 days; (3) history of sudden or rapidly progressive hearing loss within the previous 90 days; (4) acute or chronic dizziness; (5) unilateral hearing loss of sudden or recent onset within the previous 90 days; (6) significant air-bone gap; and (7) visible evidence of cerumen accumulation or a foreign body in the ear canal.[32] Many dealers are reluctant to refer a first-time user to an otologist if the individual appears to be healthy, has had a recent medical examination, and has a hearing loss.[33] Also NHAS has authorized the use of a waiver if the patient does not want a medical examination because of religious convictions or personal reasons.[34] The NHAS proposals

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29 Robert J. Ruben, M.D., Professor and Chairman, Department of Otorhinolaryngology, Albert Einstein College of Medicine, Tr. 3978; Lindsey Pratt, M.D., American Council of Otolaryngology, Tr. 3695; Robert I. Oberhand, M.D., practicing otolaryngologist, Tr. 3034.

30 See, e.g., Jane Madell, Director of Audiology, New York League for the Hard-of-Hearing, New York City, Tr. 5856-57; David Barwell, audiologist and hearing aid dealer, Tr. 5174, 85-86; Henry C. Hecker, audiologist and hearing aid dealer, Tr-5174, 85-86; A. Bruce Graham, Chief, Division of Audiology, Henry Ford Hospital, Tr. 7423.

31 NHAS, Note 1, supra at 3537-38.

32 Id. at 3538, n.71.

33 See, e.g., the testimony of Luke Fortner, President, National Hearing Aid Society, Tr. 2846-47. There is evidence in the record that many dealers do not recommend that prospects visit a physician initially; see RPAG Report, Note 26, supra at I-8.

34 NHAS, Note 1, supra at F-3-3538.

have been somewhat overtaken by events as the Food and Drug Administration of the Department of Health, Education and Welfare (FDA) has recently issued regulations which prohibit a hearing aid dispenser from selling a hearing aid unless the prospective user presents a signed written statement from a licensed physician indicating that the patient has been medically evaluated and may be considered a candidate for a hearing aid.[35] The regulation goes on to provide that a prospective user who is over 18 may waive this evaluation requirement if afforded the opportunity to do so by the dealer and if he executes a prescribed waiver form.[36]

Otologists sometimes refer patients to an audiologist and sometimes directly to a hearing aid dealer. Those who follow the latter practice state that dealers have the ability to conduct the necessary tests to fit an appropriate aid, and that audiological consultations are not necessary in many cases.[37]

2. Audiologists. According to the American Speech and Hearing Association, an audiologist is a health and rehabilitation professional concerned with prevention, identification, evaluation, and rehabilitation of individuals with auditory disorders which impede or prevent the reception and perception of speech and other acoustic signals.[38] Audiologists see themselves as the link between the otologist and the hearing aid dealer believing that following the medical examination the hearing-impaired should be examined and tested by an audiologist who would determine if they are candidates for a hearing aid and if so of what type.[39]

A detailed discussion of the functions and role of the audiologist is set forth in Part V of this report. It is appropriate to note at this point, however, that in recent

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35 21 C.F.R. 801.421(a)(1), 42 Fed. Reg. 9296.

36 21 C.F.R. 801.421(a)(2), 42 Fed. Reg. 9296.

37 Oberhand, Note 29, supra at 3034-37; Richard M. Carter, M.D., Tr. 3649-50; Joseph C. Elia, M.D., Tr. 7475; Austin T. Smith, M.D., who said that in his opinion audiologists simply duplicate the work of the otologist and are not an essential part of the hearing aid delivery system, Tr. 8156; August Martinucci, M.D., Tr. 8385-86.

38 ASHA, Note 1, supra at 1609.

39 Id. at 1610, 1623. See, e.g., James Langford, Associate Professor of Audiology, Northern Illinois University, Tr. 8009.

years some audiologists have commenced dispensing hearing aids to their patients rather than sending them to a dealer for that purpose. This has served to place the dispensing audiologist in direct competition with the dealer.[40]

3. Hearing aid dealers. The hearing aid dealer and hearing aid salesman engage in the retail sale of hearing aids. They are sometimes referred to as "hearing aid specialists," "certified hearing aid audiologists," or as "dispensers." The propriety of using such designations is discussed in Part V of this report and the business practices of hearing aid dealers generally are discussed in Part III. In addition to selling hearing aids, the dealer also fits aids and this requires, at least with respect to those persons who are not referred to him with a specific recommendation for a particular model or type of aid, that he measure hearing loss, determine if an aid will be appropriate, and, if so, select the proper aid.[41] This work puts the dealer in competition with the audiologist for many otologists refer patients directly to dealers rather than to audiologists, and, of course, many patients go directly to dealers. Because of this competitive factor, the proceedings were characterized by lengthy expositions of the qualifications or lack of qualifications of the members of both groups to assume desired roles in the provision of hearing aids to consumers.[42]

Although continuing efforts are being made to upgrade the qualifications and training of dealers,[43] their education and training falls far short of that of other members of the hearing aid delivery system.[44]

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40 Johnson, Note 1, supra at 4331; John R. Franks, Assistant Professor/Audiologist, Arizona State University, R-10-6527; David D. Bartels, N.C. Speech, Hearing, and Language Assn., Tr. 6293; Jane Madell, Note 30, supra at 5862, 5899.

41 HAIC, Note 1, supra at 3885.

42 See, e.g., NHAS, Note 1, supra at 3535, n.69; HAIC, Note 1, supra at 3884; Alfred B. Berkove, M.D., Tr. 11,001; Oberhand, Note 29, supra at 3034-37; Paul Burris, Manager of Professional Service, Dahlberg Electronics, Tr. 2488.

43 NHAS has encouraged the enactment of licensing laws in the states for this purpose, R-3-3535.

44 Final HEW Task Force Report, Note 14, supra at 24. Of the 6,000 retail outlets only 2,500 dealers have been certified as hearing aid audiologists by NHAS, R-3-3521.

D. Test and examination procedures. The examination and tests performed by otologists, audiologists, and hearing aid dealers vary in complexity and objectives. The otologist is perhaps most aware that a hearing impairment or loss may be only one manifestation of a serious and perhaps life-endangering disorder. He, therefore, looks for other symptoms of ear disorders which may coexist with hearing difficulties.[45] Once the otologist has determined that there are no medical problems which he can resolve and that the patient is a candidate for a hearing aid, the patient is referred to either an audiologist or to a hearing aid dealer. Similarly, if a dealer or an audiologist believes that there are no medical problems which should be further examined by an otologist, they proceed to administer those tests which comprise a hearing examination. The extent and nature of these tests, depending upon who administers them, may vary to a considerable degree. The procedures employed by dealers are discussed in Part III while those used by audiologists are considered in Part V of this report. However, a look at evaluation procedures in general and the types of tests used is appropriate at this time.

Pure-tone tests for hearing are the most basic tests and seem to be relatively simple to administer. They measure an individual's ability to hear pure tones within the frequency range of about 125 through 8000Hz, within which most speech falls. If performed and evaluated correctly, the results provide a useful basis for predicting whether the patient's hearing is normal or impaired.[46]

The instrument used in these tests is an audiometer, which is an electronic device designed to produce pure-tone and speech signals over varying frequencies within a given range. Air-conduction pure-tone tests are given through earphones while bone-conduction tests are given by means of a bone-conduction device or receiver placed behind the ear. Although both involve the transmission of sound to the inner ear, the bone-conduction test is designed to determine to what extent a hearing loss is due to a conductive hearing loss (problems in the external and middle ear) and to what extent it is due to a sensorineural loss (inner ear or neural problems). It is, of course, essential that each ear be tested without the participation of the other ear, if the hearing ability of one ear is to be determined.

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[45] D. T. R. Cody, "Otologic Assessment and Treatment," in Audiological Assessment, Prentice-Hall, Inc., 1971, R-8-Exh. D-43-44.

[46] Price, Note 21, supra at 168-69. Unfortunately, obtaining valid results requires a considerable amount of knowledge and training. Ira Ventry, Professor of Audiology, Teachers College, University, Tr. 1709.

To prevent participation by the untested ear, a masking noise is introduced into that ear by means of an earphone so that it can not hear the pure-tone signals administered to the ear being tested.[47]

The sound intensity used in hearing tests is expressed in decibles (dB), that is, a measure of the number of times that sound is stronger than the weakest sound audible to the normal ear. The louder the sound, the more decibles involved.[48]

A second type of test, speech audiometry, is designed to ascertain the lowest intensity at which the listener can barely identify simple speech; how well the listener can understand everyday speech under normal conditions; and the highest intensity of speech that the listener can tolerate.[49] In conducting tests, the thresholds of the individual will be identified. These are the "threshold of hearing," that is, the lowest level at which the person will hear the stimulus,[50] and the "threshold of discomfort," that is, the loudness level at which the listener reports the sounds as being uncomfortable.[51] The "most comfortable level" is that level at which the listener indicates that the intensity of the sound is most pleasing to him.[52] A person with normal hearing has a threshold of hearing of 0 dB and a threshold of discomfort at 120 dB.[53]

Tests will also show whether the hearing loss is equal across all frequencies. For instance, if the threshold of discomfort increases upward at the same rate as the threshold of hearing and across all frequencies, the individual can tolerate louder noises. If the threshold of hearing shifts for the various frequencies, the individual might be able to

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47 Id. at 169, 178-79.

48 "Hearing Aids," Consumers Union Reprint, May, 1971, R-8-D-228-3.

49 K. Berger, "Speech Audiometry" in Audiological Assessment, Prentice-Hall, Inc., 1971, R-8-Exh. D-207.

50 The threshold for a stimulus is the lowest level which will elicit a response 50% of the time. Price, Note 21, supra at 204.

51 Berger, Note 49, supra at 228-29.

52 Id. at 227-28. The listener is asked to make this determination on the basis of comfort rather than on how well he understands the speech at the given levels.

53 "Hearing Aids," Note 48, supra at 4.

hear lower tones normally but have problems with the high tones. If the threshold of discomfort falls at the same time, the individual cannot tolerate the louder sounds necessary for him to hear in the higher ranges.[54]

Upon completion of the testing and evaluation of the results, the examiner should be able to determine within reasonable limits whether the amplification provided by a hearing aid would assist the individual and if so, the degree of amplification required. These are really subjective determinations in which factors other than the test results must be considered.[55]

B. Hearing aids. A definition of the term "hearing aid" is included in Section 440.2(a) of the proposed rule.[56] Basically, it is a device for the amplification of sound entering the ear. It consists of a microphone which picks up the sound waves from the air and feeds them, in the form of electrical signals, into an amplifier which enhances their strength and a loudspeaker, called a "receiver," which converts the amplified signals back into sound waves. It is equipped with a battery which provides the electrical power necessary to operate the system.[57]

1. Development. The original hearing aids were speaking tubes or ear trumpets which had very limited capabilities to amplify sound. These were followed in the early part of this century with the development of a "hearing machine" which weighed several hundred pounds and was fitted into a large cabinet. This machine used principles taken from the early telephone. The first wearable hearing aids were powered by batteries, weighing up to six pounds, which were carried in a separate case or strapped to the body or clothing in some fashion. With the advent of the vacuum tube, a wearable aid was developed in the mid-thirties which weighed about two and one-half pounds. A single unit which incorporated the battery was introduced in about 1946. The monopack included the microphone, amplifier, and batteries in one unit. Only the receiver and cord were separate. Transistors and integrated circuitry made possible great advances in the miniaturization of the hearing aid and permitted all of the components to be incorporated into

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54 Id.

55 Jane Madell, Note 30, supra at 5900-02; Luke Fortner, Note 33, supra at 2889; Dr. Sam Houston Sanders, National Hearing Aid Society, Tr. 3583; David Vreeland, hearing aid specialist, Tr. 3833-34.

56 40 Fed. Reg. 26646.

57 Corliss, Note 16, supra at 14.

earmolds, eyeglass frames, and compact units which would fit behind the ear. This miniaturization, coupled with corresponding developments and improvements in the materials and conformation of the chassis and case, made hearing aids less noticeable, easier to use and more acceptable to the potential user.[58]

2. Types and styles of hearing aids. Hearing aids may be of the air-conduction type in which sound is fed directly into the ear or of the bone-conduction type in which the receiver sets up vibrations in the bony structure directly behind the ear. The air-conduction type is generally used unless it is necessary, because of the physical condition of the patient, to use a bone-conduction type.[59]

Hearing aids are also classified by the type of system employed. A monaural hearing aid system provides sound amplification for only one ear. A binaural hearing aid system consists of two complete hearing aids, one for each ear. The Contralateral Routing of Signal (CROS) system places the microphone beside the poor ear and feeds the amplified sound to the better ear. The BICROS system utilizes two microphones, one above each ear, which deliver signals to a single amplifier and then to a single receiver which in turn deliver the sound to the better ear.[60]

The earmold or earpiece is a plastic insert designed to conduct the amplified sound from the hearing aid receiver into the ear canal as efficiently as possible. It is an important part of the hearing aid system. It must be both comfortable and properly fitted. Since an earmold may enhance or distort the sound passing through, it must be acoustically designed to transmit this sound clearly and often with some modification in order that the user can receive the best use of the amplified sound.[61] There are a variety of earmold types or styles designed to fit the particular application or the type of receiver or system used. Most earmolds, except those used in certain types of hearing aid systems are coupled to the hearing aid by means of plastic tubing. This tubing together with the earmold itself are referred to collectively as the coupler.[62]

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58 HAIC, Note 1, supra at R-3-3863-66.

59 Corliss, Note 16, supra at 14.

60 Id. at 15, 16.

61 B. Langford, "Coupling Methods" in Amplification for the Hearing Impaired, Grune & Stratton, 1975, R-8-Exh. B-82-83.

62 Id. at 84-88.

Hearing aids are configured into a variety of styles or models. The all-in-the-ear type fit directly into the earmold and have no external wires or tubes. The behind-the-ear models are housed in a curved case which fits behind the ear and is coupled to the earmold by a plastic tube. In the eyeglass models, the device with components is built into the temples of the frames. Body aids are enclosed in a case which can be carried in a pocket or attached to the clothing. They are equipped with an external receiver which is attached to the earmold. The external receiver is connected to the amplifier in the case by a wire.[63]

3. Technical data. In its recent regulation on hearing aid devices, FDA specifies what technical data must be disclosed in the labeling.[64] This data relates to the technical performance of the aid and includes such characteristics as the saturation output, the average gain, the frequency range, and other information useful in the selection, fitting, and checking of the performance of the hearing aid.[65] Hearing aids are designed to provide the amplifications needed by persons with differing degrees of hearing loss. Thus, they may be classified as being strong, moderate, or mild in power.[66] For example, all-in-the-ear aids generally provide sufficient gain and power output to accommodate only those with a mild hearing loss.[67] A person with a profound hearing loss may require the power output that can be provided only by a body aid.[68]

4. The hearing aid candidate. Basically, it can be said that a hearing aid should be fitted whenever it will help the

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63 Corliss, Note 16, supra at 14-15.

64 21 C.F.R. 801.420(c)(4), 42 Fed. Reg. 9295.

65 Id. K. Berger and J. Millin, "Hearing Aids" in Audiological Assessment, Prentice-Hall, Inc., 1971, R-8-Exh. D-498-99.

66 See, e.g., the classification set forth in "Hearing Aids," Note 48, supra at 10-12. The problems associated with the measurement of hearing aid characteristics is described by Michael C. Pollack in "Electroacoustic Characteristics" in Amplification for the Hearing-Impaired, Grune & Stratton, 1975, R-8-Exh. B-39-66.

67 D. Teter, "Clinical Considerations of Hearing Aids," in Hearing Disorders, Little, Brown and Company, 1976, R-13-2045.

68 Id. at R-13-2043.

individual using it to hear better.[69] Unfortunately, there are no established criteria to determine on a scientific and precise basis who will benefit from a hearing aid.[70] Prospective users need to be informed about the limitations of what they can expect the aid to accomplish and of what it will not do; they need to know that a hearing aid is not a cure for deafness and that it will not restore their hearing to normal or make an impaired ear hear perfectly.[71] Hearing aids will not permit the totally deaf to hear.[72] However, many authorities believe that a hearing aid is worthwhile if only it enables the user to hear some noises or sounds of the everyday world--even though the aid may not enable the person to distinguish words and understand speech.[73]

The variables which affect an individual's success with a hearing aid are many. They include room acoustics, individual needs which include the nature and extent of social activities, work requirements, lip reading skills, degree of hearing loss, the extent of discrimination impairment, psychological tolerance for amplified sound, and the degree of personal acceptance of the aid in the light of the help it gives the user.[74] As one audiologist said: "It is impossible for anyone to predict with certainty just how the interaction of these variables will affect a person's total experience with amplification."[75]

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69 Teter, Note 67, supra; Berger and Millin, Note 65, supra at 489.

70 Teter, id.; Angela Loavenbruck, Audiologist, Teachers College, Columbia University, Tr. 1564; Ira Ventry, Professor of Audiology, Teachers college, Columbia University, Tr. 1717-18.

71 Teter, Note 67, supra; Paul Burris, Note 42, supra at 2560; Stephen Epstein, M.D., otolaryngologist, Tr. 4569. A hearing aid will not halt the progression of a hearing loss; Hubert L. Gerstman, Chief, Hearing and Language Center, New England Medical Center Hospital, Tr. 2466.

72 Austin T. Smith, M.D., Tr. 8161.

73 Joseph C. Elia, M.D., otolaryngologist, Tr. 7472, 7519-21.

74 Judith A. Rassi, Audiologist, Northwestern University, Tr. 5735; Darrel E. Rose, Director of Audiology, Mayo Clinic, Tr. 466.

75 Rassi, id. at 5735.

F. Summary of findings and conclusions.

a. Findings. There is a substantial number of people in the United States who have impaired hearing, many of whom have not sought assistance and do not know whether or not they can be helped to regain a portion of their lost hearing.

Many of the hard-of-hearing are inclined to be reclusive and to conceal the fact that their hearing is impaired from others; they are also reluctant to admit their loss to themselves.

There is a strong and continuing disagreement among the otologists, audiologists, and hearing aid dealers who are the principal providers of hearing health care regarding the roles that each should assume in providing the hearing-impaired with assistance. The audiologists question the capability of hearing aid dealers to conduct examinations. Hearing aid dealers and some otologists question the ability of audiologists to fit hearing aids and indeed question the need for audiologists in the system. Although hearing aid dealers give lip service to the need for an initial medical examination before the fitting of a hearing aid, many do not believe that it is necessary in every case.

There are many causes of hearing losses. Some hearing losses may be alleviated by medical and surgical treatment. Others may be overcome to some degree through the use of a hearing aid, while still others may not be so reduced. Audiological examinations vary in complexity and to the extent that they sometimes require the making of subjective decisions regarding the type and degree of a hearing loss and whether or not it is desirable to fit a person with a hearing aid.

There are a variety of types and models of hearing aids designed to satisfy the differing needs of individuals with different types of hearing losses. It is important that the individual be fitted with an aid that will be most effective in light of his particular type and severity of hearing impairment.

A hearing aid is primarily an amplifier that increases the intensity of the sounds it receives and conveys them in an enhanced form to the middle ear. Its use is warranted if it will help the individual to hear better. However, the degree of actual assistance it will provide in overcoming a hearing handicap depends upon a number of variables including the ability of the individual to make effective use of it in his particular environment.

b. Conclusions. There is a need to affirmatively seek out individuals with impaired hearing and to encourage those who can be assisted by amplification to obtain a hearing aid and to make effective use of it.

The disagreements among the providers of hearing health care regarding the propriety of the roles each group should assume in providing hearing care are strong and pervasive. Much of the record is devoted to a propoundment of the conflicting opinions and views of the members of various groups. Moreover, not all of the members of a group share or support the views of other members of that group. Under these circumstances, the making of objective findings and conclusions is more difficult, for in evaluating the evidence contained in the rulemaking record, due consideration must be given to the obvious prejudices and self-interest reflected in the comments of various groups' members.

PART III. SELLING TECHNIQUES

A. Introduction. Many reports and surveys concerning vital hearing aid industry and consumer problems have recognized that there are competent and ethical "practitioners" at all levels of hearing health care delivery and distribution. Nonetheless, some of these same reports, in addition to others, document the existence of selling techniques and other practices that reflect the need for additional regulatory efforts to protect consumers, the industry, and those dealers upon whose good reputations the actions of the less ethical or unethical and less competent or incompetent may reflect.[1] These unlawful practices have continued in spite of some fairly substantial efforts made by various interests to curtail them. They are many and varied; and, in order to get a complete picture of them and of the framework within which they occur, attention must be focused initially upon the hearing aid dealer, his background, and his methods of sales operations.

As many participants in the rulemaking proceeding felt that the ills currently existing in the retail segment of the industry are as much the fault of the system in which the salesman (including the dealer) works, this discussion begins with Issue 2 which

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1 American Speech and Hearing Association (ASHA), R-10-1627-28; Sound Trap, Hearing Aid Sales in Iowa, Iowa Student Public Interest Research Group (ISPIRG), June, 1974, R-8-D233-7-42; Paying Through the Ear, A Report on Hearing Health Care Problems, Public Citizen's Retired Professional Action Group, Preliminary Draft, 1973, (RPAG Report), R-8-D421; Hear Ye! Hear Ye! A Study of Hearing Aid Sales Practices in Queens, New York Public Interest Research Group (NYPIRG), undated, R-8-D232-9-10; Survey of Hearing Aid Dealers in the District of Columbia, Legal Research and Services for the Elderly, National Council of Senior Citizens, Inc., Wash., D.C., October, 1975, R-8-D546; Staff Study of the State Licensing Laws and Training Requirements for Hearing Aid Dealers, Permanent Subcommittee on Investigations of the Committee on Government Operations, U.S. Senate, 94th Cong., 1st Sess., 1975, R-8-D543; You Know I Can't Hear You When the Cash Register's Running: The Hearing Aid Industry in Michigan, Public Interest Research Group in Michigan (PIRGIM), Dec. 3, 1973, R-8-D231-12-23; Prices of Hearing Aids, Report of the Committee on the Judiciary made by its Subcommittee on Antitrust and Monopoly pursuant to S. Res. 258, Senate Rpt. No. 2216, 87th Cong., 2d Sess., 1962, R-8-D224-27-36; Hearing Aids and the Hearing Aid Industry in Minnesota, Minnesota Public Interest Research Group (MPIRG), Nov. 13, 1973, R-8-D229-31-47; Paul M. Shuford, counsel, VA Hearing Aid Dealers Association, Tr. 637, 671; Barbara Stroup, clinical audiologist, Tr. 941, 1003-04; Maurice J. Peters, Jr.,

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deals specifically with the training of sales personnel upon their entry into the field, the types of motivation that they have or are given for making sales, and the control exercised over their sales practices. Sections B, C, and D will deal, respectively, with these topics in some detail. Next, in order to give the reader an overview of the types of selling techniques that are being questioned, the subject matter of Issue 1 will be commenced in subpart E, Methods of Operation, with a discussion in paragraph 1 of how salesmen or their associated manufacturers obtain "leads" to consumers who may have some interest in hearing aids and who may be potential customers. As both Issues 13 and 14 deal with the capacity and tendency of certain initial representation to mislead the consumer as to the nature and intent of the advertiser and the purpose of their "ads," they will be discussed in connection with the obtaining of leads. With an understanding of how salesmen initially "spot" potential buyers, the discussion proceeds in paragraph 2 to consider the aspects of the sales "pitch." Although sales efforts occur both in the home and in retail outlets, special attention will be devoted to the in-home sale as the record indicates that a substantial number of questionable practices occur during sales presentations of this type; accordingly, Issue 11 which questions the effectiveness of the proposed rule section requiring that the seller obtain prior written consent before making such a call will be discussed in this part. The paragraph 2 discussion of the sales effort also includes a brief description of the testing salesmen frequently use in finding, identifying, and determining the degree of the consumers' hearing loss (if any). Attention will be specifically paid to the alleged shortcomings of the testing and the reading of test results.

As the use of master hearing aids in the testing and selecting processes has caused a good deal of controversy, Issue 10, involving whether these "master" devices are used deceptively (to demonstrate to the prospective buyer a hearing improvement in the test situation that he will not be able to achieve with his personal hearing aid) will be specifically taken up in paragraph 3. Proceeding next to the sale of hearing devices, the failure to disclose that a hearing aid has been used, and the

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[1] (Continued)

Assistant Director of Law and Legal Counsel for the Dept. of Consumer Affairs of Mayor Harvey I. Sloane, Tr. 1006-79; Nettie Murray, consumer, Tr. 4837-57; An Answer to the MPIRG Report, Hearing Aid Industry of Minnesota, Mar. 16, 1973, R-8-D230-Introduction; National Hearing Aid Society (NHAS), P-3-D646-I-II; Hearing Aid Industry Conference (HAIC), R-3-D647; James F. Wallace, hearing aid specialist, Chairman of the Tennessee Board for Hearing Aid Dispensers, Tr. 3466; John C. Kenwood, hearing aid dealer, President, J. C. Kenwood Inc., representing NHAS, Tr. 9294.

materiality of such fact to consumers' purchase decisions, will be discussed in paragraph 4, incorporating Issue 12. The overcoming of the prospective buyer's resistance to a purchase and the closing of the sale will be treated in paragraph 5. Finally, the practices covered in paragraphs 1 through 5 will be summarized in paragraph 6 as a specific answer to Issue 1, bearing in mind that the practices dealt with are examples and are by no means inclusive of all of the practices reported or alluded to in the rulemaking proceeding.

Following a summary of findings and conclusions in Section F, the report will then proceed to discuss the proposed general remedy (buyers' right to cancel, Part IV). The proposed remedies designed to deal with specific areas and practices are considered in Parts V, VI, and VII.

Issue 2.

How are hearing aid sellers trained, motivated, and controlled? How does that training, motivation, and control bear on whether consumers are subjected to selling abuses or whether consumers purchase hearing aids that provide no significant benefit?

B. Training. It has been suggested that the system, not the individual, forces the hearing aid dealer to do certain things to hearing-impaired customers that are not in the customers' best interests.[2] To assist in understanding why this conclusion has been drawn by some rule proponents, it is helpful to examine the training of the new hearing aid dealer or salesman.

For the most part, hearing aid dispensers are not required to possess any particular pertinent qualifications of training in order to embark upon a career of evaluating hearing, prescribing and fitting aids, and dealing with hearing-impaired consumers.[3] Rather, 4 years of high school seems to be the only basic requirement for entering the commercial sales field.[4] In fact, out of the approximately 15,000 hearing aid dealers and salesmen active currently, approximately 2,200 have received any training directed toward maintaining standards of competence, education, ethics, and reliability; and the training received has consisted,

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2 Maurice Miller, Professor, Speech Pathology and Audiology, New York University, Tr. 4755-56.

3 MPIRG, Note 1, supra at 49; see e.g., John B. Davis, Executive Secretary, Illinois Association of the Deaf, Tr. 8535-36; Lou Jungheim, Chairman of the Board of Directors, Chicago Metropolitan Area Senior Citizens Senate, Tr. 8874.

4 ASHA, R-10-1645; Senate Staff Study, Note 1, supra at 10.

for the most part, of home-study courses, manufacturer programs, conferences, and workshops.[5]

Dealers argue, on the other hand, that their "education is practical in nature" and that they possess "training by experience;"[6] but rule proponents, of which the Minnesota Public Interest Research Group (MPIRG) is typical, counter this argument with their own contention that "Only adequate training plus experience equals competence; [while] years of experience without proper training equals only prolonged incompetence."[7] Also, one must wonder how much consumers suffer while high school graduate salesmen gain the necessary experience to become competent in selecting and fitting hearing aids.

The National Hearing Aid Society (NHAS) does offer a nationwide program of instruction for dealers. It consists of 20 home-study lessons involving readings from three textbooks along with lesson summaries prepared by NHAS. The applicant studies in his own home and returns his completed lessons to NHAS for grading by an outside firm especially under contract with NHAS for this purpose.[8] When the dispenser has successfully completed all 20 lessons, he is considered a noncertified member of the NHAS; to receive further recognition from this industry group, he must take and pass a final proctored examination. Unfortunately, NHAS has not kept any pass-fail statistics on this test.[9] Nonetheless, the passing of this exam, along with approval of the individual by local dealers and other community leaders who consider

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5 RPAG, Note 1, supra at III-22; Myron M. Samole, Executive Vice President, Fidelity Electronics, Ltd., Tr. 6670-71; David Barnow, former president of HAIC, Tr. 1627; Ira Kolman, Ph.D., Chairman of the Department of Speech Pathology-Audiology at Loyola College of Baltimore, Tr. 1883.

6 Wayne J. Staab, Ph.D., Director of Education, Telex Communications, Inc., Tr. 7030; James Delk, independent hearing aid specialist, Tr. 10926; John H. Payne, hearing aid dealer, Indianapolis, Indiana, Tr. 9261-62; John C. Kenwood, Note 1, supra at 9285-86.

7 MPIRG, Note 1, supra at 51.

8 Senate Staff Study, Note 1, supra at 2-4; see also MPIRG, Note 1, supra at 49-51; PIRGIM, Note 1, supra at 11.

9 Senate Staff Study, Note 1, supra at 2-4; John Kenwood, Note 1, supra at 9287-88; Raymond Rich, NHAS member, Tr. 2982-83.

his character and credit rating, entitles him to receive a plaque, suitable for office hanging, which declares him to be a "certified hearing aid audiologist."[10]

Rule proponents charge that the use of such title by a dispenser who has completed this course and exam is deceptive because most consumers do not know the difference between the practice of a "certified audiologist" and that of a "certified hearing aid audiologist" and may be misled to their detriment by confusing the qualifications of members of these two hearing health care delivery components, e.g., by believing they are being examined by an "audiologist" when, in fact, the examiner is a dealer.[11]

Of course, the industry genuinely considers dealers to be "well trained" after attending industry sponsored workshops, seminars, some accredited college courses, and various training courses offered by manufacturers.[12] Rule proponents do not support this belief; MPIRG feels that any notion that a course of 30 1/2 pages in length, capped off by an unsupervised, in-home examination constitutes advanced training for "service to the hearing handicapped" or solid ground work in basic sound physics, the functioning of the ear, the testing of human hearing, and the fitting of hearing aids, is "patently absurd."[13] For a further look at the quality of the NHAS course, the Permanent Subcommittee on Investigations of the Committee on Government Operations, United States Senate, established panels of experts

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10 Senate Staff Study, Note 1 supra at 3-4; MPIRG, Note 1 supra at 49-51; John Kenwood, Note 1, supra; Raymond Rich, Note 9, supra.

11 MPIRG, Note 1, supra at 50; Bonnie Smith, clinical audiologist, Tr. 273; Darrel E. Rose, Ph.D., Director of Audiology, Mayo Clinic, Tr. 531-32; Barbara Stroup, Note 1, supra, at 968-69; Beverly D. Ryan, enrolled in a Master of Science degree program in audiology at Teachers College, Columbia University, Tr. 1531; Dorothy A. Shannon, audiologist, Chief of the Speech and Hearing Section of Sinai Hospital of Baltimore, Tr. 1860-62; Ira Kolman, Ph.D., Note 5, supra at 1884-88; Angela Loavenbruck, Chief Supervisor and Adjunct Assistant Professor in Audiology at Teachers College, Columbia University, Tr. 1559; George Shanta, President, Chicago Area Council of Senior Citizens Organization, Inc., Tr. 8870; Mike Pasiewicz, individual witness, Tr. 8922-23; John J. Fennema, Maryland Hearing Aid Service, Tr. 1752.

12 David Barnow, Note 5, supra at 1627; Raymond Rich, Note 9, supra; NHAS, R-3-3534; John Kojis, President, Maico Hearing Instruments Company, Tr. 1978.

13 MPIRG, Note 1, supra at 50.

from the Veterans Administration, the American Council of Otolaryngology, and the American Speech and Hearing Association to review the course material. These panels' findings characterized the home-study course as "not only inadequate but potentially dangerous." It neither equips dealers to properly evaluate hearing losses and detect and analyze hearing disorders that require medical attention, nor to make professional judgments on such losses and/or recommend corrective action therefor.[14]

Moving on to another prong of the training argument, the record revealed that dealers receive even less relevant training from manufacturers. Since salesmen are hired to generally work out of a dealership on a commission basis, the little training they receive from the manufacturer is generally focused on selling.[15] In its Report on the Prices of Hearing Aids, the Subcommittee on Antitrust and Monopoly noted that it is no accident that many industry salesmen are high-pressure experts,[16] since they are trained by manufacturers' manuals which emphasize the importance of selling and sales techniques rather than help for the hearing-impaired customer.

To appreciate the latter statement, one need only read and analyze various sales manuals' sections wherein salesmen are taught to make their calls and close their sales. Sales presentations are tailored to fit any prospect, whether he is found alone or in the company of a friend or relative. The salesman is trained to deal with any third party who is present by manipulating him, as well as the hearing-impaired individual, in accordance with what he has learned about the "psychology of the deaf" and of the psychology of their friends and relatives. In particular, third parties may fall prey to being subtly used by the saleman because of their predisposition to "help" their loved one, regardless of the cost. In many cases, it is even the relative who wants the hearing aid for the hard-of-hearing person in the first place, not realizing that perhaps it may not even help his hearing or that it could make it harder for him to hear. Furthermore, the relative can also be very useful and important in the making of financial decisions and in arranging for payments

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14 Senate Staff Study, Note 1, supra at 5. See also Ira Kolman, Note 5, supra at 1883; Dr. Roger Kasten, Tr. 777, 786; Elma Griesel, Tr. 9475.

15 RPAG, Note 1, supra at XIV-2; How to Sell Hearing, Beltone Consultant's Manual, section IV, R-8-0250; Dahlberg Training Guides for Hearing Aid Salesmen: How to Get in the Door, R-8-0344, How to Convert Objections into Sales, R-8-0347.

16 Prices of Hearing Aids, Note 1, supra at 27.

the hearing aid.[17] To understand the importance placed on the presence of a third party, consider the following Beltone manual excerpt:

> Arrange specific places for both the prospect and the buying influence. You will want them to sit so that both will be comfortable and attentive throughout the presentation. Be sure to seat the buying influence where he can see both you and the prospect and hear everything that is said. *** [18]

Salesmen and salesman-trainees are generally taught not to present themselves as salespersons but rather as experts on hearing loss, hearing aids, and other corrective measures. They will many times introduce themselves using a title that states or implies a professional status and impressive rank; such titles are many and varied but among those most commonly used are "hearing aid specialist," "hearing aid audiologist," "hearing aid counselor," "hearing aid consultant," and "certified hearing aid audiologist." In some cases, the word "aid" is omitted from such titles.[19] The implications of such use for both the salesman and the consumer is discussed in Part V infra and will not be dealt with further in this part.

The record is replete with citations to sales manuals illustrating the techniques which salesman are trained to employ: from use of the proper tone of voice in asking, "May I come in?" through the qualification of himself as an "expert," down to the extensive tactics used in "closings." Through a carefully calculated series of steps which include gaining entrance to a home, holding the interview, completing various tests, and getting a signature on a sales contract, the salesman employs both subtle approaches and high-pressure practices to make the prospect (1) believe in his (the saleman's) "expertise," (2) recognize that he (the prospect) has a serious problem, (3) recognize that the "expert" can help solve this problem, and (4) recognize that the time to do something about the problem is now.[20] Rule proponents charge

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17 How to Sell Hearing, Note 15, supra; Maico Sales and Technical Training Course, R-13-851-62; Dahlberg Training Guides for Hearing Aid Salesmen: How to Get in the Door, R-8-D344, What Is a Lead?, R-8-D345, Just Ask . . . The Key to Referral Sales, R-8-D346, How to Convert Objections into Sales, R-8-D347; Miracle Ear Hearing Sales Presentation, Dahlberg Electronic, Inc., Selling Information for the Dahlberg Hearing Aid Consultant, R-8-7033-68.

18 Beltone Consultant's Manual, id. at IV-14.

19 Ira Kolman, Note 5, supra at 1884.

20 ASHA, R-10-1631; MPIRG, Note 1, supra at 31-46; PIRGIM, Note 1, supra at 15-17.

that taken in the entirety, such presentations too often include and constitute deceptive and unfair acts and practices.

Additionally, the record indicates that many representations made during the course of the sales pitch, whether they occur in the home or at a retail outlet, go well beyond the instructions given in the various manuals. While many are borderline in their capacity to mislead or to encourage misinterpretation, there is an untold number of others that are blatantly false and misleading. It would seem in such latter instances that the salesmen either do not know what they are talking about or are intentionally making false representations.21

As a result of such inadequate or misguided training, numerous instances of gross misfittings have occurred; the following examples are but a miniscule sample of the hundreds placed in the record in support of the position that remedial action must be taken:

> A 64 year old woman with a bilateral sensori-neural hearing loss was fitted by a dealer with binaural hearing aids. Her speech discrimination (understanding) impairment in one ear was so severe that no aid could have helped her and in fact it would have increased the distortion.
>
> A 68 year old stroke victim with expressive aphasia (a loss or impairment of the capacity to use words as symbols of ideas affecting the ability to speak) was sold binaural hearing aids even though he had normal hearing and the aids could in no way have benefited his type of impairment.
>
> A 44 year old man with bilateral otosclerosis (a hereditary disease which involves the restriction or immobilization of one of the bones in the middle ear whose vibrations normally transmit sound to the nerves of the inner ear) had worn two hearing aids for many years. When he finally did see a physician, surgery was performed which brought his hearing to within normal range. (In a high percentage of cases, otosclerosis can be helped by surgery if diagnosed in time.)
>
> A 68 year old man with a sharply sloping sensori-neural loss was tested and fitted

21 ISPIRG, Note 1 supra, at 30.

by a dealer with an all-in-the-ear aid that was not reaching his loss (this type of aid can supply only mild amplification). An otological and audiological work-up found the aid to be completely inadequate and a different aid was prescribed.

The grandparents of a 10 year boy suffering from external otitis media were sold a hearing aid for him. The boy had very little hearing loss--an aid was not necessary--and his condition was eventually treated medically.

An 82 year old woman with a severe bilateral sensori-neural loss was sold two different types of aids by a dealer--both a body aid and an ear level aid. Both were inadequate and were, in fact, increasing the distortion of the sounds that were reaching her.[22]

c. Motivation. Motivation of the hearing aid salesman is directly related to his making a living from the sale of hearing aids.[23] A clear conflict exists between his desire to provide consumers with good services and the correct answers to their problems and with the necessity for him to pay his bills out of the receipts from the number of hearing aids he sells.[24] He thus has "***a built-in incentive to misdiagnose" persons whom he sees, and to do so in the direction of finding that they need hearing aids.[25]

Industry argues that, as a matter of self-interest, the hearing aid dealer will not be unduly motivated to make a sale in order to get still another commission or to make an extra amount of profit, for, by operating in such a fashion, he will not long remain in business.[26] Rather, the industry feels, he

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22 All of these examples were taken from MPIRG, Note 1, supra at 51-52.

23 ASHA, R-10-1642; see also PIRGIM, Note 1, supra at 12.

24 Maurice Miller, Note 2, supra at 4761-62; see also John B. Davis, Note 3, supra at 8550-51.

25 PIRGIM, Note 1, supra at 12; see also Mary Ruth Whitman, audiologist, Illinois Department of Public Health, Tr. 8593-94.

26 David Barnow, Note 5, supra at 1652, see also Dr. Sam Houston Sanders, Jr., NHAS, Tr. 3577; Dean Harris, Ph.D., Director of Audiology, Southern Methodist University, Tr. 10422; Ronald Scheurer, audiologist, Vice President of Audible Wholesale, Tr. 11519; Wayne J. Staab, Note 6, supra at Tr. 7043-44.

is going to make every effort to please the customer.[27]

On the other hand, however, manufacturers appeal directly to dispensers' competitive instincts through pressure upon them to exceed certain sales quotas each month in order to make "above average income," to receive discounts,[28] and to "win" free trips offered by manufacturers for outstanding numbers of sales.[29] ASHA cites examples of such encouragement to increase sales volumes and these do appear to be typical:

> Siemens announces our old bonus program.
>
> (Just in case you missed it.)
>
> Sometimes word on the best laid plans never gets around.
> We hate to admit it but there's good reason to believe that some of our dealers have overlooked our dealer bonus plan.
> Not that it's too complicated to understand.
> In fact, it's one of the simplest programs in the industry.
> The more instruments you sell the more instruments we don't bill you for. For example, if you sell five, we send you a sixth, no charge. The chart shows how you do as you sell more units. The whole theory behind the program is to make the Siemens line more profitable for you.
> Like our service program, our informative monthly newsletter and some of the other activities we've introduced, we think the bonus plan makes for a better relationship with our dealers.
> If you aren't already one of our dealers or would like to get on the mailing list for the Siemens Hearing News, send us the coupon below. ASHA, R-10-D57, Exh. 69-A.

D. Control. Rule proponents argue that dealers are permitted to sell hearing aids without any effective controls over their

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27 Sanders, Note 26, supra at 3577; Lawrence E. Murphy, Attorney, Nebraska Hearing Aid Society, Tr. 7966-67; Ronald Scheurer, Note 26, supra at 11519.

28 ASHA, R-10-1642.

29 Robert C. Beiter, representing the Association of Clinical Programs in Speech Pathology and Audiology, Metropolitan Chicago, Tr. 9030.

operations.[30] This situation is frequently due to the lack of appropriate laws that would protect the hearing-impaired consumer, to the failure to enforce already existing laws, or to inadequate enforcement of same.[31] For example, dealer-control over many, if not all, state licensing boards, is cited to illustrate that such agencies are naturally biased against the consumer.[32]

Of course, the industry disagrees with such a flat-out assertion citing as effective means of control over dealer operations the imposition of cooling-off periods provided by various statutes,[33] the certification program provided by the National Hearing Aid Society,[34] and the state licensure laws and the regulatory boards established thereunder.[35] By these means, unethical persons are already screened out of the industry and consumers are protected; therefore, no further measures are needed says the industry. The certification program of NHAS has been examined previously and further comment is unwarranted at this time; the matter of states' licensing and regulation of dealer operations will be discussed at length in Part VIII infra and will not be undertaken here. Additionally, the "control" exerted by manufacturers over their dealers is generally discussed in section

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30 See, e.g., PIRGIM, Note 1, supra at 26-38; Kenneth O. Johnson, Executive Secretary, American Speech and Hearing Association, Tr. 4265; Michael Stahl, Director of Clinical Services, Hearing and Speech Center, Grand Rapids, Michigan, Tr. 5537-38.

31 ISPIRG, Note 1, supra at 29; Judith Munger, National Council of Senior Citizens, Tr. 4505; Michael Stahl, Note 30, supra; James D. Jefferies, Assistant Attorney General, Wisconsin Department of Justice, Tr. 5592; Nancy Eichelberger, audiologist, Connecticut Speech and Hearing Association, Newington, Connecticut, Tr. 8715; Leslie W. Dalton, Jr., Ph.D, Professor of Audiology, New Mexico State University, Tr. 8721-22.

32 ASHA, R-10-1656; John J. Fennema, Note 11, supra at 1750-51; Angela Loavenbruck, Note 11, supra at 1551; Judith Munger, Note 31, supra at 4502.

33 Luke Fortner, President of the National Hearing Aid Society, Tr. 2860; see also Jeffrey H. Joseph, Director of Consumer Affairs for the Chamber of Commerce of the United States, Tr. 4237; Donald W. Schaefer, Director, Dane County Hearing and Speech Center, Madison, Wisconsin, Tr. 8278.

34 NHAS, R-3-3534-35; see also John C. Kenwood, Note 1, supra at 9287-88 regarding the "Rigors of NHAS Certification"; Raymond Pich, Note 9, supra at 2982-83.

35 James F. Wallace, Note 1, supra at 3466.

C of this Part supra and will not be repeated, except to note that this type of "control" heavily emphasizes the need for dealers to increase their sales volumes with little attention paid to other matters.

Basically then, it appears that Issue 2 must be answered as follows: Hearing aid dispensers for the most part are lacking in formal training pertaining to the basic sciences related to hearing and hearing aids. Although various types of certification and improvement programs are provided by NHAS and some manufacturers, this type of "education" is at best shallow, piecemeal, and of questionable effectiveness. While dealers certainly do gain a lot of training through practical experience, if the training procedures learned do not initially involve correct techniques, then they merely perpetuate incompetence rather than improve the dispenser's ability to function as a fitter of hearing devices. Although the home study courses associated with the NHAS certification program give the dealer some useful information; it may give him so little as to be of minimal benefit in his work. Various experts assigned to investigate the merits of this course have not only agreed with this finding, but have also gone so far as to characterize such a course as "potentially dangerous" (see Note 14, supra).

In its role in the dealer's training, the manufacturer places heavy emphasis upon sales and the increasing of sales volumes. Through the use of various manuals, which do not differ radically from each other in "teaching" approaches, the dispenser is taught to make his sales calls and "close" transactions in as many instances as possible, often through the manipulation not only of the hard-of-hearing person, but also of a third party present during the sales pitch. To handle both parties in a manner conducive to making a "closing," the salesman uses the principles he has been taught through manuals that play up and explain the "psychology of the deaf" and of his friends and relatives.

Manufacturers' training may also include the encouragement of the dealer or salesman to represent himself as having a status approaching, if not actually attaining, professionalism and as an "expert." In this guise, he holds himself out to the prospective customer as the expert who has the ability to solve the prospect's serious hearing problem now. Nonetheless, it appears from the record that some salesmen even go well beyond the pitches they are taught in manuals in their efforts to induce or cajole the hearing-impaired individual into making a hearing aid purchase. Because of the obviously inadequate training the salesmen receive, it is difficult to assign a number to the instances in which false and misleading representations are made to consumers through ignorance, but it appears certain that in many cases, such phony come-ons are part and parcel of previously planned and well thought out methods of making a sale on each call, with insufficient regard for the benefits that the purchaser may receive from the hearing device sold to him.

The salesman's primary motivation for selling amplification systems is his need to make a living from his commerical enterprise. A secondary motivating force, although extremely important to some dealers, is the need to help the hearing-impaired person by optimally answering his hearing care needs through fitting of amplification and rendering of related services. Still, if there is any doubt about a hearing loss, the reason is there for the dealer to misdiagnose the customer in favor of finding that he needs a hearing aid. Industry is correct in noting that many dealers would not dare to stoop to such practices if they want to remain in business for long, but on the other hand, such motivation may be peripheral at best to those salesmen who are competing for manufacturer-offered discounts, trips, etc., and for higher incomes.

Dealers appear to operate with few effective controls. Although various consumer protection laws and state licensure statutes do exist, it has been charged that these laws are not enforced at all, or not enforced as well as they should be--Part VIII infra should be referred to for more on this subject, but it must be noted that the record indicates that this position is probably correct for numerous reasons.

The NHAS certification program is at best meager and manufacturers' control over dealers is of a type that would seem to more often encourage rather than discourage consumer abuses as it basically emphasizes increased sales, frequently at the consumer's expense.

Therefore, it may be concluded from the record that the currently prevailing system of hearing aid delivery provides no guarantee that consumers will be dealing with competent or service-motivated dealers. Although many instances of improper sales and fittings of hearing aids may be attributed to ignorance on the part of the dispenser involved, it must also be concluded that a great many other instances are due to unfair practices and false and misleading representations that dealers are motivated to make in their quests for profit. Those dealers who are so inclined are able to "get away" with various consumer abuses because of the poor or nonexistent control exercised over them by law enforcement authorities, trade associations, and others who should be in the position to exert such control. It may also be concluded that, for all of these reasons, the consumer who undertakes to find help for his hearing problem should be advised that the rule of caveat emptor certainly still obtains in the dealer segment of the hearing aid industry.

E. Methods of operation. Now that the training, motivation, and control of sales personnel have been explored, the sales techniques employed by such sellers must be examined for a full appreciation of the practices that exist in this part of the industry. The following description of practices in use primarily focuses upon Issues 1 and 10-14. These issues will be

treated in conjunction with the narrative text where permissible, or individually at the end of this part, where appropriate.

1. Initial consumer contact. Initial contact between hearing aid dealers and prospective purchasers is established in a variety of ways. Some individuals are referred by their otologist following medical evaluation. Others visit audiologists first for their screening tests and are thereafter referred to the dealer; although there are some audiologists today who dispense aids themselves, it is nonetheless still usually the dealer-salesman who undertakes this function.[36] Consumers may also be referred to dealers by health agencies, family doctors, friends, and family members, or they may simply perceive that they are having hearing difficulties and go into a dealer's office on their own initiative. However, one of the most common means of initial contact is between a salesman and the potential customer and ordinarily results from the salesman's followup on a "lead," often by visiting the prospect's home without advance notice.[37] These leads are obtained by salesmen in a variety of ways. Advertising and mailing lists[38] are frequently used to seek response through, for example, free offers of literature, "information," various gifts, Bibles, nonworking models of hearing aids,[39] hearing tests, etc.[40] Although these "finding" methods are not unique to the hearing aid industry, there are many techniques particularly adapted for use in the selling of hearing aids.

Manufacturers regularly advertise for leads and refer those they get directly to dealers. Mailing lists, especially for the aged population, are bought and sold as part of the trade,[41]

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36 This summary report does not give details of noncommercial dispensing systems operated by government and other agencies. For discussion of various systems see William H. Cutler, "Dispensing System," in Amplification for the Hearing Impaired, Grune & Stratton, Inc., 1975; R-8-Exh. B-387-408. Neil H. Offen, Senior Vice President and Legal Counsel, Direct Selling Association, Tr. 1483; Darrel E. Rose, Note 11, supra at 455; Robert I. Oberhand, M.D., Westfield, New Jersey, Tr. 3034-37.

37 ASHA, R-10-1631; Mary Ruth Whitman, Note 25, supra at 8558-59; Patricia G. Mastricola, audiologist, Otologic Professional Associates, Tr. 8168.

38 ASHA, R-10-1632.

39 See nonworking model--Physical HX-3, R-12-Shelf 7 in Section 62. Maurice Miller, Note 2, supra at 4763-64, HX-77.

40 ASHA, R-10-1632; see also Lloyd Mosley, Supervisor of Speech and Hearing Services, University of Illinois, Tr. 7740.

41 Maurice Miller, Note 2, supra at 4765.

and personal referrals are constantly solicited. The offering of "free" hearing tests at various locations, (e.g., homes, schools, "golden age" clubs, county fairs, and community health screening centers), is a prime lead-gathering technique. Telephone surveys are used also to gather leads--sometimes deceptively.[42] No media (newspapers, magazines, television, radio, Yellow Pages, match books, etc.) is overlooked as an effective method of sparking interest in hearing aids, and storefront advertising has become a common practice.[43]

PUBLIC NOTICE

HARD OF HEARING

Goldentone Division, Raco Electronics Corporation of Minneapolis has chosen the Colorado Springs area to conduct field testing of a hearing aid featuring a custom circuit built to the patients individual hearing loss that is worn entirely inside the ear cavity with no attachments.

We wish to fit these hearing aids on a variety of age/occupation groups, both rural and urban.

* * *

Persons electing to participate will be required to have their hearing tested, necessary ear impressions taken and report their wearing experience over a two week period and may purchase the hearing aids at a reduced price at the end of that time. There is no expense whatever to participants.

If you wish to participate, please telephone*** before April 11th or write to:[44]

* * *

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42 Thomas W. Norris, Ph.D., Director, Division of Audiology and Speech Pathology, University of Nebraska Medical Center, Omaha, R-10-6498; Angela Loavenbruck, Note 11, supra at 1557-59; Dahlberg Telephone Lead (DTL) Telephone Survey, 1974, R-8-7068-86.

43 ASHA, R-10-1632.

44 R-8-2015; see also R-8-2396, for a similar type of advertisement.

The following examples were taken from promotional materials for lead gathering given by the Vicon Instrument Company to its dealers:

AS PERSONAL AS YOUR PORTRAIT

This booklet is
excellent in
getting leads.
Advertise and ask
prospects to
come in for
a free Booklet
showing why
hearing is
AS PERSONAL AS YOUR PORTRAIT

* * *

VICON Form 129

A 2-fold mailer designed to emphasize "forward facing" hearing--and emphasizing that Soundtennas are free of extra charge.

We have found this to be effective to non-qualified lists (i.e., mailing lists which contain names of non-users).

For added effectiveness we suggest the return card be sent to Vicon. It will be promptly forwarded to you for action.

On the card is the following notation in the corner:

Help a friend
If you do not intend to use this card, please give it to a friend who can benefit from the new Soundtenna.

* * *

VICON Form 815

This mailer was designed to be used with Vicon's "Personal As Your Portrait" booklet.

This mailer is an excellent lead getter with its "FREE BOOKLET OFFER."

* * *

VICON METRI-PHONIC TWO-FOLD MAILER

This shocking color is designed for reader appeal and motivation. We think this mailer will generate leads and ultimate sales for you.

The mailer has two boxes which could be checked:

☐ Yes, I have a hearing loss and would like to receive your brochure on the Metri-Phonic series.

☐ Please have your nearest Vicon dealer call upon me and give me a free hearing test.

At the botton of the mailer there is the notation:

If you know a friend experiencing hearing difficulty, please forward their name, maybe we can help them hear again.[45]

* * *

This lead gathering offers a "free working model" to those who respond:

Want To
Hear Better?

Chicago, Ill.--A free offer of special interest to those who hear but do not understand words has been announced by Beltone. A non-operating model of the smallest Beltone aid ever made will be given absolutely free to anyone requesting it.

Try it to see how it is worn in the privacy of your own home without cost or obligation of any kind. It's yours to keep, free. It weighs less than a third of an ounce, and it's all at ear level, in one unit. No wires lead from body to head.

These models are free, so we suggest you write for yours now. Thousands have already been mailed, so write today to Dept. 4533, Beltone Electronics, 4201 W. Victoria, Chicago, Ill. 60646.[46]

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45 R-8-2326; R-8-2312-13; R-8-2316; R-8-2318-19, respectively.

46 R-8-2549.

A general type of media advertising used by manufacturers to induce expressions of consumer interest follows: (this particular ad was designed for television broadcast)

> Has your family--or your family doctor--urged you to get a hearing aid? And have you hesitated because you thought it might be conspicuous?
>
> Well, let me show you something. This is a complete Beltone Hearing Aid . . . and it fits right in the ear itself.
>
> Now, if you've been missing some of the sounds that are important to you--or if you just don't understand all you hear--why not find out how tiny hearing help can be?
>
> * * *
>
> A tiny aid like this may be all you need to hear the things you've been missing . . . .
>
> Yet it's so small, it will go through a lady's wedding ring.
>
> See for yourself. Send for a free non-operating model now.[47]

Quite often to get leads, advertisements may be placed in newspapers in such a fashion as to give consumers the impression that government-sponsored programs are involved; the following is such an example which appeared in the HOUSTON CHRONICLE:

> NEW HEALTH PLAN
>
> Free Hearing Aids
> Funded by State
> HOUSTON--Plans are being made to provide hearing aids FREE, to many Texans made eligible under Social Securities Supplementary Security Income (S.S.I.) health care plan.
> This program will even include some, NOT YET age 65.
> Prosthetic needs will be 100% funded for those eligible under the new program. In case of hearing aids, this includes test, ear tip, service and warranty.

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47 R-R-2348; see also R-R-2346.

> Due to an expected demand for the limited number of aids to be allocated for this program, Texas State Audio Inc. (vendor) suggests an early application.
> For information: Write 'Free Aid' P.O. Box 13257, Houston 77019 or call 526-1101.[48]

These few examples, representative of the many contained in the proceeding record itself, bring us to the questions posed in Issues 13 and 14 by illustrating the types of practices that inspired them:

> Issue 13: Does the offering of a hearing test, without disclosure at the outset that the tester is a seller of hearing aids and may attempt to sell a hearing aid to the person being tested, have the capacity or tendency to mislead consumers as to (a) the status of the person doing the testing and/or (b) the true nature or purpose of the offer and test?
>
> Issue 14: Does an advertisement which is not readily recognizable as an advertisement by the audience to whom it is addressed have the capacity or tendency to mislead consumers as to the nature and/or purpose of the communication?

The evidence in the record indicates that the answers to both of these questions is "yes."

The Goldentone Division, Raco Electronics Corporation advertisement cited in the text above, along with a similar Raco advertisement which appeared in the HOUSTON CHRONICLE in November, 1974, (R-8-D329) indicate to consumers that participants in the offered "hearing tests" are involved in field testing measures at no expense to such persons. Although Raco does identify itself by name in both these advertisements, it does not make clear to readers the fact that it is a hearing aid manufacturer; instead the ads are phrased in such a manner that consumers may misinterpret them to mean that the hearing tests involved are completely unrelated to any sales attempts or with any company having a direct interest in the sale of hearing aids. From the language, it would be easy to lead consumers into the belief that Raco is a consumer marketing surveyor or a field testing group rather than a manufacturer gathering sales leads for its dealers.

When this type of test offer is used in the absence of an indication that the offeror is a manufacturer or seller of hearing devices and that a sales effort will necessarily be involved

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48 R-8-2413.

the hearing test situation, consumers are misled as to both the status of the establishment or person doing such testing and as to the true purpose of the offer (i.e., the test).

For further examples and discussions of this type of advertising, reference should be made to Part V infra for a more thorough coverage of such misleading representations made in advertisements.

The record shows that some dealers misrepresent themselves as professionals, misrepresent the nature of their establishments, and use advertising offers of free hearing tests as a means to establish contact with the hearing-impaired. Taken as a whole, this advertising in conjunction with the other practices has the capacity and tendency to mislead and confuse hearing-impaired persons.

Turning to the type of confusing representations which have given rise to Issue 14, the advertising example cited above entitled "New Health Plan," placed by Texas State Audio, Inc., illustrates the type of advertisement which may not be readily recognized by readers as an attempt by a profit-oriented dealer to elicit interest in his particular brand of product. Rather, it is couched in such terms that, although the firm name is given along with the notation that it is a "vendor," the reader may readily confuse the name, utilizing the word "state" therein, with the type of state-funded programs that are being referred to in the body of the ad itself and to come out with the misinterpretation that the State of Texas, through one or more of its agencies, is attempting to locate and provide hearing health care benefits to its hearing-impaired citizens who qualify under a specific program. This is certainly not the case. Part V infra should be referred to for a full discussion of various representations that dealers had made to camouflage the profit-seeking nature of their hearing aid sales establishments by leading consumers to believe that they are some type of governmental public service, or charitable institution. Certainly ads of this nature have the capacity and tendency to mislead consumers, especially when they are placed in the media in a format which makes them appear to be by-line articles or public service announcements informing consumers of government-sponsored programs or field testing projects involving newly developed hearing aids. It can be concluded that many of these representations are aimed specifically at the elderly consumer by the mere fact of their playing on government programs such as Social Security Supplementary Benefits.

2. The sales pitch and procedures: in-home or at the retail outlet. With the lead in hand, the salesman who works outside a retail facility is ready to make his sales presentation. Sometimes, perhaps even often, he makes an appointment by telephone or mail to call upon a prospective customer, but it is a common custom of the trade to instead pay an unannounced visit

upon the prospect at his home, other place of residence, or at his business.[49] In this type of situation, the experienced salesperson catches the inexperienced prospective hearing aid purchaser at a considerable disadvantage. Here, too, occurs frequently the cunningly subtle and high-pressure sales pitches, the aggressive smooth talking of a salesman who practices the artful techniques he has learned in the sales manuals, the cutting of corners, and the making of commissions. All too often the result of such visits is that consumers are induced to make on-the-spot emotional purchases of hearing aids that are useless to them or inappropriate to their hearing losses, assuming that they do have a hearing loss.[50] At the same time, this is also frequently the scene of incompetent testing of hearing, the giving of poor or incorrect advice, and the making of improper recommendations, accidently or on purpose. And, this is the area in which incompetent, dishonest, and unethical salespeople have probably inflicted the greatest harm upon the good reputations of honest and competent salesmen and dealers. Ironically, the home, institution, or other place of residence has also been the site where many of the finest services have been performed by diligent and dedicated dealers who frequently travel long distances to accommodate those who are unable or disinclined to call at their regular places of business.[51]

While objectionable sales practices in the hearing aid industry are by no means limited to sales made outside the store or office, the record indicates that some whose positions involve the surveying of recurring sales abuses have found that the majority of complaints regarding such practices are made in connection with in-home sales.[52]

RPAG notes that a 1968 industry survey indicated that better than 60% of the total number of hearing aid sales occurred

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49 H. T. Lebrenz, consumer, R-4-42; Mrs. Harold C. Dean, consumer, R-4-407; Arnold McKee, consumer, R-4-351-351a.

50 Rafael A. Penalver, Jr., Esquire, on behalf of the National Council of Senior Citizens, Tr. 4909-10; see also Irene Bowen, Student Director, National Council for the Law and the Deaf, Tr. 1908-09.

51 ISPIRG, Note 1, supra at 33; William J. Brown, Esq., Attorney General, Ohio, R-6-298; see also Sections R-3 and 11 generally.

52 RPAG, R-8-421-II-4; see also A. L. Luzi, Southeastern Wisconsin Area Agency on Aging, Tr. 7708-10, 7715; James Langford, Associate Professor of Audiology, Northern Illinois University, Tr. 8004; Emma Gunterman, Legislative Advocate Senior Program, California Rural Legal Assistance, Tr. 9721-22.

in consumers' homes while several dealers indicated to the group that as high as 80% of their sales were of this nature.[53]

Elderly persons and parents of hearing-impaired children seem to be particularly vulnerable in regard to hearing aid salesmen making such approaches.[54] At the same time, however, it must be granted that many reputable dealers are able to seek out hearing-handicapped persons through in-home visits when such persons might otherwise not take the initiative to seek help for themselves and also to provide valuable services to those persons who are physically unable to get to a doctor or dealer.

Not of least importance in the unannounced visit is the fact that the salesman is totally prepared to meet the often surprised consumer. His first objective is to get his foot in the door,[55] by overcoming the myriad of objections which consumers can come up with on the spur of the moment.[56] For example, note these instructions from "How to Get in the Door":

> I MEET TOO MUCH RESISTANCE AT THE DOOR.
> WHEN I GET IN TO GIVE A HEARING TEST AND
> MAKE THE DEMO I CLOSE THE RIGHT PERCENTAGE.
> GETTING IN IS MY PROBLEM.
> 'Getting in' is an universal sales problem.
> You face it in common with everyone who
> earns a living in sales. The most important
> sale every successful salesman MUST learn
> to make is that FIRST SALE as soon as the
> door opens.
> WHAT DO YOU MEAN 'FIRST SALE'?
> NO ONE EVER MAKES A SALE UNTIL HE GETS IN.
> Think about that statement a minute . . .
> and you'll realize that no one GETS IN until
> he makes a FIRST sale--he sells his right
> to come in for the test and demo.
> HOW CAN HE DO THAT WHEN THE PROSPECT FLATLY
> DENIED HE HAS A HEARING LOSS? OR DENIED HE
> SENT IN THE CARD YOU ARE HOLDING IN YOUR

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53 RPAG, R-8-421, II-3 & 4; see also ISPIRG, Note 1, supra at 34; Irene Bowen, Note 50, supra at 1908.

54 ISPIRG, Note 1, supra at 36; see also Arthur S. Flemming, Commissioner, Administration on Aging, HEW, Tr. 610-11; Patricia G. Mastricola, Note 37, supra at 8618; George Shanta, Note 11, supra at 8866; Laszlo Stein, David T. Siegel Institute of Communicative Disorders, Michael Reese Hospital, Tr. 8977-79.

55 How to Get in the Door, Note 15, supra; Peltone Consultant's Manual, Note 15, supra at 12.

56 Id.

> HAND? It takes skill and the average salesman finds he becomes tremendously more successful when he masters the art. In a way, it is like jiu-jitsu: With proper leverage, you can use your opponent's thrust to help you gain your objective. And like jiu-jitsu, you can't gain the skill by reading about it and just talking. It takes study . . . and PRACTICE, PRACTICE, PRACTICE . . . to perfect your skill.
> Study the following typical objections and learn how the 'first sale' was made in each case (underlined to help you). Then practice, practice, practice and watch your close-to-call ratio improve.[57]

* * *

The in-home sale has been so effective in the obtaining of signed hearing aid purchase contracts, often through the use of abusive techniques and the element of consumer surprise, that rule proponents feel there is a need to place definite restrictions on such sales efforts. Accordingly, Issue 11 asks:

> Will the requirement that a seller obtain express written consent from prospective hearing aid buyers, prior to making visits to their homes or places of business (for the purpose of selling hearing aids) enhance the ability of such buyers to protect themselves against deceptive or unfair acts or practices (including high pressure sales tactics) which might be used by the seller?

The answer to this issue is "yes." In the words of the American Speech and Hearing Association, the requiring of prior and express written consent from a prospective hearing aid buyer "will enhance the ability of the buyer to protect himself from deceptive or unfair acts and practices utilized by a seller," although it is also noted that such requirement will not protect a buyer against the seller's possible high-pressure sales tactics used once the seller has gained entry to the buyer's place of residence or business. R-10-1764. However, if the consumer is aware that a hearing aid salesman will be calling at a specific time, it will allow him to be mentally prepared to better evaluate what the salesman has to tell him and to make more reasoned decisions than he might ordinarily make on the spot, following an unexpected high-pressure sales presentation. Sometimes getting one's "foot in the door" is made much easier if he is delivering the prize the

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57 How to Get in the Door, Note 15, supra.

consumer won by filling out a card at a fairground booth,[58] or by delivering a real aid instead of the nonworking model the consumer had ordered through a magazine advertisement,[59] or by making the call to deliver information the consumer had requested.[60] If there are objections on these approaches, the handy manual offers some good advice to the salesman:

> ALL I WANTED WAS INFORMATION. I EXPECTED A FOLDER IN THE MAIL, NOT A SALESMAN. Did you want the information for yourself, or a member of your family, Mrs. Jones?
>
> (answer)
>
> I didn't know who it was for, but I learned long ago that a booklet could cause a lot of unnecessary worry because the facts are not pinpointed. Could you spare a few minutes just to discuss your loss or ('s loss) with me? Then the booklet will be twice as valuable to you since you'll know exactly what you want to know!
>
> * * *
>
> I NEVER WROTE YOUR FIRM. I HEAR FINE. You are a fortunate person, Mr. Jones. If you didn't send in this card, you have a relative or friend with such high regard for you he was concerned about your hearing. As long as I am here, would you take a few minutes to have your hearing tested? If it is o.k., I'll note it on your card so you won't be bothered again. But if it should be off--even just a little--wouldn't you rather know? There's no charge whatever, and we'll be finished in a matter of minutes.
>
> * * *
>
> I KNEW THERE WAS A CATCH. I JUST WROTE FOR THE FREE _____ THAT WAS OFFERED. AND NOW YOU COME RUNNING OUT TO TRY TO SELL ME SOMETHING.

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58 Evelyn Sudbrock, Eugene, Oregon, R-4-D400.

59 Mrs. Arnold B. McKee, Aiken, South Carolina, R-7-351.

60 How to Get in the Door, Note 15, supra.

> I'm not here to sell you a thing, Mrs. Smith. The _____ is a free gift exactly as the ad stated. But we have found there are so many unanswered questions when we just mail them, we now deliver them in person as an added service. It will only take a few minutes to explain this fully so the gift will be of genuine value to you. May I come in and answer all your questions?[61]

* * *

So, once he overcomes any resistance, he next proceeds to make his presentation. The format he uses may depend upon whether the potential user is an elderly person, the parents of a young child, a present user, or a present nonuser. But in any case, either at the beginning of this presentation or when the prospective customer first greets him at the door, he often takes the opportunity to introduce himself using a professional or seemingly professional title to initially instill in the prospective buyer the belief that he (the salesman) is more qualified than he really is. To succeed later in his presentation, he must qualify himself as an "expert" in order to build even greater customer confidence in his abilities. Once again the sales manual speaks:

> Q. - Qualify as an Expert
>
> After the problem has been built and the prospect is aware of the seriousness of the problem, you must establish beyond any doubt that you are the person most qualified to help him with his problem.[62]

The next step may be to question the prospect about his "hearing problem," proceeding then directly to testing of the hearing facility. The record demonstrates that all too often such testing is conducted improperly by inadequately trained salesmen using unreliable instruments under unsuitable, if not deplorable, circumstances.[63]

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61 Id.

62 Beltone Consultant's Manual, Note 15, supra at 11. See also Robert Beiter, Note 29, supra at 9035.

63 ASHA, R-10-1629, 1635-36; Janet Levy, Director, California Department of Aging, Tr. 11648; Susan Kline, MPIRG, Tr. 7574-79; Duane Anderson, Unit Manager, Hearing Aid Dealers Registration, Oregon Health Division, Tr. 11727-88; Irene Bowen, Note 50, supra at 1911.

The test results should indicate whether or not the person is a candidate for a hearing aid.[64] These tests should be conducted in a sound-treated room, but this is not possible in in-home testing, and is not usual in a dealer's office. Testing, in order to be accurate, must also be done with a properly calibrated audiometer and should minimally include pure-tone, air and bone-conduction threshold tests and speech reception threshold and speech discrimination tests.[65] (Part II supra discusses the types of hearing tests that would be involved in a complete hearing evaluation.) Yet the RPAG study noted that "the testing done by all dealers consisted almost entirely of air-conduction and pure-tone testing."[66]

Dealers record their test results on a graph or audiogram that is based on norms obtainable only in a soundproof test environment; thus, it is really impossible to accurately compare such results with such norms unless the dealer's testing was done under conditions identical to those under which the graph (audiogram) was produced. Accordingly, when the dealer attempts to match up his findings with the norms, the audiogram of a person with normal hearing shows below normal hearing if the person has been tested under noisy conditions. At the same time, the graph of a person with a hearing loss will indicate that person's loss to be worse than it actually is.[67] Not only may the consumer be misled by the objective test results but, during the sales presentation, he may be subjected to confusing tactics such as the salesman's use of obscured speech, strategic shifting from a room with good acoustics to a room with poor acoustics, use of high-frequency word discrimination tests for unaided hearing and use of low-frequency word discrimination tests for aided hearing (which are especially misleading in the cases of the elderly with sensorineural losses), and the use of out right false audiograms with misplaced scores which indicate a loss when none exists.[68]

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64 ISPIRG, Note 1, supra at 26.

65 Id. at 26, 30-31; see also Austin Smith, M.D., retired otolaryngologist, Tr. 8157; Richard Scott, Siemans Hearing Instruments, Tr. 2316-18.

66 RPAG, Note 1, supra at I-11-12.

67 Id. at I-9-10; Earl Harford, Professor of Audiology, Vanderbilt University Medical School, Tr. 131; John Fennema, Note 11, supra at 1753; see contra, Vincent Giglia, President, Audio Instrument Company, Tr. 2740.

68 ASHA, R-10-1635-36; see also Maurice Miller, Note 2, supra at 4780-81; Nettie Murray, consumer, Tr. 4840-41.

Also, although the presence of various physical symptoms should indicate to the dealer that medical referrals should be made (and, in spite of the fact that ten states, by law, require such referrals), there are many dealers who do not even recognize these conditions. In fact, dealers seldom advise people to see a doctor even when they are asked if this would be appropriate prior to a hearing aid purchase.[69] Some encourage hasty customer decisions in order to be sure that a sale is made;[70] witness the following training manual excerpt:

> [Mr. Peters] you've waited long enough. The time for talk is past. Now is the time for action. Let's call your doctor right now while everything is fresh in your mind, and while I'm here to answer any technical questions he might have. But before we do, tell me--do you have a doubt in your mind? Have I failed to answer any question you might have about how much your hearing can be helped?[71]

Or as an example of the common dealer approach toward medical referrals:

> --For example, a few specific patients come to mind, one was a patient whom we saw who had a severe bilateral conductive hearing loss. He had had this loss for approximately 15 to 20 years. He came to us wearing hearing aids and informed me that he had been told by his hearing aid dealer that he didn't need to bother to go and see a doctor because they couldn't do anything for him anyway. He did, in fact, have a surgically treatable condition.[72]

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69 RPAG, Note 1, supra at II-6-7; see also Nettie Murray, Note 68, supra at 4841; Frank Butts, audiologist, Tr. 4166; Dr. Stephen Epstein, otolaryngologist, National Council of Senior Citizens, Tr. 4563; Maurice Miller, Note 2, supra at 4755-60.

70 Dr. John C. Bess, Georgia Speech and Hearing Association, Tr. 6232.

71 How to Convert Objections into Sales, Note 15, supra.

72 Laura Ann Wilber, Ph.D., Associate Professor and Director, Hearing & Speech Service, Albert Einstein College of Medicine, R-8-5327.

3. Use of master hearing aids. In their testing, dealers usually use a master hearing aid. This instrument is used to determine the degree, pattern, and remedial needs of particular hearing losses, and the customer's tolerance for sounds. Through the findings of this instrument, it can be determined whether ample amplification is being provided to the user, what the proper frequency response characteristics of the instruments should be, and how much sound can be tolerated in the wearing of a device, i.e., the threshold of pain or discomfort is located so that the person wearing the hearing device will not suffer pain because of a sudden loud noise. Using the information he gains through use of this instrument, the dealer next employs a "fitting guide" to select the model of hearing aid and the setting required by the particular customer.[73] It has been charged, however, that this instrument has been used by dealers to give potential customers illusory hopes of what they can expect in the way of improved hearing ability with a commercially available, personal hearing aid.[74] Often the performance of the master hearing aid differs substantially from that of the individually worn aid for one or more reasons.[75] ASHA notes that master hearing aids and similar devices have better sound amplifying characteristics; at the same time, they do not duplicate the electroacoustic properties of all models of hearing aids. R-10-1761, 1763.

Furthermore, as master hearing aids can vary as widely from manufacturers' specifications as normal hearing aids do, the simulated sound they deliver may be grossly misleading to the consumer in the absence of requirements that the instruments be periodically calibrated or rechecked. R-10-1763. A survey conducted by Wendel K. Walton and Peggy S. Williams, reported in their article, "Stability of Routinely Serviced Portable Audiometers," (LANGUAGE, SPEECH & HEARING SERVICES IN SCHOOLS, Volume III, No. 2, 1972) indicated that 82% of the instruments tested did not meet calibration standards in at least one area. R-13-2014-20. However, their later survey reported in "Stability of Pure-Tone Audiometers during Periods of Heavy Use in Identification Audiometry" (LANGUAGE, SPEECH & HEARING SERVICES IN SCHOOLS, Volume V, No. 1, January 1974) suggested that audiometers' stability was good (R-13-2025) so that calibration is perhaps not a problem to the degree once thought.

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73 David Barnow, Note 5, supra at 1644-45, see also Robert Briskey, audiologist, Beltone Electronics Corporation, Tr. 7253-54.

74 John C. Brennan, consumer, Laurel, Maryland, Tr. 247; A. L. Luzi, Note 52, supra at 7726-27; ASHA, R-10-1760-61.

75 A. L. Luzi, Note 52, supra at 7727; John Franks, Assistant Professor of Audiology, Dept. of Speech and Theater, Arizona State University, Tr. 9810, and ASHA, R-10-1761; contra, Leslie Paul Leale, dealer, Tr. 11732.

John Franks, Assistant Professor of Audiology at Arizona State University, testified that the hearing aid ultimately received from the manufacturer does not do "the same things" in terms of the preprocessing of speech signals as the master hearing aid does, and the difference in the electroacoustical characteristics of the two instruments are again cited. Tr-9810. Kenneth W. Berger, writing in "The Search for a Master Hearing Aid" (Amplification for the Hearing-Impaired, Pollack, ed., Grune and Stratton, 1975) points out that the frequency responses in the master units may not represent frequency responses typically found in contemporary models of personal hearing aids made by the same manufacturer; also although four or five frequency responses are common to most master instruments, the terms used to describe these responses and the responses themselves vary considerably. R-8-Physical Exhibit B, page 318. A survey of clinical attitudes regarding the performance of master aids in the 1960's was generally unfavorable toward their use because at the time the test results based on measurements with the master aid could not be readily applied to various brand and model recommendations. R-8-Physical Exhibit B, pages 312-13.

The record does not indicate that this situation has substantially changed today. Berger states that the already confused state resulting from such variances is hardly helped by the direction booklets distributed to dealers by master aid manufacturers; these publications include and discuss the respective specifications and technical data of the master devices much less completely than do printed hearing aid data on personal aid models manufactured by the same companies. He feels that it is not unfair to characterize these booklets as, for the most part, sets of instructions to help the hearing aid dealer sell the manufacturer's product rather than to evaluate the client's performance or need for amplification. For example, he points out that it is rare to find a hearing aid dealer who cannot consistently and readily "prove" with the use of a master hearing aid that virtually every client tested performs significantly better under the binaural mode than under the monaural mode although it is well known that differences between monaural and binaural amplification are often extremely difficult to determine under highly controlled and objective test conditions. R-8-Physical Exhibit B, page 318. If the master instrument is ever to play the important role of which he believes it is capable, Berger states that there must be a general agreement between audiologists, hearing aid dealers, and hearing aid industry members as to what the instrument should accomplish and how it should do it. R-8-Physical Exhibit B, pages 318-19.

Even the industry admits that master hearing aids may not duplicate exactly the hearing provided by personal hearing aids, but, nonetheless it does contend that the instrument is

invaluable in determining which hearing aid may be the most suitable for a particular consumer.[76]

Whatever the dealers' proper purposes are for utilizing master aids, the record shows that in many instances they have been deceptively used to demonstrate a performance that the consumer does not achieve with a personal hearing aid, although he may be led to believe that the "simulated" performance of the master aid is a duplication of the hearing aid's performance. However, because of specification and performance differences in addition to whatever calibration problems exist, representations implying similar performances between master devices and actual hearing aids would have a significant capacity or tendency to misrepresent the true state of hearing a customer can expect from his purchase.[77] The failure to disclose that the sounds would not be the same would, of course, also be misleading and unfair.

Although the frequency of master aid usage cannot be quantified from the evidence in the record, as ASHA states, "The proportionality of such use does not . . . diminish our concern that such master hearing aids inherently can be deceptive and misrepresent the benefit to the prospective purchaser."[78] (Berger indicates that master aid use in clinics is apparently not widespread. R-8-Physical Exhibit B, page 305).

Thus, Issue 10, which asks:

> Do "master hearing aids" or similar devices perform in a materially different manner from the actual performance (in actual use situations) of the hearing aids sold to consumers? To what extent are "master hearing aids" or similar devices utilized to demonstrate the performance a consumer can expect from a hearing aid?

should be answered as follows: regarding the first question, performances of master devices may be materially different from those of actual hearing aids in many, if not most, cases. While

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76 John Kojis, Note 12, supra at 2082; see also James Delk, Note 6, supra at 10925, 10948, 10953-54; Robert Briskey, Note 73, supra at 7253; HAIC, R-3-3959-60.

77 ASHA, R-10-1763; see also Thomas W. Norris, Note 42, supra at R-10-6497; John C. Brennan, Note 74, supra at 247.

78 ASHA, R-10-1761.

a statement characterizing all such performances as "materially" different would be too broad to accurately state the situation, the difference potential is present in virtually every instance due to the multiple variations of performance characteristics that exist between different master aids and between master aids and the hearing aids that are fitted to individuals for everyday use. Regarding the issue's second question, it is unknown to what precise extent master devices are used in the selection and fitting processes, but use does not appear to be uncommon except perhaps in clinical situations. Because material performance discrepancies may occur and because, when they do, hearing facility may be improved to a much greater degree with the master aid than with the actual commercially available hearing device, it is obvious that some consumers are disappointed to learn that their individual instruments do not approximate the improved facility they have encountered in the testing situation; in this sense, they have certainly been misled, whether intentionally or not. On the other hand, these performance differences would present the dealer who is inclined to misrepresent such matters in order to close sales with an excellent opportunity to do so.

Following completion of the test procedures, the dealer attempts to make a sale. If the consumer is a hearing aid user, the dealer may advise that the presently owned aid is either not repairable or is not economically repairable, or even that it is too old to be repaired.[79]

4. Sale of used aids as new. Hearing aid dealers strongly contend that there is no market for used aids.[80] Therefore, if a dealer had on hand a supply of used aids, there would be some incentive to sell them as new. If a dealer does in fact sell a used aid, a failure on his part to disclose to a potential purchaser the fact that a hearing aid offered for sale as "new" is actually used would most definitely have the capacity or tendency to mislead the consumer regarding a material fact affecting the purchase decision. Furthermore, such a failure would be especially misleading when one also considers the definite buyer prejudice against purchasing a "personal" product of

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79 See, e.g., Pauline Schwartz, consumer, Tr. 4879; Michael Stahl, Note 30, supra 5535-36.

80 NHAS, R-3-3555; see also Robert Baesemann, Ph.D., Professor of Economics, Northwestern University, Tr. 7322, referring to HX-112; HAIC, R-3-3987; James C. Keyes, Executive Vice-President of the Audiotone Division of Royal Industries, Tr. 10754-57.

this nature that has been previously rejected by someone else. The record supports the fact that such sales are made.[81]

Accordingly, the answer to Issue 12, which asks:

> Does failure to disclose previous use of a hearing aid have the capacity or tendency to mislead consumers as to a fact material to them in making their decision as to whether to purchase the particular hearing aid?

must be in the affirmative. If a consumer knew that an aid offered to him was used, he would probably not make the purchase if he were asked to pay the new aid price for it. Certainly if he paid the "new" price for a used hearing aid, believing his purchase involved a new hearing aid, the failure to disclose the fact of prior use would definitely be deceptive as to this very material fact. Since the evidence does indicate that "used" hearing aids have been sold as "new," in a substantial number of cases, Section 440.7(c) is warranted to curtail the practice.

5. Overcoming buyer resistance. If the dealer recommends the purchase of a hearing aid but meets with reluctance or resistance on the part of the consumer, he may resort to intimidating or shaming the consumer into a purchase. The manuals suggest to him various methods of this type for his use. An example from the Beltone Consultant's Manual:

> How many people don't come to visit you anymore? Why? Because you act like a bump on the log in a conversation. Because you don't answer right--you feel uncomfortable and that makes them feel uncomfortable.[82]

But, if these milder methods do not induce the purchase, he may then turn to the use of scare tactics: the consumer will lose his hearing completely if he does not buy an aid immediately or his hearing will deteriorate further and faster.[83] An example from the Dahlberg Training Guide for Hearing Aid Salesmen:

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81 NHAS, R-3-3555; James C. Keyes, Note 80, supra at 10755; Helen Kelly, Special Assistant Attorney General, State of Minnesota, Tr. 7524-25; Cyril F. Brickfield, Legal Counsel, NRTA/AARP, R-10-883; Nadine Woodard, International Association of Parents of the Deaf, Tr. 4139-40; Elma Griesel, Note 14, supra at 9460; David H. Marlin, National Council of Senior Citizens, R-10-467, R-8-D646.

82 See Beltone Consultants Manual, R-8-D250, Section IV-30.

83 See, e.g., Betty K. Hamburger, National Council of Senior Citizens, Tr. 5355-56; Susan Kline, Note 63, supra at 7579-80; Mary Ruth Whitman, Note 25, supra at 8562-63.

> I STILL THINK I HEAR WELL ENOUGH. I CAN GET ALONG WITHOUT AN AID.
> You're 100% right Mr. Samuels, you're not deaf. I'm not blind either (or anyone in the room) but I wear glasses to help correct my vision just as you should wear an aid to correct your hearing. The big difference is this--the longer you wait with a hearing loss, the worse it becomes AND THE HARDER IT WILL BE FOR YOU TO GET THE KIND OF HELP YOU WILL NEED. Remember,--(then review his loss, his word score, etc., and the improvement with a correction--and reemphasize that in a year or two it may be difficult to get the same results).

Even present users may be threatened with hearing deterioration if they display a reluctance to purchase a replacement device.[84] Sometimes dealers use every opportunity to sell and resell to the same customer; the following instances illustrate how this policy operates to consumers' detriment:

> A . . . patient came to us and told us that they had been told by the hearing aid dealer that they would have to buy body aids and then they were told that after they used them for a while they would be able to purchase behind the ear aids and after they had learned to use those satisfactorily they would be able to purchase in-the-ear hearing aids. This was for both ears in each case which would amount to almost $2,000 worth of aids when, in fact, through Master Plan we were able to find an appropriate hearing aid for less than $200 to take care of the problem.[85]

> Another hearing aid dealer in the State of Minnesota . . . would advertise . . . or contact his former customers and indicate that their hearing aids needed factory improvement, that the factory had now issued some type of warning that the aid had to be adjusted. Well, in fact the factory had not issued that type of warning, but this particular dealer used it as a ploy

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[84] Susan Kline, Note 63, supra at 7580.

[85] Example taken from comments of Laura Ann Wilber, Note 72, supra at 5327-28.

> for getting back to the consumer and then attempting to sell them a new aid, if possible.[86]

This policy also sometimes results in "oversell" of binaural systems or in sales of amplification devices when other procedures, e.g., surgery, may be appropriate:

> [A] Mr. William Perry of Pine Bluff, Arkansas, was fitted in 1975, with a hearing aid on a nonfunctional ear. This aid was fitted as a second aid; this gentleman was already wearing an aid on his better hearing ear. Due to the nature of this hearing loss, he was not able to use any type of amplification on the poorer hearing ear.
>
> * * *
>
> [A] Mrs. Lois Rossi, of Conway, Arkansas, was told that her hearing loss was not surgically correctable and that she should wear hearing aids. She later had Stapedectomies in both ears and now has hearing within the normal range.[87]
>
> * * *
>
> A third patient came to us with bilateral hearing aids while, in fact, he only had a unilateral hearing loss, but he did not know that the bilateral hearing aids were not necessary.[88]

The matter of binaural hearing systems and their merits for certain types of hearing-impaired individuals is discussed at length in Part VII infra, as is the existence of a group of individuals who only believe that they have traditional hearing losses for which amplification may give them significant hearing improvement, but who have no such losses and cannot benefit from amplification.

In some cases, promises of refunds in the event that the hearing device proves unsatisfactory are used to lay resistance to rest; in fact, many so-called guarantees are not honored

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[86] Example given in testimony of Helen Kelly, Note 81, supra at 7526.

[87] Sharon S. Graham, M.A., The Ear, Nose, and Throat Clinic, P.A., R-8-5273-74.

[88] Laura Ann Wilbur, Note 72, supra at 5327.

although consumers in the past have gone to some lengths in attempts to obtain satisfaction where such representations have been made to them.[89]

6. Issue 1. Although the foregoing discussion by no means incorporates all of the many descriptions of abusive techniques reported in this proceeding, it does provide the answers to the questions presented by Issue 1 that are relevant to the rule.[90] This was a general issue that asked what techniques are used to sell hearing aids; in what respects do those techniques have the capacity and tendency to deceive consumers; how such techniques might be unfair to consumers; and how prevalent is their use.

Virtually all of the practices described in this part of the report are not only unfair but they also have the tendency and capacity inherent within them to mislead consumers primarily because they portray untrue or distorted facts or situations that the consumer, in his general ignorance of hearing problems and of the hearing health care delivery system, does not recognize for what they are. In responding to "come-ons" designed to produce leads, consumers usually are totally misled in regard to what they can expect in response to their inquiries, i.e., they do not expect the response to take the form of an almost irresistible sales pitch--when the "expert" salesman confronts the novice consumer. The uses and benefits of amplification are too often intentionally misrepresented as being greater and more effective than the given state of technology and the "art" of fitting devices permit. The qualifications of the dealers, too, are often disguised beneath titles that imply an expertise or professionalism that he often does not possess. Incorrect or misinterpreted test results may be used to pinpoint a hearing loss that does not exist or may not exist to the degree "indicated." When the consumer is accordingly misled into purchasing an instrument at a cost of several hundred dollars only to learn that he receives

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[89] A. L. Luzi, Note 52, supra at 7710-11. Frances O'Brien, consumer, R-4-396; James H. Price, consumer, R-4-357-60; C. J. Corelli, consumer, R-4-303; A. L. Stoll, R-4-294-95.

[90] General (designated) Issue 1, 40 Fed. Reg. 59748:

> As relevant to the Proposed Rule, what are the sales techniques employed by sellers (at any and/or all levels of distribution) in connection with the offering for sale and/or sale of hearing aids? In what respects could such techniques have the capacity or tendency to deceive consumers, and how might such techniques be unfair to consumers? How prevalent are such techniques?

limited benefits or no benefit from it, he is certainly deceived. This fact becomes even more important when one considers that many consumers cannot really afford, economically, to suffer this type of loss not to mention the psychological effects such an experience has upon him. At the same time, the salesman, on the opposite side of the coin, has economically gained from the loss he has perpetrated on the impaired consumer through the use of unfair and deceptive acts and practices.

Turning to quantification of such use, it is noted that arguments citing specific cases of deception could go on endlessly without calling attention directly to information from which the frequency of use could be numerically established. Even though there are a significant number of dealers and salespersons who do not engage in such techniques, it is obvious that there are many others who have no hesitation about using them. In fact, the record shows so much evidence of abuses that it can be fairly concluded that for some dealers and salespersons, consumer abuse is not exceptional. In any event, the amount of consumer abuse coming from the dealer-salesman segment of the industry appears to be substantial.

The question of whether unfair and deceptive acts or practices in this industry are prevelant and widespread provoked extensive comments throughout the proceeding. The National Hearing Aid Society has made a serious effort to convince the Commission that there are an insignificant number of selling abuses. This effort involved a survey of consumer complaints that had been classified and recorded by federal, state, and local agencies responsible for consumer protection activities. The findings and arguments presented by NHAS in its written comments (R-3-D646-16-35) and in its final compilation of the survey presented as a rebuttal statement deserve careful consideration.[91] Summary comments on that survey are warranted here.

NHAS collected (from certain state agencies and licensing boards) data on the number of complaints received, classified, and properly recorded as relating to hearing aids. Then, NHAS compared the number of complaints with the number of hearing aids sold to determine that the ratio of complaints to sales is "incredibly low." On that basis, those experienced in problems related to various complaint recordation systems (and the lack thereof) would likely expect to find only limited factual information which, of course, would permit conclusions similar to those reached by NHAS.

Most complaint recording systems have many categories into which any one complaint might find its resting place. For

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[91] R-13-D146, entitled Consumer Complaint Analysis (in two books).

instance, a hearing aid-related complaint might be catalogued solely under one of many classifications (i.e., hearing aids, health devices, professional services, referral sales, miscellaneous, unspecified, door-to-door, mail order, failure to deliver, failure to refund, failure to perform services, failure to honor guarantee, misleading advertising, deceptive pricing, bait advertising, free offer, out of business, selling used as new, misrepresenting repairs needed, misrepresenting product performance, defective product, unethical dealer, warranty, direct selling, credit, loan, improper repairs, collection agency, home solicitation, medical, other, etc.--the list goes on). Under such circumstances, it is impossible to conclude that all hearing aid-related complaints are recorded as such. Also, it is neither reasonable to conclude that all complaints received are recorded, nor that every complaint in the universe is even received by an official governmental agency. There are countless variables to consider.

Indeed, many comments on the record concerned speculation of whether the hearing-impaired and/or elderly would or could complain to their governments. The National Council of Senior Citizens submitted a nine page rebuttal (with multiple citations to the record) to refute those who contended such consumers readily complain. That document also deserves serious consideration. R-13-D148. It itemizes some of the many reasons why such consumers fail to direct their complaints to governments.

The American Speech and Hearing Association submitted a similar rebuttal reporting on its own study which indicated that government officials experienced in consumer affairs almost always agree that hearing-impaired ard/or elderly consumers are not likely to complain in writing to governmental offices and agencies regarding industry sales abuses.[92] This, too, deserves careful consideration.

An important effort to determine that there are significant selling abuses was made by the National Council of Senior Citizens in two short-lived explorations to uncover consumer complaints. One project took place in Boston, Massachusetts, and resulted in 45 affidavits from consumers who were considered to have complaints related to the proposed rule.[93] The second project was conducted in and near Miami, Florida, and resulted in 30 affidavits from

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92 R-13-D147-IV-27-IV-37.

93 Leonard W. Finkle, Esq., Tr. 4441-95. Consumer Affidavits, R-10-4604-756.

consumers with complaints considered related to the rule.[94] Of course, the record is replete with other accounts of complaints and abuses.

Experience in determining the merits and value of consumer complaints leads one to conclude that a single complaint may be the only one of its kind while two similar complaints may be merely coincidental--but they probably point to a definite problem; five or ten complaints in an industry most likely mean real trouble and are most probably only the "tip of an iceberg." But when the FTC collects hundreds of complaints against one small industry, with relatively few consumers, there is an absolute certainty that untold thousands of consumers have been victimized. Given these facts and the evidence that hearing-impaired and/or elderly persons are disinclined to complain to their government for many reasons apparent on the record as a whole, it is impossible to avoid the obvious truth. The evidence is overwhelming.

In contrast to NHAS's above mentioned professional effort to refute the evidence that there are a significant number of abused and dissatisfied consumers, many dealers encouraged satisfied consumers to voice their satisfaction with dealer products and services, and to object to the proposed rule. One rule proponent reviewed these "solicited" letters and concluded that NHAS had obviously sent form letters to its state chapters as part of a nationwide letter writing campaign of scare tactics designed to solicit support for the industry's objections to the rule.[95] In addition, several petitions were circulated by dealers. Tr. 1913.

Any objective analysis of the responses to such efforts casts shadows over the credibility of the organizations and individual dealers who employed these form letters or similar tactics because of the extremely biased manner in which the dealers' opinions were presented to their customers and the total failure to even present summary information concerning the content or purpose of the proposed rule. R-13-779-83.[96] However, these letters do tell us that there are many hearing aid users (1) who need and want dealer service in their homes, (2) who have a great deal of faith, trust, and confidence in their dealers, and (3) who are being satisfied by dealers who are inclined to

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[94] Rafael A. Penalver, Jr., Esq., Note 50, supra at 4895-985. Consumer Affidavits, R-10-4482-506, 4509-93. The Florida Hearing Aid Society submitted rebuttal statements to nine of the complaints against dealers in Florida. R-13-2402-27.

[95] Irene Bowen, Note 50, supra at 1913-16.

[96] Section 11 of the record contains most of the communications received from consumers opposed to the rule but some are in Section 4.

tell their customers less than the whole truth and, thereby, deceive them. These hearing aid users become extremely dependent on their dealers who are well aware of the unusual trusting relationship that develops between buyer and seller in this industry. But, it is evident on the record as a whole that there are too many cases where the dealers have failed to recognize that relationships of reliance, trust, and confidence demand a high degree of care, objectivity, and honesty on the part of the person being trusted.

F. Summary of findings and conclusions.

1. Findings. Hearing aid dealers and salesmen are frequently lacking in the proper training that would allow them to effectively and accurately test hearing, fit and adjust appropriate hearing devices, and render followup services to a customer; no specific educational requirements are mandated for entry into this commercial but health care related field and although courses and workshops are offered by the trade association, NHAS, and various manufacturers, the training provided thereby is at best meager. As a result, most of the training received by sales personnel comes from manufacturers' sales manuals that are generally geared to "teaching" high-pressure and deceptive sales efforts.

For every hearing aid dealer-salesman, there is a conflict between the need to make a profit, and thus to remain in business, and the desire to render service to the hearing-impaired customer. For some dealers and salesmen, the profit motive is the primary concern. This latter group is aided and abetted in its sales efforts by the manufacturers' encouragement in the form of contests in which trips are awarded for the highest sales volume, discounts given to dealers on the basis of volume of business, and the like.

Dealers and salesmen function in a relatively control-free environment insofar as their ethics and practices are concerned. Although almost all of them could be controlled to some extent, at least theoretically, either by the manufacturers of the lines they carry, by their trade associations, by the states through the enforcement of licensing and regulatory laws, or by the states through the enforcement of various consumer protection statutes, in fact, they are not effectively controlled. The national and state trade associations count only a relatively small percentage of the sales component of the industry in their membership; the states for various reasons have been unable to adequately enforce their laws in this area, and the "control" exerted by the manufacturers consists mainly in encouraging of sales.

The repertoire of the hearing aid salesman is made up of a broad spectrum of questionable practices and devices, beginning with the use of misleading or outright deceptive advertising

designed to elicit consumer responses through various means as free gifts, information, etc. Although such ads may be so worded as to prevent the consumer from identifying the advertiser as a sales agency, his indication of interest in any aspect of the ad's content generally brings a high-pressure salesman to his doorstep with a wealth of tactics formulated to counter any resistance that he may have to a sales presentation. To convince the prospect that he has a serious hearing problem with which the salesman can help him, incomplete or misinterpreted test results derived from examination documented under less than perfect testing conditions are played upon; quite often, however, the salesman doesn't even have the training, equipment, or ability to properly conduct such tests or to interpret them. Although testing weaknesses may be found less often in the retail outlet than in the in-home sales situation, all segments of the hearing aid sales industry is afflicted to some extent by this general lack of testing ability. If the test results fail to convince the prospective customer of his need, he may then be pressured, taunted, or shamed by the salesman who uses all of the principles of the "psychology" of the deaf that he has at his command to finally "close" the sale.

The use of a master hearing aid device, producing in many instances a superior hearing experience than that which can be achieved through the use of a commercial hearing device, is a powerful sales point for those salesmen who use it; guarantees, warranties, and offers of refunds in case of dissatifaction may also figure importantly in the sales presentation although in reality the pledges and promises made are often hollow and refunds are not made when requested.

2. Conclusions. Lacking as they often are in proper training, highly motivated by profit concerns, and relatively free of outside control of their business ethics and practices, salesmen often employ the practices just discussed, either singularly or in combination, to deceive and mislead consumers into buying hearing devices that they either cannot use at all or from which they receive little or no benefit due to the fact that it is ill-fitted or because it is inappropriate to the particular hearing loss involved. When this is the case, the consumer suffers a substantial monetary loss which he often cannot afford, in addition to the psychological detriment the experience has upon him. On the opposite side of the coin, the dealer who has used such unfair acts and practices stands to economically gain from the same loss that he has caused.

The record, therefore, supports the need for remedial action in this area. As regulation of the training of sales personnel and exercise of control over each unit of sales operation seems to be almost impossible (not to mention the impossibility of controlling motivation), other methods must be used to deprive the unfair, deceptive, and misleading practices of their effectiveness. Requirements of mandatory disclosures involving the nature and

purpose of initial sales contacts and the nature and business interest of the person or firm making them (see also Part V infra) along with similar disclosure requirements involving the nature and effectiveness of amplification (Part VI infra), the discrepancy between the performance of a master hearing aid device and a personal hearing aid and the disclosure of certain negative aspects of hearing aids or certain types of hearing systems (Part VII, infra) will go far in solving some of the consumer problems discussed in this section. At the same time, although it is recognized that the requiring of prior written consent for an in-home sales presentation will not eliminate high-pressure sales tactics, it will at least assure that the consumer is put on notice that a sales attempt will be made at a certain time and he can be accordingly prepared not to yield to pressure and make unwise purchase decisions on the spur of the moment. Taken together with the buyer's right to cancel (Part IV infra) the consumer might be able to act in time to save himself from the harm that might come from this type of sale. Also, or at the very least, advertising used to gather leads should disclose that "a salesman will call."

PART IV. BUYER'S RIGHT TO CANCEL

A. Why a trial period is justified.

1. General considerations. Section 440.4 of the proposed rule requires the seller to include in every contract or receipt pertaining to the sale of a hearing aid a provision according the buyer the right to cancel a purchase or rental for any reason at any time prior to midnight of the 30th day after the receipt of the hearing aid.[1] This proposed provision was addressed in most of the written comments received in the course of this proceeding. It was also either supported or denounced by nearly all of the witnesses who testified at the public hearings. Much of this comment and testimony was cumulative.

Some of those who supported the provision gave as one reason therefor the profit motives and sales techniques of hearing aid dealers which they considered to be unfair to the consumer.[2] These techniques were discussed in Part III of this report, and that discussion will not be repeated here. Similarly, some based their support for this provision of the rule in part on dealers' lack of competency and on misleading or deceptive representations made by hearing aid sellers regarding their qualifications.[3] These matters are considered in Parts III and V of this report. Other participants in the proceeding said that the provision was necessary because of false and misleading advertising regarding hearing aids generally.[4] This subject is treated in Parts VI and VII of this report. The inadequacy of other consumer protection measures was also cited by some as a justification for according the buyer the right to cancel the purchase of a hearing aid.[5] A description and assessment of these measures is in Part VIII of this report.

Perhaps the reason most often cited as justifying the need for the buyer's right to cancel, however, was that the procedures

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1 40 Fed. Reg. 26647.

2 See, e.g., Susan Kline, Minnesota Public Interest Research Group, Tr. 7581-83; John B. Davis, Executive Secretary, Illinois Association of the Deaf, Tr. 8536.

3 See, e.g., Richard Conlin, Public Interest Research Group, Michigan, Tr. 7771-72.

4 See, e.g., David M. Link, Acting Director of the Bureau of Medical Devices and Diagnostic Products, FDA, Tr. 1116-17.

5 See, e.g., Judith Munger, National Council of Senior Citizens, Tr. 4502-05.

employed in selecting and fitting hearing aids are not truly scientific, making it impossible to predict accurately whether an individual can or will make successful use of a hearing aid.[6]

Those who opposed the adoption of the provision strongly contended that it was unnecessary, unfair to hearing aid dealers, and not in the best interests of the hard of hearing since it would provide an easy out to those who need to be persuaded to wear a hearing aid.[7]

Perhaps no other provision of the rule has the greatest potential for economic effect on manufacturers, dealers, and consumers alike. There is little doubt that the potential economic effect of the rule dictated the position adopted by many of those in favor of the inclusion of the buyer's right to cancel in the final rule as well as by those who opposed its inclusion. The economic effect of the buyer's right to cancel is considered in Part IX of this report.

In this part of the report those issues which relate to the need for a buyer's right to cancel for reasons other than selling techniques, advertising representations, the adequacy of other consumer protection measures, and economic considerations are reviewed. The designated issues which are obviously closely related are as follows:[8]

Issue 5

> Do a significant number of consumers buy hearing aids from which they receive no significant benefit (or no significant additional benefit if they are current hearing aid users buying a second hearing aid or a "better" hearing aid)?

Issue 6

> Is it necessary for a significant number of prospective hearing aid buyers to wear the selected hearing aid in a representative variety of actual use situations before it can be determined whether a significant benefit (or a significant additional benefit) will in fact be received?

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6 See, e.g., Judith A. Rassi, audiologist, Tr. 5736.

7 See, e.g., David Barnow, former President, Hearing Aid Industry Conference and a former officer of Beltone Electronics Corporation, Tr. 1637; James H. Johnson, HAIC, Tr. 2262, 2265; Vincent James Giglia, President, Audio Instrument Company, Tr. 2706.

8 40 Fed. Reg. 59748.

Issue 7

Are there a significant number of prospective hearing aid buyers who cannot determine the relative importance to themselves of the advantages and limitations of a hearing aid without wearing the selected hearing aid in a representative variety of actual use situations?

2. Some purchasers receive no benefit. Evidence that there are a significant number of consumers who do not receive a significant benefit from hearing aids they have purchased is provided by data from the National Health Survey. This data collected in 1962-63 showed that 36.6% of those persons who had used a hearing aid had stopped using it.[9] Thirty percent of those who had worn an aid had stopped using it even though they could not hear and understand spoken words without it.[10] An even greater number, 38%, had stopped using an aid even though they could hear and understand only a few spoken words.[11] Another survey found that hearing aids did not assist 18.6% of those who wore them and that 1% reported that their hearing had gotten worse.[12]

A study sponsored by the National Hearing Aid Society and the Hearing Aid Industry Conference in 1971 showed that 15% of the respondents had tried a hearing aid and did not like it. Reasons for their dissatisfaction with the hearing aid were not given.[13] In response to another question, 29% of the respondents reported that they would not buy an aid in the future. Again their reasons could not be attributed to a failure to receive significant benefits.[14]

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9 Public Health Service, U.S. Department of Health, Education and Welfare, Characteristics of Persons with Impaired Hearing, (National Center of Health Statistics, Series 10, No. 35, 1967), Table G, p. 12. The reason the aid was no longer used was not given, id. at 11.

10 Id.

11 Id.

12 J. Schein and M. Delk, The Deaf Population of the United States, National Association of the Deaf, Silver Spring, Maryland, in Cooperation with the Deafness Research and Training Center, New York University, 1974, p. 121, R-10-2257, ASHA, Exh. 90.

13 The Hearing Aid Industry, A survey of the Hard of Hearing, Market Facts, Inc., Chicago, Illinois, R-8-D223-17.

14 Id. at 18.

In its final report, the Interdepartmental Task Force reported:

> Misevaluation of a patient's need for a hearing aid and the subsequent sale of a hearing aid device which is ineffective, and possibly unsafe for its intended use, are major problems in the present hearing aid delivery system. The problem of misevaluation and misfitting may be the result of a number of factors, including lack of medical attention to otologic disorders which appear as hearing impairments; lack of competent evaluation by the dealer of the need for a hearing aid; and, in some cases, dishonesty by dealers for financial gain.15

The report noted that exact situations to show how often patients are fitted with hearing aids which are of no benefit are not available.16 Nor is such information provided by this record. The Task Force apparently based its conclusion on the surveys conducted by various consumer groups in particular upon the conclusions in the New York City and Baltimore surveys which showed that in over 40% of the cases studied, dealers recommended the purchase of a hearing aid when audiologists had determined that the patient could not benefit from the use of such a device.17 Suffice it to say dealer selling techniques and practices result in the sale of hearing aids to consumers who will not receive a substantial benefit from them or a substantial additional benefit from the purchase of an additional or replacement hearing aid.18

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15 Final Report to the Secretary on Hearing Aid Health Care, (Prepared by the Department of Health, Education and Welfare Interdepartmental Task Force on Hearing Aids, July, 1975, (Final HEW Task Force Report), R-8-D494-22.

16 Id.

17 Id. at 22-23. In the New York study the figure was over 50%. See Hear Ye! Hear Ye!, New York Public Interest Research Group, R-8-D232. In Baltimore the figure was 42%. See Paying Through the Ear, Public Citizen's Retired Professional Action Group (1973), R-8-D421-I-15. Although both of these surveys can be criticized in a variety of ways, e.g., Ralph J. Oravec, Price Waterhouse and Company, Tr. 3133-36, they obviously show that some hearing aids are sold under conditions in which the buyer will not receive a significant benefit.

18 See Part III of this report.

Perhaps the most compelling evidence in the record indicating the purchase of unnecessary hearing aids is provided by the testimony of the audiologists. While this testimony can and probably should be discounted to some extent because of the audiologists' strong bias against hearing aid dealers who conduct tests and fit aids without the benefit of audiological participation, it nevertheless shows that a significant number of consumers are fitted with aids which do not provide them with significant benefit.

Dr. Darrel E. Rose, Director of Audiology, Mayo Clinic, testified that his clinic was able to document over forty grossly misfitted individuals in just over a year (Tr. 456). He went on to say that there were more replacement aids sold which did no better for the individuals than the aids the individual had used previously. He thought that such instances occurred far more frequently than did the gross misfitting of aids. For example, the clinic saw ten persons who had been fitted with an all-in-the-ear aid from which they were receiving essentially no benefit, some of them had previously owned an ear level aid that was beneficial. Similarly, persons had purchased directional microphone aids supposedly to assist them in discrimination only to find that the aids provided them with less gain than the aids previously owned and thus with less benefit. Tr. 456-58.

Dr. Douglas Noffsinger, Director of Audiological Activities, Northwestern University School of Medicine, stated that in reviewing the files of the audiological clinic they found that between 4% to 10% of the patients had been fitted with hearing aids for an ear that had no hearing loss, or for an ear that had no hearing capability (a dead ear). Tr. 7665-66. He testified that out of 400 patients with Miniere's disease, 16 had purchased but not worn their hearing aids. Out of 300 patients with "sudden-onset" cases, 30 did not wear their hearing aids after purchasing them. Tr. 7668-69.

Mark McShane of the Memorial Medical Center related some of his experiences with patients who had been fitted with aids which did not benefit them. In the first case, a woman who simply could not understand speech had been sold an aid although her hearing was normal with excellent speech discrimination ability. The aid was useless for her. Tr. 8097. In the second case, the patient had purchased four aids over the previous seven years. Examination showed that she had a moderate conduction loss of hearing sensitivity bilaterally and cholesteatoma eroding the middle ear cavity. She needed medical attention rather than hearing aids. Tr. 8098.

In the third case, a congenitally deaf 6-year-old boy, who had been carefully examined at the clinic and fitted with a body aid of a particular type, was fitted with an all-in-the-ear device which did not provide the benefits of the body aid and which was, in fact, an unnecessary purchase. Tr. 8099, 8100.

Other audiologists reported similar experiences in which persons were sold aids from which they received no significant benefits or no significant additional benefits.[19] On the other hand, some audiologists doubted that this number was very large.[20]

State officials reported instances in which hearing aids had been sold to consumers who received no significant benefit from them.[21] As one official said, while these incidents are not too common, if only 5% of the population experiences them, that is too large a number.[22] One state official said he had witnessed misfittings by both clinical audiologists and hearing aid dealers but not in very large numbers.[23]

Consumer representatives also related similar incidents. Susan Kline, representing the Minnesota Public Interest Research Group (MPIRG) described in summary form the survey conducted by her

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19 Mary Ruth Whitman, audiologist, Illinois Department of Public Health, Tr. 8594; Robert C. Beiter, Director, Department of Speech Pathology and Audiology, Schwab Rehabilitation Hospital, Tr. 9031; David Rompala, clinical audiologist, Schwab Rehabilitation Hospital, Tr. 9093-95; Bonita Simon, clinical audiologist, Tr. 9156-60; Donald E. Morgan, Chairman, Audiology Task Force of the Commission on Legislation, California Speech and Hearing Association, Tr. 9578-79; Michael Stahl, Director, Clinical Services, Hearing and Speech Center, Tr. 5542-43; Dr. James Langford, Supervisor of the Audiology Clinic, Northern Illinois University, Tr. 8008, 8054.

20 See, e.g., Dr. Donald Krebs, Director of Speech, Hearing and Neurosensory Center, Tr. 11834-35; Donald W. Schaefer, Dane County Hearing and Speech Center, Tr. 8310, 8313.

21 Maurice A. Byrne, Jr., Assistant Director of Law and Legal Counsel, Department of Consumer Affairs, Louisville, Kentucky, Tr. 1010; Helen Kelly, Special Assistant Attorney General, State of Minnesota, Tr. 7523; Lloyd Mosley, Supervisor of Speech and Hearing Services, University of Illinois, Division of Service for Crippled Children, Tr. 7738; Emma E. Gunterman, Legislative Advocate, Senior Program, California Rural Legal Assistance, Tr. 9654-67; Janet Levy, Director, California Department of Aging, Tr. 11648.

22 Mosley, Note 21, supra at 7738.

23 Donald W. Schaefer, Note 20, supra at 8313. Mr. Schaefer is also a member of the Wisconsin Board of Examiners of Hearing Aid Dealers, Tr. 8253.

organization[24] in which volunteers visited dealers in Minneapolis and St. Cloud. One of the subjects used was a 67-year-old woman whose hearing was in normal range and who did not need a hearing aid. Tr. 7572-74. Four of the five dealers she visited told her she had a significant hearing loss and should buy either one or two hearing aids. Tr. 7576-77.

Margaret Person, Co-Chairman, Senior Citizen Coalition, Chicago, reported an instance in which a woman was fitted and bought a hearing aid from a dealer. Two weeks later her physician found that her ear was blocked with wax and that she did not need the aid. Tr. 9270.

Consumers likewise related instances in which they were sold hearings aids which did not provide them with significant benefits. John C. Brennan of Laurel, Maryland, was advised by his physician that he suffered from nerve deafness in his left ear, but that a hearing aid would not assist him. Nevertheless, he ultimately bought an aid which did not help him. Tr. 243-45. Nettie Murray, another consumer, had an almost identical experience in Miami, Florida. Tr. 4838-42. Jack Wortzel, also of Miami, reported the purchase of two hearing aids which did him no good. Tr. 4857-60. Despite having a prescription for one type of aid, Gertrude Filwett of Itasca, Illinois, purchased aids for both ears which proved to be unsatisfactory. Tr. 6093-97. Similar instances were described by other consumers who testified in these proceedings.[25] In short, the record is replete with relevant "horror stories."

All of the foregoing support a finding that a significant number of consumers buy hearing aids from which they receive no significant benefit. While some witnesses have attempted to distinguish the concepts of "benefit" and "satisfaction," it is not believed that such a distinction serves any useful purpose. The argument goes as follows: a patient who cannot hear or adequately comprehend conversational levels of voices, but who can do so with an aid should be said to benefit from the hearing aid. On the other hand, this same individual may not wear his aid because he sees it as a source of social embarrassment or because he does not want to listen to the background noises that we all are trained to eliminate, e.g., automobile sounds, air-conditioning hums, and so forth which by virtue of the hearing aid he is now suddenly hearing for perhaps the first time since he lost his hearing. Since "benefit" can be measured objectively through known tests and "satisfaction" is a psychological sense of well-being, these two factors are not synonymous and should be considered

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24 This is included in the record, R-8-D229.

25 Arthur Peterson, Tr. 6090-6114; Stephen Varga, Tr. 6367-70; Audrea Stutz, Tr. 8995-97; ASHA, R-10-57-1723-25.

separately.[26] An otologist testified that although the tests may show that a patient is not receiving a significant benefit in the objective sense, the actual subjective experience may show that a high degree of satisfaction has been achieved, e.g., from the simple ability of the wearer to hear background noises.[27]

Although such a distinction was used in formulating Issues 6 and 7, with Issue 6 raising the objective question of benefit and Issue 7 the subjective question of satisfaction, the fact remains that a patient who may in theory receive some benefit from a hearing aid will not do so--if for psychological or other reasons, he chooses not to wear it. Therefore, in finding that a significant number of consumers do not receive significant benefits from hearing aids they have purchased, no attempt has been made to determine why they do not do so. The illustrative material from the record cited in this section does show that in many cases, using the objective standard, many consumers still have not received significant benefit from the aids they purchased.

3. User predictions of efficacy and satisfaction. Issues 6 and 7 inquire as to the ability of the purchaser of a hearing aid to assess the efficacy of that hearing aid and to determine whether he will wear it without actually using it in a variety of situations. These issues will be considered together.

The view has been frequently expressed in this proceeding that whether a person with impaired hearing can benefit from amplification can be ascertained by testing.[28] Those holding this view argue that such tests can determine the residual hearing capability and thereafter also determine the degree of improvement that may be provided by amplification. Other tests can determine whether hearing can be improved in noisy, as well as in quiet, environments and if recruitment and reduced speech discrimination will follow from the use of an aid. Using these results persons with sensorineural hearing impairment can

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26 Robert I. Oberhand, M.D., a practicing otolaryngologist, Tr. 3040-41. For a more complete exposition of this view see NHAS comment, R-3-3510-20. Of course, many would disagree that such an objective determination is possible; see, e.g., K. Berger and J. Millin, "Hearing Aids" in Audiological Assessment (Prentice-Hall, Inc., 1971), pp. 488-91, R-8-Exh. D.

27 Lindsey Pratt, M.D., American Council of Otolaryngology, Tr. 3692-93.

28 NHAS, R-3-3560-62 and references cited therein.

be fitted with an aid which will improve hearing through amplification without reducing speech discrimination to a serious degree. This is done by selecting the aid with the requisite technical performance characteristics. For these reasons, it is said that a trial use of an aid is unnecessary to determine whether the selected aid will benefit the patient.[29]

The foregoing view is premised on the assumption that the individual is fitted with the hearing aid having the configuration and characteristics best suited to filling his needs. It overlooks the situations described in the preceding section where persons have been fitted with the wrong aid, with an aid for the wrong ear, with binaural aids when they should be wearing only one aid or with an aid when they are not candidates for amplification at all. Finally, it is not possible in many cases to replicate in the testing room the sound conditions of the environment in which the patient lives and functions. Assuming objective results can be assessed in the testing room, this would not necessarily insure that the individual would receive a significant benefit from the aid in his everyday environment.[30] Thus in many cases a trial period would be indicated. Dr. Rose of the Mayo Clinic said:

> . . . [T]here are situations in which I flat don't know whether some one will benefit from amplification or not, but they have got a problem . . . . The only way I can solve that is to send them and let them try amplification and let the patient, in his own environment, decide whether or not it helps him. Tr. 495.
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> . . . [I]t is the environment that allows him (a patient) to determine whether or not the amplification is beneficial. At least, significantly beneficial to warrant the purchase. Tr. 509.

As one audiologist testified, it is important that the clinical evaluation for hearing aid candidacy be conducted in a soundproof environment so that the effects of various types of stimuli

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29 Id.

30 See, e.g., Laura Ann Wilber, audiologist, Tr. 1353-58; Dr. Darrel E. Rose, Director of Audiology, Mayo Clinic, Tr. 466, 495, 509; Dr. Roger Kasten, President-Elect, Academy of Rehabilitative Audiology, Tr. 709, 768; Dr. John C. Best, Georgia Speech and Hearing Association, Tr. 6230.

can be carefully controlled. However, the testing and fitting procedures must be accompanied by counseling of the wearer and by a trial period to permit actual use of the selected aid in typical use situations. She added that a trial period is of particular importance for elderly people whose peripheral hearing problems may be complicated by other neurological or health problems associated with aging, for children, for the hearing-impaired of all ages whose loss makes them borderline candidates for amplification, and for whose motivation to wear a hearing aid is questionable. As an example of the latter category, a person who lives alone and does not have many communication requirements would be a poorer candidate for amplification than one who has a real need for it and whose efforts to adjust to a hearing aid would be supported by family and friends.[31]

A consumer who has been fitted with a new aid needs time to evaluate the performance of the new aid in light of the benefits he already received from his old aid. The question such an individual must answer is whether the new aid provides an improvement which is significant enough to make the new aid worth the cost.[32]

While some audiologists reported that, following a hearing aid evaluation test, they could ascertain whether the patient would receive benefit from amplification, they nevertheless recommended that the patient undergo a trial period when certain circumstances were found to exist.[33] Among this group was Dr. A. Bruce Graham, Chief, Division of Audiology, Speech and Language Pathology, Henry Ford Hospital, who said that he could not predict which people with precipitous high-frequency losses could be helped by a hearing aid. Tr. 7450. Other audiologists recommended trial periods only where they anticipated that the

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31 Angela Loavenbruck, audiologist-speech pathologist, Assistant Professor, Teachers College, Columbia University, Tr. 1554.

32 Jane Madell, Director of Audiology at the New York League for the Hard of Hearing, Tr. 5860.

33 James Langford, Associate Professor of Audiology, Northern Illinois University, Tr. 8036.

patient would not be able to ascertain or weigh the advantages and limitations of amplification except by actually wearing the aid.[34]

One audiologist voiced the thought that if hearing aid dealers would refer more of their customers to audiologists for a thorough prefitting hearing aid evaluation, trial periods would be necessary only in a relatively few cases.[35]

Some audiologists view the trial period as part of the evaluation process. During this time, it is possible to determine whether the client can recognize and report any enhancement of his ability to understand speech in difficult situations.[36] This is particularly important with respect to children whose hearing losses are more difficult to evaluate than those of adults. In very young children, it is necessary to determine the effectiveness of the aid by keen observation of the child wearer following its fitting.[37]

The view was also expressed that a trial period is justified to determine the ability of the patient to make a psychological adjustment to the hearing aid in day-to-day living, but that it should be required for those patients whose ability to benefit from the aid may be doubtful. This latter group would include those with profound hearing losses, narrow dynamic ranges, severe recruitment problems and poor speech discrimination.[38]

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34 See, e.g., Nancy Eichelberger, audiologist, Connecticut Speech and Hearing Association, Tr. 8710, who also said that the trial period had more significance as a consumer protection measure than as a supplement to professional judgment, Tr. 8698-99. Selective use of the trial period was also recommended by Dean Harris, Director, Audiology Program, Southern Methodist University, Tr. 10414.

35 Leslie W. Dalton, Professor of Audiology , New Mexico State University, Tr. 8727.

36 John Franks, Assistant Professor of Audiology, Arizona State University, Tr. 9760.

37 Laszlo Stein, Director, David T. Siegel Institute of Communicative Disorders, Michael Reese Hosptal, Tr. 8982-83. Dr. Stein said that an adjustment period was particularly important for a child who may be reluctant to wear a hearing aid and have difficulty in overcoming the imagined stigma associated with it, Tr. 8976-77.

38 Robert I. Oberhand, M.D., Note 26, supra at 3037-39; Richard M. Carter, M.D., Tr. 3649-51; Austin T. Smith, M.D., retired, Tr. 8192.

Some of the medical doctors who testified in the proceeding thought the matter of the trial period should be left to the discretion of the professional for trials would not be required in all cases.[39] Another doctor voiced a contrary view. He said that a patient cannot make an evaluation of an aid he is going to purchase unless he actually tests it. There is a real variability in performances of ostensibly identical hearing aids now manufactured. The recommendation for a particular aid by model and serial number will not eliminate this type of problem.[40]

Difficulties of adjustment to the use of a hearing aid are significant. Judith A. Rassi described these in her testimony which is summarized as follows. The new hearing aid user must learn to cope with the amplification of undesirable environmental sounds which the aid and earmold cannot fully suppress. At the same time, he must learn to tolerate the presence in his ear of a foreign object, i.e., the earmold. He must also learn to adjust to the unnatural quality of sound provided by the hearing aid--a sound quality which persons with normal hearing do not experience. Hearing aid users must learn to accept the limitations of the device--it cannot make speech sound any clearer than their damaged hearing mechanisms will allow. The user must learn to insert and remove the earmold properly, and adjust the controls which regulate the volume and tone settings to meet the needs of various listening situations. The purchaser of a replacement aid not only needs time to learn to operate the new device but also time to evaluate the performance characteristics of the new aid as compared with the old one. The purchaser of a second aid for a binaural system must also be allowed time to assess whether the performance benefits provided are sufficient to justify the purchase of the additional device. Tr. 5732-33.

Both audiologists and hearing aid dealers agree that many people who purchase hearing aids will have adjustment problems and that the magnitude and nature of these problems require counseling and encouragement of the wearer and persistence on his part to achieve optimum benefits from the aid.[41] For

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39 August Martinucci, M.D., Tr. 8384, 8446; Gale Gardner, M.D., Tr. 10348.

40 Robert J. Ruben, M.D., Chairman, Department of Otorhinolaryngology, Albert Einstein College, Tr. 3975-77.

41 Jane Madell, Note 32, supra at 5856-57; Herbert E. Richenberg, Director, Henry C. Barkhorn Memorial Hearing and Speech Center, Newark, Tr. 3547.

example, some emphasize the importance of giving the patient a realistic and factual description of just what benefits should be expected from amplification as well as a preview of the problems that the user may expect to have.[42]

Many hearing aid dealers oppose the buyer's right to cancel included in the proposed rule while recognizing that a trial period may be justified if either the client or the seller is uncertain whether the hearing aid will provide the expected benefits.[43] However, they would refer to it as a trial-rental plan or simply as a rental period.[44]

In part, due to criticisms about dealer practices, the National Hearing Aid Society announced in May of 1975 that its dealer members would have available a trial-rental purchase plan to permit hearing aid users to wear hearing aids at reasonable costs while they were making a final decision on whether to purchase such aids. This voluntary policy is summarized as follows:

> In order to provide a trial period for those clients who desire it, the National Hearing Aid Society hereby requires all its members to make a rental/purchase option plan available on hearing aids. Each member may establish his own terms for such plan, based on the needs of the client and his own operating costs. Where a specific hearing aid is recommended by anyone other than a NHAS member, (such as a medical doctor or a clinical audiologist), the availability of the rental/purchase option plan is not required. In all hearing aid fittings, the individual makes the specific recommendation and should be responsible financially and otherwise, for the decision. R-3-3540.

John J. Fennema, a hearing aid dealer in Maryland, voluntarily adopted a trial-rental period because he believed that it was necessary for customers to actually use their aids in

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42 Mary Burke, audiologist, Tr. 6414; Dr. A. Bruce Graham, Chief, Division of Audiology, Speech and Language Pathology, Henry Ford Hospital, Tr. 7453; Luke Fortner, President, National Hearing Aid Society, Tr. 2964-67; NHAS, R-3-3510; Alfred R. Dunlavy, hearing aid specialist, Tr. 3402-03.

43 Fortner, Note 42, supra at 2936; DuWayne Tremmel, Tr. 8335-37; Joel Mynders, Tr. 11574-75.

44 Id.

order to determine if they would be satisfied with them. Tr. 1745-46. The second reason for his adoption of a trial-rental period was the encouragement it offered to the otherwise hesitant and reluctant customers to try out aids. Tr. 1746.

Sam Hopmeier, another hearing aid dealer, has adopted an "Assured Result Plan" which offers both new and repeat users a 30-day trial arrangement. He does not see such a period as necessary to a determination of benefits; rather he uses it as a sales measure. Tr. 3342.

There is little doubt that the fact that referring audiologists desire that their patients be accorded trial periods at nominal costs has been and is a primary reason for dealers' adoption of such plans.[45] In fact, many audiological clinics ask for assurances that their referrals will be accorded such rights.[46] Unfortunately, the dealer who gives a rental agreement to a referred patient will not necessarily accord that same arrangement to customers who simply walk into his place of business.[47]

Audiologists report that they are much more willing to prescribe a hearing aid if a rental plan is available to patients in borderline cases or in cases where test results cannot determine the benefits to the patient from the aid. An erroneous recommendation for an aid on their part in such cases will not be so costly to the patient if it developes that he cannot benefit from the device.[48] While some such trial periods have been requested, only in those instances in which it seemed essential to have one, the practice in many clinics is to uniformly recommend trial periods for patients.[49]

One audiologist noted that the concept of "significant benefit" provided to an individual by a hearing aid consists of many complex factors. There is an interaction between test results

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45 ASHA, R-10-57-1726-28; Loavenbruck, Note 31, supra at 1555.

46 ASHA, Note 45, supra at R-10-57-1727-28.

47 See, e.g., Patricia G. Mastricola, Otologic Professional Associates, Tr. 8615; Laszlo Stein, Note 37, supra at 8976.

48 Rose, Note 30, supra at 527-28.

49 Patricia G. Mastricola, Note 47, supra at 8614-15; John Franks, Note 36, supra at 9760, 9799; Lee Wilson, clinical audiologist, Tr. 10024; Darrell Teter, speech pathologist and audiologist, Tr. 10229-30.

obtained and the characteristics and needs of the person tested--the latter includes the personality, motivation, and particular communication requirements of the individual. To determine the overall degree of benefit, there must be a subjective evaluation of all of these factors and certainly the beliefs of the individual, including an assessment of his need for an aid and the difficulty perceived in its use, play an important part in this assessment.[50]

4. Arguments against trial period. The need for a trial period, or in other words a need for an individual to use the aid in his daily activities before finally deciding to purchase it, is hotly disputed by many participants in this proceeding as has been noted. (As previously stated at the beginning of this part of the report, those economic considerations and arguments relative to this provision of the proposed rule will be discussed in Part IX infra.)

The strongest arguments against the buyer's right to cancel are contained in the comments of the National Hearing Aid Society (NHAS).[51] These arguments are that the degree to which a hearing-impaired person can benefit from the use of a hearing aid can be determined without trial use;[52] that it is unreasonable to expect a hearing aid seller to guarantee that every purchaser will be satisfied with the purchased hearing aid;[53] and the fact that hearing aid users may need to adjust to the amplified sound provided by the hearing aid does not demonstrate that a trial-use period is an inherent necessity.[54] In its rebuttal submission in support of its arguments, NHAS described its efforts to ascertain the number of complaints from hearing aid purchasers received by both federal and state consumer protection agencies.[55] It reported that the total number of complaints from data submitted by 36 states for 1975 showed the receipt of 722 complaints. The total hearing aid sales in those states during that year were 325,066 providing a ratio of complaints to sales of 0.2%.[56]

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50 Loavenbruck, Note 31, supra at 1564. See also Maurice Miller, Professor of Speech Pathology and Audiology, New York University, Tr. 4778-80; William E. Lentz, Director, Hearing Clinic, Colorado State University, Tr. 11237-38.

51 NHAS, R-3-3557-76.

52 Id. at R-3-3560-62.

53 Id. at R-3-3562-65.

54 Id. at R-3-3565-76.

55 NHAS rebuttal, R-13-D146-1-17.

56 Id. at R-13-D146-4-7.

In its comments, the Hearing Aid Industry Conference (HAIC) also voiced its opposition to the buyer's right to cancel provision of the proposed rule.[57] Like NHAS it questioned the legal authority of the Commission to include such a provision in the final rule.[58] HAIC also asserted that compelling the dealers to afford the buyer a right to cancel would be a detriment to those with impaired hearing. This is premised on the expressed belief that a buyer who knows he will be able to return the aid to a dealer and receive a refund will be less willing to compel himself to go through a difficult adjustment period which requires not only patience and perserverance but also strong will power and tenacity to learn to use his instrument to his optimum advantage.[59] It is said that it will undermine the resolve of the hearing impaired to continue working with the aid until he achieves a successful adjustment.[60]

Representatives of hearing aid manufacturers who testified at the hearings uniformly supported the view that a mandatory right to cancel would be a serious disincentive to purchasers of hearing aids to persevere in the necessary efforts to learn to use the aids effectively.[61] These representatives referred to the fact that many dealers already offered a trial-rental period and indicated that they thought more would do so in the future for competitive reasons. This policy they said did not have the same unfortunate impact upon all concerned as would a universal mandatory right of cancellation.[62]

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57 HAIC, R-3-3910, et seq.

58 Id. at R-3-3915-23. The NHAS views regarding these legal issues are at R-3-3655-84.

59 Id. at R-3-3912-13.

60 Id. at R-3-3914.

61 See, e.g., Myron M. Samole, Executive Vice President, Fidelity Electronics, Ltd., Tr. 6662-63; James H. Johnson, HAIC, Tr. 2301; John Kojis, President, Maico Hearing Instrument Company, Tr. 1986; David Barnow, former President, HAIC, Tr. 1637.

62 Vincent James Giglia, President, Audio Instrument Company, Tr. 2704-06, Samole, Note 61, supra at 6681, 6701; Richard Scott, Executive Vice President, Siemens Hearing Instruments, Tr. 2330.

Some of the audiologists who testified at the hearings shared the views of the manufacturers and dealers that an across-the-board right to cancel would have an adverse effect on the commitment of a patient and would not be in his best interest.[63] In support of its contention that there is no justification for the buyer's right to cancel, HAIC had marketing experts review the testimony of various witnesses (audiologists, dealers, and manufacturers' representatives) who testified regarding the percentages of returns of hearing aids to dealers because of dissatisfaction or for other reasons. Based on her review of the testimony of 30 such witnesses, one expert, Eleanor Goddard May, stated in an affidavit[64] that the return rates varied from 1% to 17%; the median percentage of returns was 4.5% with over half reporting rates between 2.5% and 7%.[65] She went on to say that these return rates were significantly lower than those reported for a large number of other consumer products. For example, she said that the median rate of general returns of merchandise for all large department stores was 7.4%.[66]

Another marketing expert reviewed these rates and also stated in an affidavit[67] that the rate of return for hearing aids was less than that for other consumer product lines, such as television (11.0%), radio and audio appliances (9.6%), and photo and other audio visual goods (7.3%).[68]

The arguments offered against the mandated trial period are not persuasive. Based on a review of the conflicting testimony and material included in the record, it is the Presiding Officer's view that the benefits that a significant number of consumers will ultimately receive from the use of particular hearing aids cannot be accurately assessed before those aids are purchased and used. Secondly, an attempt to isolate and treat separately

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63 Hubert L. Gerstran, Chief, Hearing and Language Center, New England Medical Center Hospital, Tr. 2402; Herbert E. Richenberg, Director, Henry C. Barkhorn, Memorial Hearing and Speech Center, Tr. 3512-13; Dr. Donald Krebs, Director of Speech, Hearing and Neurosensory Center, Tr. 11831.

64 Rebuttal submission, HAIC, R-13-D93.

65 Id. at R-13-D93-4-5.

66 Id. at R-13-D93-6.

67 Anthony F. McGann, HAIC rebuttal submission, R-13-D94.

68 Id. at R-13-D94-4-5.

the concept of benefits objectively determined and those subjective benefits based on individual satisfaction is unjustified. The concept does not recognize that many consumers are improperly fitted with hearing aids to begin with and that many are sold hearing aids which they do not need or cannot use and cannot return. The concept does not recognize the complex interrelationship between the degree and nature of hearing loss and the ability of the individual to tolerate and make effective use of amplified sound, to adjust and set the controls of the hearing aid, or to determine whether the benefits derived are worth the cost, difficulty, and trouble involved in using the aid.

The argument that a mandatory trial period, such as that which would be imposed under the buyer's right to cancel, would have a different psychological effect on the hearing-impaired person than would a trial-rental period offered by sellers on a selective basis is not persuasive.

The failure of the NHAS to obtain a statistically significant number of consumer complaints regarding hearing aid purchasers from consumer protection agencies is also not persuasive. The difficulty and virtual impossibility of even attempting to quantify the number of consumer complaints of a particular classification from the myriad of agencies who may initially receive them is well known to any one who has attempted the task. There is neither a uniform nor accurate reporting system nor any means of making a proper classification of such complaints. Moreover, there is every indication that many hearing-impaired persons would not complain and would not even know where to address their complaints if they elected to make them.[69] The evidence of unfair and deceptive selling techniques described in Part III of this report, justifies a conclusion that a significant number of purchasers of hearing aids do not receive a significant benefit from their devices.

The median rate of return identified in the HAIC rebuttal submission discussed above can hardly be projected to provide an indication of the true median rate or return for the industry as a whole. The testimony of the audiologists from which these figures were derived showed that these returns followed exhaustive and painstaking audiological examinations which had been preceded by medical examinations.[70] Such a detailed

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69 See, e.g., Arthur Lynch, AARP/NRTA, Tr. 1451; Paul Sypniewski, Cape Atlantic Legal Services, Tr. 1604, 1606, 1616-18; Irene Bowen, National Center for Law and the Deaf, Tr. 1910, 1942-43; Rafael A. Penalver, Jr., attorney, National Council of Senior Citizens, Tr. 4910-14.

70 See, e.g., Dr. Earl R. Harford, Professor of Audiology, Vanderbilt University Medical School, Tr. 131; Dr. Darrel E. Rose, Note 30 supra, at 455; Dr. Roger Kasten, Note 30, supra at Tr. 708-11.

procedure would undoubtedly make it less likely that a person who could not make effective use of a hearing aid would purchase one. Thus, the low rates of return can be attributed in part to this special class of purchasers who had been thoroughly examined and tested and whose return rate was surveyed. A much higher rate could be expected from those who had not been so thoroughly examined. Most of the dealers whose names appear on the list of witnesses provided to the marketing expert by HAIC offer trial periods. Here again, it could be expected that they would not make such offers unless they exercise a considerable degree of care in their hearing aid fittings.[71] Finally, on the basis of the evidence in the record as a whole, it is fair to assume that a significantly large but unknown and speculative number of consumers were not successful in their attempts to return hearing aids to dealers who did not have trial-rental periods[72] and there are still others who did not make the attempt, but simply put the aid in a drawer where it remains unused.[73]

5. Exceptions to right to cancel. Section 440.4(i) of the proposed rule provides that under two conditions the seller would not have to accord the buyer the right to cancel the sale. The first exception would apply if the sale is made pursuant to a written recommendation of a physician or audiologist for the purchase of a specific hearing aid by serial number or by model. The second would apply in cases in which the sale involves a replacement aid, identical to a damaged or worn-out model.[74]

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71 David Barwell, Tr. 5168-69; David D. Bartels, N.C., Speech, Hearing and Language Association, Tr. 6293-99; Otto Butz, Otto Butz Laboratory of Audio Aids and Aural Appliances, Tr. 6621, 6635, 6638, 6651; Sam Hopmeier, President, Sam Hopmeier, Tr. 3342; Luke Fortner, note 42, supra Tr. 2963.

72 Cyril R. Brickfield, legal counsel, AARP/NRTA, Tr. 1430; Mamie Diogo, consumer, Tr. 4414-20; Mary A. Nevells, consumer, Tr. 4427-33; Eva Doucette, consumer, Tr. 4434-39.

73 See, e.g., Arthur S. Flemming, Commissioner, Administrator of Aging, Department of Health, Education and Welfare, Tr. 626-27; Leonard W. Finkel, attorney, Legal Research and Services for the Elderly, Tr. 4447; Dr. Harford, Note 70 supra, at 140.

74 40 Fed. Reg. 26648.

These exceptions raised the issue of whether the buyer's right to cancel should be provided in either of the two circumstances described in the two provisions of Section 440.4(i).

In its written comments NHAS strongly opposed both exceptions, saying that their inclusion in the rule was apparently based on the asssumption that a hearing aid can be prescribed or that a trial period is unnecessary when an aid is recommended by a "disinterested third party." NHAS considers that both will operate to the detriment of a dealer who does not rely mainly on referrals for his business. The reference to brand name and model, NHAS fears will produce various promotional and compensation schemes between physicians, audiologists, and manufacturers. Of more importance, the first exception presumes that hearing aids can be prescribed and that is simply not the case. R-3-3577-80.

The second exception, according to NHAS, is further unworkable for it overlooks the constantly increasing improvements in hearing aids and hearing aid technology which would make replacement of an aid with an identical model offer impossible. It charged that the exception would also deter persons from recommending improved models, and that it incorrectly assumes that a person who has previously worn a hearing aid and has been able to identify its benefits, cannot make an appropriate decision in his selection of a new model. R-3-3580.

Inclusion of the exceptions in the final rule, if one is adopted, was also opposed by ASHA in its written comments. R-10-1751-55. It states that the first exception will result in dealers informing their customers that if they first consult a physician or audiologist to obtain a recommendation for a specific hearing aid they will not be granted the right to cancel the purchase. R-10-1751. In any event, it does not believe that the consumer should lose the right to cancel simply because they have prudently obtained a specific recommendation from one of the named professionals. R-10-1752-54.

ASHA opposes the second exception because it does not believe that dealers have the equipment necessary to compare the electroacoustic characteristics of an aid with the manufacturer's specifications. It noted that recent tests had shown that at least 5.3% of new hearing aids delivered by manufacturers were defective. R-10-1754. ASHA also cautioned that a person might be sold an identical hearing aid even though nothing was wrong with the old one. For example, it said, the earmold might simply be clogged, the patient's hearing may have deteriorated further, or the damage to the old hearing aid might be easily susceptible to repair. R-10-1755.

All of the foregoing objections were raised by witnesses who testified at the hearings and whose testimony addressed the provisions of Section 440.4(i). Indeed given the uncertainty in predicting the efficacy of a hearing aid for a particular individual,

it would appear that exceptions to the buyer's right to cancel should be permitted only if the record fully and strongly provided a justification for them. This record does not contain that support.[75]

B. Summary of findings and conclusions, Issues 5-7.

1. Findings. Although the evidence in the record does not permit a precise determination of the numbers or percentages of those who do not receive a significant benefit from the hearing aids they purchase, it does show that the numbers are significant. The term "significant benefit" includes "additional benefit" if the individual or purchaser is a current hearing aid user and is buying or has bought another hearing aid.

Because of the nature and degrees of hearing losses coupled with the subjective nature of audiological evaluations and subsequent fitting and selection of hearing aids, it is not possible in many cases to predict whether a person with impaired hearing will derive a significant benefit from the use of a recommended hearing aid. In such cases a trial period in which the purchaser uses the aid in a variety of situations is necessary to make a determination of significant benefit.

It is also not possible to determine whether an individual will derive a significant benefit from a hearing aid without considering the variable factors which cannot be identified in laboratory tests. These include the communication requirements of the individual, his personality and motivation, his ability to adjust to amplified sounds, the effectiveness of counseling and training provided to him, and his actual ability to wear the device and to adjust its controls.

It makes little difference to the consumer whether this failure to receive a significant benefit results from a cause that can be measured or determined objectively or from a cause that is subjective and related to his own capabilities and desires to adjust to the requirements of hearing aid use in the light of the benefits perceived. To determine significant benefit in the subjective or psychological sense, a significant number of consumers must wear and use the aid in a variety of situations.

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75 See, e.g., Robert J. Ruben, M.D., Note 40, supra at 3975-77; Dorothy A. Shannon, Chief, Speech and Hearing Section, Sinai Hospital of Baltimore, Tr. 1862-65; Dr. Beth Urban, Director, Hearing Language and Speech, Montgomery County Health Department, Tr. 1810-13; John J. Fennema, Maryland Hearing Aid Service, Tr. 1795-96; Nadine Woodard, International Association of Parents of the Deaf, Tr. 4141-42; Elma L. Griesel, Project Coordinator, Grey Panthers, Tr. 9384-85.

The existence of a mandatory trial period during which the consumer would have the right to cancel the sale and obtain a partial refund of the purchase price would not be a material disincentive to him to learn to make effective use of the hearing aid. On the contrary, it would make it more likely that he would purchase an aid with a view toward determining whether it would provide a significant benefit. In addition, audiologists will be more willing to recommend aids than in the past because of the availability of the trial-rental plans.

The actual number of complaints consumers may have about their hearing aids, as well as the nature of those complaints, cannot be accurately determined. Moreover, the number of such complaints is not determinative of the numbers of consumers who have purchased hearing aids from which they have received no significant benefits.

The record also does not permit a determination of the actual rate of return to the seller of purchased hearing aids. It does show that a significant number of consumers have returned or attempted unsuccessfully to return to the seller hearing aids which do not provide them with significant benefits.

The record does not justify the provisions included in Section 440.4(i) which would deny the buyer the right to cancel the sale if the purchase is made pursuant to a specific recommendation of a physician or audiologist or to replace a damaged or worn-out hearing aid with an identical hearing aid. The first exception is not justified because in many cases it is impossible for a physician or an audiologist to determine the specific hearing aid that will best meet the needs of the individual, or for that matter to determine if the patient will derive a significant benefit from the use of a hearing aid. The second exception is not justified because of indeterminable variations in the audioacoustical characteristics of supposedly identical hearing aids, the possibility of changes in the hearing capability of the individual, and the possibility that the hearing aid might simply require repair, or that the difficulty might be in the coupling rather than in the aid itself.

2. Conclusions. The buyer's right to cancel provision included in Section 440.4 of the proposed rule is justified because of the many uncertainties associated with the selection and fitting of hearing aids. There is no justification for the exceptions to this right set forth in Section 440.4(i).

C. Cancellation charges.

1. General. Section 440.4(g)(1)(i) sets forth two mutually exclusive formulas for determining the charges which may be imposed upon a buyer who elects to exercise his right to cancel a sale.[76]

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[76] 40 Fed. Reg. 26648.

The first formula (Alternative A) states that the charge may not exceed $15 plus 5% of the purchase price. The second formula (Alternative B) permits the seller to retain a maximum of $30 or 10% of the price of the aid, whichever is less. This latter alternative also authorizes an adjustment of the $30 maximum to account for changes in the annual percentage adjustment in the United States City Average All Items Consumer Price Index. Neither of the alternatives include provision for the cost of the earmolds or batteries. Rather, for these items, paragraph (g)(1)(ii) provides that in addition to the other charges, the seller may retain an amount not in excess of twice the actual cost of an earmold and batteries supplied the buyer.

The foregoing provisions of the rule relate to Issues 8 and 9.

2. Are cancellation charges sufficiently high? Issue 8 is:

> Are the "cancellation charges" permitted by § 440.4(g)(1) high enough to effectively discourage casual or frivolous cancellations?[77]

Perhaps the best way to address Issue 8 is to assess the experiences of those who have used or have been acquainted with the results of various trial-rental and similar plans offered now and in the past by some dealers and manufacturers.

Zenith has had a money-back guarantee policy since the 1940's; the term of the guarantee was extended in 1975 from 10 days to 30 days. Roughly a little over 4% of the Zenith's hearing aids have been returned under this policy; refunds were granted in only 1% of the return cases, and the remainder of the returns involved exchanges of the initially purchased aids for other aids after the purchaser had agreed to accept a replacement.[78]

In a letter dated July 15, 1974, addressed to all dealers, R. M. Tatum, Vice-President, Marketing, Radioear Corporation, noted the insistence of referring audiologists that their patients be accorded a 30-day trial period, and stated that Radioear estimates indicated that 2%-3% of aids so fitted were returned.[79]

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77 40 Fed. Reg. 59748.

78 James H. Johnson, HAIC, Tr. 2299-2300; letter from Zenith, R-8-1953. The record indicates that some Zenith dealers did not follow this plan.

79 R-8-1972.

Dahlberg's Deltagram No. S-470, dated January 10, 1975, described the company's new 30-day evaluation program for new hearing aid users.[80] Under this plan, if a dealer sells an aid on the evaluation plan and it is subsequently returned by the purchaser, he may return the aid to the factory and receive a new replacement for it for $25. Alternatively, at the request of the dealer, the factory will recondition the returned aid without charge and return it to him for sale as a used or reconditioned device. Under this plan, the dealer may charge a nominal fee of, say, $15 for the earmold and batteries plus $1 a day for a minimum of 30 days, or, he may charge nothing. The company estimates that 90% of such trials will result in sales.[81]

Hearing aid dealers who have offered their own trial periods report a relatively small number of returns. John J. Fennema of the Maryland Hearing Aid Service testified that he had offered every purchaser a 30-day unconditional trial period for the past 3 years. If at any time the purchaser became dissatisfied, the full purchase price was refunded less a rental charge of $1 per day plus the cost of the earmold which varies between $12.50 and $17.50. Tr. 1745-46, 1768. In 1974 and 1975, only 1.4% and 1.8% of his purchasers, respectively, returned the aids for refunds. Tr. 1749.

A mail order seller of hearing aids introduced a free trial policy originally for a 20-day period, but subsequently extended it to a 30-day period. Although he would not disclose the percentage of returns, he noted that the policy had proved successful.[82]

Otto Butz of the Otto Butz Laboratory of Audio Aids and Aural Appliances testified that his firm gave all first time hearing aid users a trial-rental period. Tr. 6621. Mr. Butz would not disclose the amount of his rental charge but said only that it was reasonable and proper (Tr. 6628); however, he criticized the $1 a day rental charge suggested in the proposed rule as being insufficient in view of the charges imposed by manufacturers. He reported a return rate of 2% under his plan. Tr. 6622. He did not address the question of casual or frivolous cancellations.

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80 R-8-1974-78.

81 Id. at 1975.

82 Marvin Palmquist, President, Lloyd Hearing Aid Corporation, Tr. 6556-57, 6572, 6579, 6591.

Sam Hopmeier, President of W. H. Hopmeier, Inc., a St. Louis hearing aid dealer, said that his company offered all purchasers, both first time and repeat users, a 30-day trial arrangement, which has been beneficial to both the company and to consumers. Tr. 3342. Only one to two percent of the total fittings are returned because consumers are not satisfied with them. Tr. 3343.

A Chicago hearing aid dealer, John Kuptz, the owner of the Master Plan Service Company, dispenses hearing aids only on the recommendation of a physician or audiologist. His company offers a full money refund in 30 days if the aid does not prove to be satisfactory. He will also permit the purchased aid to be exchanged for another aid during that time period. Tr. 5642. The patient is charged $12 for an earmold and sometimes is asked to pay a $30 rental charge based on $1 per day fee schedule. However, if the aid is returned (his rate is about 2%) because the patient is not satisfied with it, the rental charge is refunded to him while the dealer retains the charge for the earmold. Tr. 5719.

Greater charges are made by DuWayne Tremmel, a hearing aid dealer of Marshfield, Wisconsin. His firm uses a rental program rather than a trial period with a monthly charge amounting to 5% of the cost of the hearing aid assessed over a period of 90 days. At the end of the period, the user can either continue the rental period or purchase the aid. Charges for the initial evaluation and earmold are stated separately and are not included in the rental charges. Tr. 8335-36. Mr. Tremmel said the rental charges for the aid average $18.50 per month. Tr. 8368.

John C. Kenwood, President of J. C. Kenwood, Inc., reported that his firm used a 30-day rental trial plan. The charges for this period include the cost of the earmold and batteries. The program is primarily offered to referral patients from physicians and audiologists, but it will be offered to other customers who specifically request it, although it is not advertised. Tr. 9298-300.

Lee Wilson, an audiologist in a professional clinic, testified that all hearing aids recommended by the clinic are done so on a 30-day trial or exposure period. Tr. 10024. About 9% are returned, but the dispenser charges only for the earmolds with all other money refunded. Tr. 10030-31. The clinic with which he is associated is staffed with otolaryngologists and hearing aid dispensers, as well as himself. Tr. 10036-37.

The view was also expressed in the course of the proceeding that the relatively small charges permitted to be retained by dealers would lessen the motivation of patient to adapt to their

hearing aids and would encourage unjustified cancellations, i.e., cancellations in spite of the fact that the aid was, in the light of the patient's requirements, capable of providing significant benefits.[83]

In reviewing the record in an attempt to answer the question of whether the cancellation charges are sufficiently high to discourage such casual or frivolous cancellations, one is struck by the impossibility of providing a documented answer. The trial-rental periods currently in use provide cancellation charges of striking consistency in amount with the exception of the few dispensers whose plans impose no cancellation charges at all upon the purchaser who returns a hearing aid. The numbers or percentages of cancellations reported by the various proponents of these plans are relatively consistent, a fact which can perhaps be attributed to the amount of the cancellation charge. As reported in section 4 of this part of the report, the testimony of some 26 witnesses indicated that a median cancellation rate of 4.5% obtains in the cases of those dealers who offer trial periods. Is it then likely that the buyer's right to cancel contained in the proposed rule would result in a materially greater cancellation rate? Seemingly, it would if a substantial number of consumers who do not now have the right to cancel their sales are sold hearing aids from which they do not derive significant benefits. Here again though, it does not appear likely that the amount of the cancellation charge would have any greater effect on this group than it would on those who are presently accorded the right to cancel the sale. While, depending upon the number of consumers who are sold aids from which they do not derive a significant benefit, the cancellation rate might well increase, it does not follow that the amount of the cancellation charge itself will have any measurable effect upon the rate. Indeed, if this were the case, one could have expected the industry to present evidence demonstrating that this would occur. They did not do so.

As the cancellation charges authorized in the proposed rule are similar in amount to those currently used in various trial-rental programs, it does not appear that they would result in any increase in "casual or frivolous" cancellations. Whether they are sufficiently high to effectively prevent such cancellations can only be left to conjecture. If this record supports the need for a trial period as the Presiding Officer has concluded that it does, the amount of the cancellation charges should be based on the economic needs of the manufacturer and dealer balanced against the losses suffered by consumers who have been sold hearing aids

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83 Herbert E. Richenberg, Note 41, supra at 3513-14; James Keyes, Executive Vice President, Audiotone Division, Royal Industries, Tr. 10693-94; Ray Stallons, clinical audiologist, Tr. 7661.

from which they derive no significant benefits. The possibility of frivolous or casual cancellation does not, given the amount of the cancellation charges proposed, seem to be a consideration which should play a crucial role in this determination.

3. Charge where two aids are sold. Issue 9 reads as follows:

> What would be an appropriate 30 day cancellation charge in situations where the sale of two hearing aids (one for each ear) is involved?[84]

This issue presents the difficult question of whether it is appropriate to fit a hard-of-hearing individual with an aid for each ear simultaneously. As used in this part, the terms "simultaneous," "at the same time," and expressions of similar import refer to the sale of two hearing aids in one transaction or the sale of a second hearing aid to a buyer prior to the expiration of his right to cancel the sale of the first hearing aid purchased by him from the same seller. The alternative to this type of fitting is the fitting of the patient with an aid for one ear, testing its effectiveness, and, if the results are favorable, fitting a second aid to the other ear.

If it is generally considered to be a good practice to supply the complete binaural system initially, it would appear that the seller should be entitled to a cancellation charge for each aid sold. On the other hand, if there is a serious question as to the advisability of fitting two aids in any situation, it would appear that the seller should not be entitled to a cancellation charge greater than the amount he would be authorized to retain if he had sold only one aid.

It should be noted that the question of the potential of binaural aids to provide significantly greater benefits than a single aid for persons with bilateral hearing losses is raised by Issue 35, which is discussed in Part VII of this report.

ASHA in its written comments expressed the view that only one rental or cancellation charge should be permitted where two hearing aids are fitted at the same time. This position is premised on the common practice of most audiologists in recommending the use of only a single aid initially, and on the need to discourage the initial selling of two hearing aids where only one or none, is justified.[85] ASHA added that, if the dealer, audiologist, or

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84 40 Fed. Reg. 59748.

85 R-10-1744.

otologist strongly believed that in a particular case a simultaneous binaural fitting were required, the dispensing seller should be willing to balance possible loss of cancellation fees against the expectation of greater profit from the sale of two aids.[86] These ASHA views were supported by most of the audiologists who testified at the hearings.[87] In fact, a hearing aid dealer who is also an audiologist and a strong believer in the superiority of binaural aids for most of the bilaterally hard of hearing testified that he usually fitted the better ear with a hearing aid initially and did not attempt the second aid until the patient had adjusted to the first aid. Tr. 400, 428.

From the standpoint of the consumer, there is a substantial financial risk in purchasing two hearing aids before it is known whether he will benefit from even one aid. Here it must not only be ascertained that he can adjust to amplification, but whether the second aid will provide such a significant benefit to him as to warrant its purchase must also be determined.

Looking at the question through the eyes of the dealer who must run the risk of losing two sales rather than one, it appears that protection against such a contingency lies in his own hands. If he wants to avoid the risk of being inadequately compensated in the event the purchaser cancels the sale of both aids, he can simply refuse to sell the complete binaural system at the same time.

The consumer, on the other hand, may not be aware of the risk involved in the purchase of two aids simultaneously and thus he buys in reliance upon the advice of the dealer who has a financial interest in selling both aids rather than one, or upon the advice of the audiologist who may have recommended a binaural purchase.

Given the uncertainty of predicting the benefits to be derived from a monaural device, as discussed in sections A and B of this part, it would seem that the risk should properly be placed on the party to the transaction who is best able to appreciate it and who has the option of knowingly taking the inherent risk or avoiding such risk altogether.

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86 R-10-1745.

87 Judith A. Rassi, Note 6, supra at 5733; Gretchen Sybert, Coordinator of Audiological Clinical Program, Gallaudet College, Tr. 5204-06; Frank M. Butts, audiologist, Williams Otology Clinic, Tr. 4164-65; Laura Ann Wilbur, Associate Professor of Otorhinolaryngology, Albert Einstein College of Medicine, Tr. 1388; Michael Stahl, Director of Clinical Services, Hearing and Speech Center, Tr. 5542.

D. Summary of findings and conclusions, Issues 8 and 9.

1. Findings. The record in this proceeding does not show that the number of purchasers of hearing aids who fail to purchase the aid at the conclusion of the trial-rental period is materially affected by the amount of the charges imposed for the trial period. The failure to purchase an aid at the end of the trial period is considered to be synonymous with the election of a buyer to cancel the sale as envisioned in the proposed rule, or with the election of the buyer to return an aid under a "satisfaction or your money back guarantee" as the results are the same. In all of these arrangements, the buyer is, in effect, accorded the right to try out the hearing aid in order to ascertain whether he should buy it, and to return the aid if he feels he should not.

The fact that the record does not show that the amount of a cancellation charge has a very great effect on the number or percentage of cancellations can possibly be explained by the similarity of the amounts charged under currently used plans. These charges range from nothing up to relatively nominal amounts. However, material increases in these charges might lessen the desire of audiologists to refer borderline cases to dealers or might make prospective purchasers more reluctant to try out an aid. Thus, the record does not provide an answer to the question presented in Issue 8. However, it is submitted that, given the various economic backgrounds of hearing aid purchasers, even if it is conceded that their resources are less than those of the population as a whole, an attempt to ascertain the magnitude of a cancellation charge sufficient to "effectively discourage casual or frivolous cancellations" is virtually impossible, and, in fact, is not relevant to a determination of the formula which should be used to compute the cancellation charges that the seller retains in the event the buyer elects to cancel the sale.

Where the buyer has been simultaneously sold two hearing aids, the question is presented as to how much of a cancellation charge the dealer should be permitted to retain. Should it be double the amount for one hearing aid, or should it be some lesser amount such as that authorized in the sale of only one aid. This is a policy question. However, the election to make such a sale rests with the dealer who is in a better position than the buyer to assess the risks involved. While the record does not provide a conclusive answer to this question it would seem that the risk attached to the sale of the second aid should be placed upon the seller especially in view of the possibility that the buyer may not even receive any significant benefits from the second aid or from either aid.

2. Conclusions. The record does not show the amount of a cancellation charge that would be necessary to effectively discourage casual or frivolous cancellations. Nor is it likely that such an amount could be determined with any degree of accuracy, through receipt of additional evidence.

The appropriate cancellation charge for sales of binaural systems sold simultaneously should be no greater than the cancellation charge permitted for the sale of one aid (a monaural system). Where two aids are sold, the seller should be permitted, however, to retain the amount allowed for each earmold and the total number of batteries supplied.

PART V. PROHIBITED REPRESENTATIONS CONCERNING HEARING AID SELLERS

A. General discussion. The record shows that consumers frequently do not know the meaning of the terms audiologist, hearing aid audiologist, certified hearing aid audiologist, consultant, or hearing aid clinic; neither do they know the degree of professionalism associated with each.[1] Accordingly through the use of such terms, some dealers have confused and misled consumers regarding their qualifications by surrounding themselves with an unjustified aura of professionalism.[2]

On the other hand, dealers and industry members believe that these terms are appropriately and deservedly applied to hearing aid dealers. They say that because dealers do a significant amount of advising and counselling of customers, they properly qualify as "consultants" and can truly represent themselves as such.[3] Furthermore, dealers working under the titles "audiologist" and "hearing aid audiologist" were on the scene long before professional audiologists, as defined by proposed Section 440.2(h), were even recognized.[4]

Dealers and their supporters seem convinced that the rule underestimates the role of the hearing aid dealer,[5] while audiologists consider themselves, because of their extensive training, to be an essential step in the hearing health care program.

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1 Dorothy A. Shannon, audiologist, Chief of Speech and Hearing Section, Sinai Hospital, Baltimore, Maryland, Tr. 1860-61. This confusion did not extend to industry members who habitually identified hearing aid dealers, salesmen, and audiologists with the terms, "dealer," "salesman," and "audiologist," respectively.

2 Barbara Stroup, clinical audiologist, Tr. 968-69; Cyril F. Brickfield, legal counsel, AARP/NRTA, Tr. 1434.

3 John H. Payne, private dispenser, Chairman, Hearing Aid Advisory Committee, Indiana State Board of Health, Tr. 9252-53.

4 HAIC, R-3-3950; John Kojis, President, Maico Hearing Instrument Company, Tr. 2090. See also NHAS, R-3-3550-51. The National Hearing Aid Society has a collective membership mark incorporating the term "Certified Hearing Aid Audiologist" registered with the U.S. Patent Office (principal register #884,337, Aug. 10, 1968) R-3-3550. ASHA, on Dec. 6, 1974, filed a petition for cancellation of the mark with the United States Patent Office's Trademark and Appeal Board, but the matter has not yet been resolved. R-10-1672.

5 Robert I. Oberhand, otolaryngologist, Tr. 3034-37; NHAS, R-3-3527-28, 3529.

Although most audiologists see the dealer as a necessary component, they believe that audiologists should have a greater role in the testing and selection of hearing aids.[6]

B. Specific issues.

1. Issue 15.

> Does a representation by a seller of hearing aids (concerning hearing or hearing aids), without disclosure that such person is in fact a seller, have the capacity or tendency to lead consumers to believe (a) that such representation is not designed to effect the sale of a hearing aid, or (b) that the person making such representation is financially disinterested with respect to the matters covered in the representation?

a. The evidence. Consumers are unsophisticated in their knowledge of the qualifications, functions, and motives of those providing hearing health care services.[7] Often the seller's approach, in his title, business name, advertisements, and his office dress and manner leads consumers to believe that he is someone offering professional services rather than hearing aids for sale.[8] Part III of this report documents these misleading selling techniques.

Section 440.8(a) of the proposed rule reads:

> No seller shall make any representation to members of the consuming public without clearly and conspicuously disclosing that it is a seller of hearing aids. The disclosure requirement of § 440.8(a) will be satisfied by a clear and conspicuous statement of the name of the seller's business, if that name includes the words "hearing aid center" or other words which clearly identify that the establishment is a seller of hearing aids.

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6 ASHA, R-10-1597, 1843.

7 ASHA, R-10-1772.

8 ASHA, R-10-1772, 1629-39.

In light of the definition of "representation" expressed in proposed Section 440.2(f)[9], the hearing aid industry views this proposed Section (440.8(a)) as potentially prohibiting any communication between the hearing aid seller and consumers, even in a nonsales contact, unless the seller identifies himself as a "seller."[10] The wording of Designated Issue 15 is cited as revealing this intent. The industry offered no real arguments, but contended that no factual basis exists to support the conclusion that such a disclosure would remedy any deceptive or unfair practices.[11]

Others argue, however, that it is an absolute necessity to initially put the consumer on notice, then, though he may be unaware of other hearing health care practitioners, he will at least understand that he is dealing with a seller of hearing aids rather than with a professional who is disinterested in making a sale.[12] Thereby, he will be less easily misled as to the professional qualifications of the dealer.[13]

b. The findings. The hearing aid seller is a valued component of the hearing health care delivery system and few would deny him his position as such. However, his use of certain terms to refer to himself or to his business could confuse and mislead consumers as to his background, and skills and as to his role or status in providing hearing care.

There is substantial evidence that sellers, through their approach, titles, business names, advertisements, and office manners do often attempt to be recognized by the public as hearing care professionals, rather than as hearing aid sellers.

c. Conclusions. Section 440.8 of the proposed rule would help to eliminate the type of consumer confusion and

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9 Section 440.2(f) defines "represent" or "representation" as "Any direct or indirect statement, suggestion or implication, including but not limited to one which is made orally, in writing, pictorially, or by any other audio or visual means, or by any combination thereof, whether made in an advertisement or otherwise."

10 Hearing Aid Industry Conference (HAIC), R-3-3961; National Hearing Aid Society (NHAS), R-3-3604.

11 HAIC, R-3-3962; NHAS, id.

12 Emma E. Gunterman, legislative advocate, Senior Program, California Rural Legal Assistance, Tr. 9722; Douglas Noffsinger, clinical audiologist, Director of Audiological Activities, Northwestern University School of Medicine, Tr. 7637-38.

13 ASHA, R-10-1772.

deception illustrated in the record. It would cause dealers little hardship in conforming to the truth. Dealers are an integral part of the system and it is doubtful that they will suffer any real harm by being prohibited from using professional or professional sounding titles to refer to themselves.

Some consumers are confused and misled into believing that the salesman-dealer they are patronizing is a professional. This is chiefly because of the way he presents himself to them. The affirmative disclosures required by Section 440.8 should help to eliminate this type of misrepresentation and deception by alerting consumers to the fact that the dealer is a seller of hearing aids. If a person is selling a product for a profit, he should not be ashamed to make that clear at the outset. Why should that fact be hidden or concealed?

2. Issue 16.

> Does the use of the terms set forth by way of example in Section 440.8(b) have the capacity or tendency to lead consumers to believe that the organization being described is something other than a retail sales outlet (i.e., a governmental or other public service organization or a nonprofit medical, educational or research institution)?

a. The evidence. "Hearing" or "hearing aid" coupled with the words "institute," "bureau," or "clinic," or with a combination of the words "hearing center," "speech and hearing center," or "speech and hearing aid center" may cause consumers to believe that the described organization is something other than a retail sales outlet.[14]

The record illustrates precisely such confusion. Helen Kelley, Special Assistant Attorney General for the State of Minnesota, noted that her office had received a consumer complaint concerning a dealership which advertised itself as an independent laboratory where testing was available. As things turned out, a sales pitch, too, was readily available. Tr. 7526.

A consumer recently questioned a certified clinical audiologist regarding whether or not the Medicare Hearing Aid Service was involved with a government-sponsored hearing testing program. She had not been able to detect from the advertising she had seen that the firm was actually a hearing aid dealership.[15]

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14 ASHA, R-10-1772-73.

15 Mark McShane, certified clinical audiologist, Memorial Medical Center, Springfield, Illinois, Tr. 8101.

An independent witness with both a hearing loss and a greater awareness of terms used in the hearing aid field, stated that he was not certain wnat such titles as "speech and hearing center" or "speech and hearing clinic" meant.[16]

A large print advertisement identified the MEDICARE Hearing Aid Service as the purveyor of "The only HEARING AID with a memory"; a hearing aid seller brought this matter to his Congressman's attention, protesting that such advertising would surely lead consumers to believe that the advertiser was related to the federal Medicare Program.[17]

Section 440.8(b) of the proposed rule seeks to reduce such confusion or misconception by prohibiting certain questionable representations of hearing aid businesses:

> No seller shall represent that it is a governmental or other public service establishment or a nonprofit medical, educational or research institution unless such is the fact. Such a representation is made by the use of names such as "hearing center" (but not hearing aid center"), "hearing institute," "hearing aid institute," "hearing bureau," "hearing aid bureau," "hearing clinic," "hearing aid clinic," "speech and hearing center," "speech and hearing aid center," and "senior citizen surveys."

HAIC and NHAS in general feel that these terms, traditionally used by hearing aid dealers, are not misleading and can be understood in the proper sense.[18]

Donald W. Schaefer, Director of the Dane County Hearing and Speech Center, Madison, Wisconsin, a hearing aid dealer, denied that his firm's trade name misled people into believing that it was affiliated with the state's public health programs. Furthermore, he believes that the Commission is out of order in attempting to make such definitions. Tr. 8260-61.

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16 Mike Pasiewicz, Antioch, Illinois, Tr. 8947-48.

17 Letter of A. W. Davis, hearing aid seller, enclosing cited ad, referred by U.S. Representative Melvin Price, R-8-D271. This ad also misrepresents the Medicare Program, which excludes the cost of "hearing aid and examinations therefor." § 102(a), P.L. 89-97; 79 Stat. 327; 42 U.S.C.A. § 1395y (a)(7).

18 HAIC, R-3-3963; NHAS, R-3-3604.

However, one must also consider that many ASHA certified audiologists provide audiology and speech pathology services through organizations described by the terms enumerated in 440.8(b), hence these audiologists believe that consumers are misled when the same terms are used by hearing aid sellers.[19]

An audiologist who works mainly with children is particularly concerned about the use of terms such as "hearing center" which may connote "professionalism" to parents who are especially vulnerable and emotionally upset. Also consumers do not take time to search out exactly what such terms actually mean.[20]

The aged, too, have their share of problems in this area. Kay Samec, the Program Director of the Area Agency on Aging, Central Iowa Association of Regional Government, supports the proposed rule section because of her experience with older people who have received the unmistakable inference that trained professionals will test and attempt to cure deafness at establishments identified as "hearing clinics" or "speech and hearing clinics." R-6-269.

b. The findings. Business names, such as "hearing clinic" and "hearing aid institute," are used to imply that businesses are something other than retail sales outlets offering services related to the product. Misleading trade names are frequently used in this industry to induce consumers to believe they will be attended by a professional in a nonprofit, service-oriented type of establishment, when, in fact, they will be served by a commercially motivated individual.

c. Conclusions. The hearing-impaired individual frequently is misled by the use of trade names for hearing aid dealerships. Such names imply that dealers are independent laboratories, nonprofit organizations, or professional firms, etc. Prohibition of the use of such representations, as noted in Section 440.8(b) would tend to lessen consumer confusion in this regard.

3. Issue 17.

Does the representation that a seller of hearing aids (or the seller's employee,

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19 ASHA, R-10-1772-73.

20 Laszlo Stein, Ph.D., Audiology, David T. Siegel Institute for Communicative Disorders, representing the Division for Children with Communicative Disorders, Council for Exceptional Children, Tr. 8980.

agent, salesperson, representative, or associate) is a physician or audiologist, when such is not the fact, have the capacity or tendency to mislead consumers as to (a) the training, skill, knowledge, specialty, and/or experience of such person, or (b) the nature of the enterprise engaged in by any such person?

a. The evidence. Dealers and their salesmen generally do not blatantly pose as physicians, but too many have given their customers the impression that they are medical personnel, audiologists, or "experts" of some kind.

Patricia G. Mastricola, audiologist with Otologic Professional Associates in Chicago, Illinois, noted an instance in which a Chicago dealer had represented himself as "Dr. So-and-So" and had cleaned a child patient's ears prior to making an earmold impression. When the child's ears were subsequently examined by an otologist, they were found to be impacted with earwax; the child's mother could not understand how this had happened since the "doctor" had already cleaned the wax from the ears. Tr. 8620.

A state Special Assistant Attorney General also recalled instances in which a few hearing aid dealers had represented themselves as being medically competent, "almost doctors so to speak." One consumer complained that her hearing aid dealer had been selling ear medicine to her, representing that he knew more about ears and ear problems than doctors did. Another complainant told of a dealer who wore a white laboratory coat in his office and was referred to or addressed by the office personnel as "doctor."[21] The record contains many other examples of this nature.

In contrast to the traditionally and commonly accepted meaning of the terms, "physician" or "doctor," about which there is little real controversy, there is much disputation about the definition of the term, "audiologist." Section 440.2(h), as proposed, describes an audiologist as:

A person who:

(1) Possesses the Certificate of Clinical Competence in audiology granted by the American Speech and Hearing Association (ASHA); or

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21 Helen Kelly, Special Assistant Attorney General, State of Minnesota, Consumer Services Division, Department of Commerce, Tr. 7523-24; see also Dorothy A. Shannon, Ph.D., audiologist, Tr. 1860-61.

(2) Meets the educational and experience requirements for ASHA certification in audiology and has successfully completed the examination required for ASHA certification in audiology; or

(3) Meets the requirements of any applicable State law which defines the term "audiologist."

Other definitions encountered in the rule proceedings and the reaction to the definition proposed in Section 440.2(h) will be discussed below. At this point, it is necessary to examine the education, role, and operating procedures of the audiologist, as the proposed rule defines that term, so that the nature of the practice of audiology as it is today can be properly placed in perspective to and contrasted with the practice of the hearing aid dealer-salesman who may also be representing himself as some type of "audiologist."

A textbook definition of audiologist reserves use of that term to one whose primary involvement is with the identification and measurement of hearing loss and the rehabilitation of the hearing-impaired.[22] A group of audiologist/consultants to the Veterans Administration would define the term as applicable to one who specializes in the hearing field and particularly in hearing impairments. The audiologist assesses hearing ability and works to habilitate and rehabilitate children and adults with losses in the auditory function. He may be a teacher at the college level, may work in research, or may perform clinical duties in or direct a university, hospital, community, or governmental hearing center.[23]

Most audiologists who participated in the proceeding agreed that the prerequisites today for becoming an audiologist include college, graduate school with the minimum of a master's degree, one year's internship, and the passing of a tough national examination. The training involved is both academic and practical,[24]

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22 Hayes A. Newby, Audiology, 3d ed., (New York: Appleton-Century-Crofts, Meridith Corporation, 1972), p. 1 (ASHA, R-10-D57, Exh. No. 70).

23 Id.

24 Bonnie Smith, clinical audiologist, Director of Audiology and Speech Program at Prince Georges County Health Department, Cheverly, Maryland, Tr. 274; David M. Resnick, Ph.D., (Continued)

including many aspects which simply take time to learn.[25] But the practice requires more than learning to obtain meaningful test results, hence the importance of formal training which teaches the audiologist how to assess the communicational, educational, or rehabilitational needs of the patient, how to plan programs to meet such needs, how to participate in the various phases of these programs, and how to arrange for whatever other forms of assistance are necessary. Dr. David Resnick emphasized that this endeavor is so complex that it can be competently done only by those who have had a great deal of both formal training and clinical experience.[26]

Actual course work covers audiology, speech pathology, speech and hearing sciences, psychology, anatomy, physiology, and the neurology of the communicative mechanism, along with a substantial amount of clinical work.[27] In connection with Dr. Ira Ventry's and student Beverly Ryan's discussions of a representative, ASHA-certified master's program,[28] it was noted that most incoming students to the Columbia University Teachers College already have some preparation in speech pathology and audiology with strong supporting backgrounds in the related science areas. If the student's nonprofessional, undergraduate courses do not include anatomy, physiology, phonemics, psycholinquistics, and/or similar courses, he would be required to take such courses on the graduate level in addition to the subjects involved in the regular master's program,[29] which consists

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24 (Continued)

National Council of Senior Citizens, Director, Hearing and Speech Center, Washington Hospital Center, Tr. 5384; Ira Ventry, Professor of Audiology, Teachers College, Columbia University, New York City, Tr. 1709.

25 Ventry, id; see also Bonnie Smith, id.

26 Resnick, Note 24, supra at 5384.

27 Newby, Note 22, supra at 390-92 (ASHA, R-10-D57, Exh. No. 71).

28 Ventry, Note 24, supra at 1705-43 and Beverly D. Ryan, graduate student in Master of Science Program in Audiology, Teachers College, Columbia University, New York City, Tr. 1521-44.

29 Ventry, Note 24, supra at 1707.

of 18-20 courses taken over a period of four semesters.[30] This graduate-level curriculum includes work in basic speech and hearing science areas such as acoustics, psychoacoustics, and psycholinguistics;[31] applied hearing science areas such as clinical and differential audiometry and electroacoustical amplification systems; and habilitation and rehabilitation procedures and conservation of hearing.[32]

Pertaining directly to hearing aids, the course on electro-acoustical amplification systems covers clinical procedures involved in the selection of amplification devices, technical interpretation of instruments, extrapolation of amplification systems' given specifications to real life cases, etc.[33]

To complement the coursework, 300 hours of supervised clinical experience is required followed by the taking of a national certification examination and a nine-month full-time period of employment under the supervision of a certified audiologist. Then the student can obtain his certificate of clinical competence and become an ASHA certified clinical audiologist.[34]

During the time spent in the academic and clinical environments, audiologists are trained to follow a formal, systematic approach in evaluations; they use a battery of standardized hearing tests that are performed in controlled auditory, acoustic conditions.[35] In outlining this evaluation procedure, the steps taken can be contrasted with the procedures undertaken by dealers in their testing; it becomes obvious in such a comparison that dealers use informal approaches involving some tests which are usually conducted in less than controlled environments.

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30 Ryan, Note 28, supra at 1523.

31 Ryan, Note 28, supra at 1523-24; Newby, Note 22, supra at 391.

32 Ryan, Note 28, supra at 1524-25 (see also her prepared statement, R-10-782-87); Newby, Note 22, supra at 390-91.

33 Ryan, Note 28, supra at 1525.

34 Ryan, Note 28, supra at 1526-27 and R-10-808; Newby, Note 22, supra at 392; Ventry, Note 24, supra at 1711-12; Bonnie Smith, Note 24, supra at 274.

35 Earl Harford, Ph.D., Professor of Audiology, Director, Division of Hearing and Speech Sciences, Vanderbilt University Medical School, Tr. 56-57.

Although procedures differ, initially audiologists should recommend that the first-time hearing aid user undergo a medical exam to determine whether his problem might be remedied medically or surgically.[36] After such consultation, the audiologist usually begins his assessment by taking a brief case history of the problem.[37] Next he conducts a thorough hearing evaluation which minimally involves tests for pure-tone air and bone-conduction thresholds, speech reception thresholds, and speech discrimination testing, among others. The tympanic membrane is also examined--a particularly important part of the procedure when an earmold is needed for testing purposes.[38] The audiologist typically conducts his evaluations of hearing impairments and hearing aids in facilities that meet the national standards set for such testing environments (i.e., calibration of audiometers, use of adequate sound insulated testing booths, etc.). The use of these facilities enhances the likelihood of accurate assessment of hearing problems and makes for more precise treatment of hearing impairments.[39] Following the preselection procedures, hearing aids that are indicated as potentially appropriate according to the preselection test results are compared. The evaluation of each aid is based primarily on the patient's reported performance in experiments conducted with the audiometer.[40] Following completion of this testing, the audiologist recommends the specific aid which the battery of tests and other considerations suggest is significantly better than the other aids tested.[41]

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36 David Barwell, audiologist and hearing aid dealer, Tr. 5174; Dr. Henry C. Hecker, audiologist, Tr. 5263; Resnick, Note 24, supra at 5385; Barbara Stroup, clinical audiologist, Tr. 948; A. Bruce Graham, Ph.D., Chief, Division of Audiology, Speech and Language Pathology, Henry Ford Hospital, Detroit, Michigan, Tr. 7423.

37 Jerome G. Alpiner, "Hearing Aid Selection for Adults," in Amplification for the Hearing Impaired, edited by Michael C. Pollack, Ph.D., (Grune and Stratton: New York, 1975) p. 148, Physical Exhibit B.

38 Kenneth W. Berger, Ph.D., and Joseph P. Millin, Ph.D., "Hearing Aids," Chapter 14, in Audiological Assessment, (Prentice-Hall, Inc., 1971) R-8-Exh. D-498.

39 Ryan, Note 28, supra at 1530.

40 Ventry, Note 24, supra at 1716-19; Berger and Millin, Note 38, supra at 501-02.

41 Berger and Millin, Note 38, supra at 500-01.

If a specific hearing aid model is recommended, the patient is usually given the exact model number along with information on appropriate adjustment, the type of earpiece needed, and battery information; although he may also be given the name and address of a dealer or dealers from whom he can obtain the instrument, he is free to choose any dealer he wishes--assuming that a choice is available.[42]

Because of the greater difficulty encountered in the testing of hearing-impaired children, it must be noted here that the identification and measurement of their auditory dysfunction are usually reserved for the audiologist,[43] although frequently the initial entry into the health care system for the child patient comes with a visit to an otologist for medical clearance purposes, according to the experience of Fern Feder, Educational Coordinator of a regional program for deaf children, Lombard, Illinois. Tr. 8515. Early identification of hearing impairment is accomplished through the use of high risk registers and electrophysiological testing of hearing, followed by fitting of instruments, if warranted, and careful medical-audiological management and provision of special educational personnel if the child is to develop basic basic language skills, establish good parent-child relationships, and function up to his level of ability in a regular classroom setting.[44] For many children, early, appropriate selection and use of amplification is the single most important habilitative tool available, making the availability and proper use under professional supervision something that must absolutely be assured.[45]

In view of the training and use of the procedures just described, the audiologist may then be better able to meet the needs of the hearing-impaired consumer, adult and child, than would the average dealer or his salesman. Not only has he already exhibited his willingness to spend time beyond college in preparing for the responsibility of providing hearing health care services, but because generally he practices his profession

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42 Rassi and Harford, "An Analysis of Patient Attitudes and Reactions to a Clinical Hearing Aid Selection Program," Asha, July 1968, Vol. 10, No. 7, pp. 283-84 (R-10-5247-8.)

43 David C. Shepherd, Ph.D., "Pediatric Audiology," in Audiological Assessment, Note 38, supra at 241.

44 Laszlo Stein, Note 20, supra at Tr. 8972-75; see also Shepherd, Note 38, supra at 241-73; Mark Ross, "Hearing Aid Selection for Preverbal Hearing-Impaired Children," in Amplification for the Hearing-Impaired, (Grune & Stratton, 1975) R-8-Exh. B-207-242.

45 Stein, id. at 8975-76; Ross, Note 44, supra at 207.

in a situation from which he does not stand to reap financial gain from hearing aid sales, his recommendations for amplification systems are made because, in all probability, the suggested instrument will help the patient to hear better.[46] Too, the strict requirements for his certification assure the consumer that no audiologist will be dealing with him without proper supervision until he has adequately completed his extensive training.[47] In light of this extensive training, he should also be able to better inform the consumer regarding benefits that can be expected from amplification, his candidacy or noncandidacy for amplification due to the type and configuration of loss, and the adjustment and relearning that the individual will need to achieve the greatest possible use from his hearing aid.[48]

However, the record demonstrates that many of those familiar with the operation of the hearing aid delivery system do not agree that the audiologist is the only member of the system qualified to assess hearing losses to determine whether use of a hearing aid should be recommended.

The need for extensive training as a prerequisite to proper and adequate testing was questioned as well as the need for such training to enable one to properly select and fit the appropriate hearing aid. It was said that the audiologist may be a "sophisticated tester of hearing," but he is surely not the only member of the system capable of conducting adequate tests for both hearing losses and the effect of amplification.[49] For example, Tennessee State Senator Ray R. Baird suffered a hearing loss during World War II and, based on his 30-35 years of experience with hearing devices, he believes that a hearing aid dealer does better testing thar audiologists do; over the years, he has been a regular customer of dispensers and has found each of them

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46 Ryan, Note 28, supra at 1529; see also Mary Ruth Whitman, Audiologist, Illinois Department of Public Health, Tr. 8594.

47 Ryan, Note 28, supra at 1530.

48 Id.; see also Angela Loavenbruck, Ed.D., audiologist-speech pathologist, Assistant Professor, Teachers College, Columbia University, New York City, Tr. 1546; Maurice H. Miller, "What Is Audiology?", in Audiology and Hearing Education, R-10-D57, Exh. No. 74; Ventry, Note 24, supra at R-10-803; Leslie W. Dalton, Jr., Ph.D., Professor of Audiology, New Mexico State University, Tr. 8722; Jane Madell, Director of Audiology, New York League for the Hard-of-Hearing, New York City, Tr. 5856-57; George E. Shambaugh, otolaryngologist, R-10-D57, Exh. No. 129-2.

49 Robert I. Oberhand, Note 5, supra at 3041-42.

dedicated to rendering high-quality service, while audiologists were unable to help him in any way. Tr. 3611, 3617-18. One non-ASHA certified audiologist believes that college-trained audiologists do not fully comprehend the relationship between the acoustics of the hearing aid and hearing losses,[50] while one physician noted that the degree in audiology did not guarantee expertise in "prescribing" and fitting hearing aids, whereas certification by NHAS of a hearing aid dealer does (bearing in mind, however, that not all dealers are certified).[51]

Wayne J. Staab, Ph.D., currently Director of Education for Telex Communications, Inc., stated that it is possible for one to become ASHA certified without ever having performed a hearing aid evaluation; while the dealer's training is not extensive from the academic standpoint, he at least does have the advantage of working with hearing aids and with the hearing-impaired almost exclusively. Tr. 7027. Dr. August Martinucci, an otolaryngologist, believes that an audiologist is not any more competent to test for the average air and bone-conduction hearing loss than is a dealer, although sophisticated problems do require other kinds of tests. Tr. 8436. Furthermore, Dr. Martinucci believes that dealers are more service oriented and provide unlimited counselling to the customers as part of the initial cost of the hearing aid. On the other hand, according to many industry witnesses, audiologists are professionals involved in the clinical or research aspects of hearing evaluation, charging fees for their services on an hourly basis, and are not service oriented.[52] While the professional does deserve a higher fee than does the dealer, it means that if the consumer first sees an otologist, then an audiologist, and finally a dealer, he will be paying more for his hearing aid; and even if the audiologist dispenses aids at cost, the consumer's bill will still be higher due to other factors.[53]

Richard Scott, a clinical audiologist working for Siemens Hearing Instruments, indicated that testing is not difficult for dealers to learn and that, although the audiologists' in-depth testing does require more schooling, that schooling is

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50 Herbert E. Richenberg, audiologist, Director, Henry C. Barkhorn Memorial Infirmary, Newark, New Jersey, Tr. 3524; see also Ima B. Payne, NHAS, Tr. 3602-03.

51 Oberhand, Note 5, supra at 3036; see also Wayne J. Staab, Ph.D., Director of Education, Telex Communications, Inc., Tr. 7035.

52 Id.

53 Id.

not related to the fitting of hearing aids. He personally had received two-three clock hours in training relating specifically to hearing aids and found that much of that was unrelated to what goes on in the real hearing aid world. Two days of intensive training, he feels, should be sufficient for a person to learn to conduct the audiometric testing necessary for determining and quantifying a hearing loss. Tr. 2319-20, 2326.

ASHA, in its rebuttal submission (R-13-D147-III), characterizes all of the comments critical of the audiologist's ability to fit hearing aids as parts of a concerted attack intended to erode the impact of the pro-rule audiologist testimony. R-13-D147-III-2. ASHA goes on to note that certain state and federal agencies have recognized the audiologists' role in determining hearing aid candidacy by requiring that an audiologist's recommendation precede certain purchases of hearing devices. R-13-D147-III-6. To even further bolster its position, ASHA offers the results of two post-hearing surveys which indicate that graduate programs in audiology do provide hearing aid related training and practical work experiences and that such training does not terminate with the receipt of the master's degree. R-13-D147-III-10.

Over and above the differences between audiologists and dealers in the amount of education and sophistication in testing and fitting procedures, however, another problem that poses potential difficulties was pointed up in the record: many consumers simply do not know the meaning of the term "audiologist," whether it is used alone or in combination with other words.[54] Many witnesses testified that use of the term by a dealer is confusing to consumers[55] while, according to clinical audiologist, Mark McShane, such a term, no matter what qualifiers may precede it, conveys the impression of more expertise than sellers of hearing aids normally possess. Tr. 8122. Specific testimony regarding use of the title "certified hearing aid audiologist"

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54 John C. Kenwood, hearing aid dealer representing NHAS, Tr. 9344; David Rompala, clinical audiologist, Schwab Rehabilitation Hospital, Tr. 9092; Darrel E. Rose, Director of Audiology, Mayo Clinic, Tr. 531; Mike Pasiewicz, independent witness with a hearing loss, Tr. 8922-23.

55 Lee Wilson, clinical audiologist, President, Society of Medical Audiology, Tr. 10081; Barbara Stroup, Note 36, supra at 968-69; Dorothy A. Shannon, Note 1, supra at 1860; Ira Kolman, Ph.D., Chairman, Department of Speech Pathology-Audiology, Loyola College, Baltimore, Maryland, Tr. 1884; Laszlo Stein, Note 20, supra at 8980; Cyril F. Brickfield, legal counsel, AARP/NRTA, Tr. 1434; Mary Ruth Whitman, Note 46, supra at 8560; ASHA, R-10-1777.

by dealers tends to support this view,[56] or indicates that such use tends to confuse the real differences that exist between audiologists, other professional groups, and dealers.[57]

Section 440.8(c) and (d) of the proposed rule provide the following remedy for the problems arising from the confusing use of terms from which consumers may receive erroneous impressions:

> (c) No seller shall represent that it or any of its employees, agents, salespersons and/or representatives is a physician or an audiologist, unless such is the fact. One example of a violation of Section 440.8(c) is the use of the term "audiologist" to describe one who is not an audiologist as defined in Section 440.2(h); and
>
> (d) No seller shall represent that the service or advice of a physician or an audiologist will be used or made available in the selection, adjustment, maintenance or repair of a hearing aid, unless such is the fact.

ASHA, representing the view of most audiologists, strongly supports Section 440.8(c) (R-10-1780), saying that confusion and misconception caused by the unlimited use of the words "audiologist" or "doctor" would thereby be eliminated.[58]

Furthermore, Sections 440.8(c) and (d) along with the corresponding definitions in Section 440.2(h) would be in harmony

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56 Rose, Note 54, supra at 532; Fern Feder, consumer, parent of a deaf son, Tr. 8530.

57 Loavenbruck, Note 48, supra at 1559; James M. Anthony, otolaryngologist, Dallas, Texas, Tr-8501-02; Fern Feder, Note 56, supra at 8527-28; Patricia G. Mastricola, audiologist, Otologic Professional Associates, Chicago, Illinois, Tr. 8619; Donald E. Morgan, Ph.D., Audiology, California Speech and Hearing Association, Tr. 9536; John Franks, Assistant Professor of Audiology, Arizona State University, Tr. 9813; Bonnie Smith, Note 24, supra at 273; Bonita Simon, clinical audiologist, works mainly with school programs, Lombard, Illinois, Tr. 9161.

58 ASHA, R-10-1777, 1780; George Shanta, President, Chicago Area Council of Senior Citizens Organization, Inc., Tr. 8870; William E. Lentz, Associate Professor, Director, Hearing Clinic, Colorado State University, Tr. 11295.

with the 27 state statutes which now regulate audiologists.[59] Several exhibits also indicate that the proposed Section 440.2(h) definition is consistent with the generally accepted meaning of "audiologist."[60]

On the other side of the issue, HAIC and NHAS believe that Section 440.8(c) and the conjunctive definition Section, 440.2(h), contain an inaccurate, restrictive, and unwarranted definition of audiologist.[61] In fact, say these groups, the definition may be so restrictive that they will disqualify competent audiologists who are practicing in states where there is no law licensing audiologists and who may not possess the Certificate of Clinical Competence granted by ASHA.[62] And not the least in importance, in industry's view, is the fact that it was through the offices of hearing aid dealers and NHAS that the word "audiologist" was brought into the public vocabulary.[63] (It must be noted here, though, that there is also a contention that the term was originated by a speech pathologist and an otologist and that it has come to properly designate the professional rather than the commercial worker in the field.)[64]

Luke Fortner, President of NHAS and private hearing aid dealer, stated that use of the term "certified hearing aid audiologist" is legitimate for the dealer in view of the many branches that exist in audiology: research, clinical, pediatric, industrial, and hearing aid, as examples. One who has made the effort to upgrade himself to a "certified hearing aid audiologist"

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59 ASHA, R-10-1776; Morgan, Note 57, supra at 9504-05.

60 "Hearing Aids, I. What the Buyer Should Know," Consumer Reports, May 1971, p. 311 (R-10-D5, Exh. No. 114); "Need to Hear Better? You Can!", Changing Times, The Kiplinger Magazine, August 1975, p. 30 (R-10-D57, Exh. No. 115); Facts About Hearing Aids, Better Business Bureau Publication, 1973, No. 03-250-73, A250873; ASHA, R-10-D57, Exh. No. 87; Facts About Hearing and Hearing Aids, National Bureau of Standards, pp. 11-12; ASHA, R-10-D57, Exh. No. 86A; see also similar instances in newspaper articles and magazines collected by ASHA in R-10-D57, Exh. Nos. 70-74, 76-85, 88-89, 91-96, 111-113, 115-129, 157.

61 HAIC, R-3-3948; NHAS, R-3-3546.

62 HAIC, R-3-3948; NHAS, R-3-3549.

63 HAIC, R-3-3950.

64 Newby, Note 22, supra at 3.

should have the right to use that term. It is, in fact, a motivating force for the dealer in this case. Tr. 2861-62. Too, in view of their qualifying adjectives, this term and the term, "hearing aid audiologist" are not misleading or confusing to the public. Tr. 2862.

John Kojis, representing HAIC, noted that consumers are not confused by use of "certified hearing aid audiologist" since many of them have never even heard the word "audiologist" (used alone) before. Tr. 1996. Joel Mynders, a hearing aid specialist, also did not think there was any possibility of confusion for the qualified terms used by dealers are precise in meaning and do not infer clinical knowledge or that the dealer is a clinical audiologist or medical specialist. Tr. 11573.

The pro-rule argument is that, precisely because many members of the public do not understand the meaning of such terms as "certified hearing aid audiologist," they are likely to believe that a person bearing such a designation has had more training and possesses more qualifications than is actually the case.[65] As support for their argument, the rule proponents cited the fact that nearly 30 states have outlawed the use of the term "hearing aid audiologist" either by legislation, court decision, or opinions of attorneys general.[66] It is also alleged that dealers and salesmen want to use such designations to enhance their status in the eyes of consumers.[67] This argument is quite compatible with Mr. Fortner's view that the privilege to use such titles is a motivating force for salesmen. Tr. 2861-62.

How consumers are confused and misled by titles such as "certified hearing aid audiologist" was exemplified by the following exchange between Commission counsel and Gordon R. Cooper, County Judge in Provo, Colorado, who testified "in the capacity of a user" of considerable experience:

> Q. Judge, what is a certified hearing aid audiologist?

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65 Nadine Woodward, member, International Association of Parents of the Deaf, Inc., Tr. 4150.

66 ASHA, id.; see also Maurice A. Byrne, Jr., Assistant Director, Department of Consumer Affairs, Louisville, Kentucky, Tr. 1020, 1075-76; Kolman, Note 55, supra at 1896-97; Roy Zum Brunnen, Hearing Aid Dispensers Examining Committee, Board of Medical Quality Assurance, State of California, Tr. 11945; James Langford, Associate Professor, Audiology, Northern Illinois University, Tr. 8006-07.

67 ASHA, R-13-D147-II-6; Loavenbruck, Note 48, supra at 1887-8.

A. A certified hearing aid audiologist, my concept of it is, from the way I have seen them, is mainly a man who is in an otolaryngologist's office who tests your hearing and gives the results to the otolaryngologist. That is the only contact I have had with him, and I have had contact with quite a few in my California experiences with otolarynogologists and Colorado and Colorado Springs and Pueblo.

I wouldn't object, of course, to the definition as contained in the proposed rules and regulations, of course.

Q. And that is the type of person you are talking about the one defined as an [audiologist] in the regulations?

A. Right. Tr. 10773.

Judge Cooper was also a member of the "Hearing Aid Dealers Licensing Board in Colorado" and, therefore, might have been expected to have known the difference between an audiologist and a "certified hearing aid audiologist." The subtle difference in titles is obviously too subtle for many consumers.

b. The findings. Dealers frequently use the term "audiologist" either alone or in combination with modifiers, to refer to themselves; this practice appears from the record to be longstanding, with dealers alleging that they originated the term and were the first in the system to use it. Dealer references to themselves as "doctors" is much less frequent, although the record indicates that such instances do occur.

When confronted by a dealer who calls himself an "audiologist" or some combination form of that term, such as a "certified hearing aid audiologist," the consumers very often do not know the meaning of such titles and, because of their lack of knowledge, they attach a professional significance or meaning to the term. Generally speaking, an "audiologist" is one who has a master's degree or Ph.D. from a college or university, is trained in the sciences of hearing, hearing impairments, testing procedures and rehabilitation; in addition, he is usually certified or regulated by the American Speech and Hearing Association, some other certifying agency, state law, or federal regulations. Therefore, he meets the criteria recognized as characterizing a professional, vis-a-vis, a nonprofessional in the system.

On the other hand, while they do not have lengthy formal training, dealers are often "well trained" regarding hearing aids in the sense that their practices involve the constant testing

for, and selection and fitting of amplification systems; they argue that, in this respect, they are better trained than audiologists who have little training or experience in actually working with hearing aids. In fact, however, the record demonstrates that audiologists are required to have extensive course work and supervised clinical work with hearing aids as part of their training and certification programs and prior to their use of the title "audiologist." Dealers and their employee-salesmen do not have this amount of training or experience when they first embark upon their work.

c. Conclusions. Although the use of the term "physician" when applied to nonmedical personnel is prohibited by other laws, some few dealers have and do represent themselves as doctors, to the undoubted deceit of consumers. Although use of the term "audiologist" is less clearly deceiving, it nonetheless does appear to have the capacity and tendency to mislead potential customers by implying that a dealer possesses qualifications similar to those of the professional audiologist, when he simply does not, regardless of the amount of his previous practical experience--which may be very great or very slight. It may be concluded that proposed Sections 440.8(c) and (d) will do much to remedy both of these problems, particularly by confining the use of the term "audiologist" or any combination thereof to those individuals who meet the criteria established in proposed Section 440.2(h), which reflects the generally recognized definition of a professional "audiologist."

4. Issue 18.

> Do the terms "counselor" and/or "consultant" have the capacity or tendency to lead consumers to believe that the individual so described can be relied upon to provide an expert and financially disinterested recommendation as to what should be done to deal with the consumer's perceived hearing problem?

a. The evidence. Many persons feel that use of the terms "consultant" or "counselor" by hearing aid dealers leads consumers to believe they are being treated by a professional. Donald E. Morgan, Chairman of the Los Angeles, California Audiology Task Force of the Commission on Legislation, stated that, in his opinion, terms such as "hearing aid specialist" or "counselor" are deceptive when used by those whom the law has classified as hearing aid dispensers and sales people involved in these businesses. He is chiefly concerned that the public know what the limitations and capabilities of a person are by virtue of their titles, i.e., the way they refer to themselves. Tr-9536-38.

Dorothy A. Shannon, audiologist and Chief of the Speech and Hearing Section, Sinai Hospital, Baltimore, Maryland, sees patients who are often confused about the roles of physicians,

otolaryngologists, audiologists, and hearing aid dealers. They frequently visit dealers on their doctors' referrals, believing such dealers are audiologists or other consulting physicians when they represent themselves as "consultants." Tr. 1860.

A veterans' hospital audiologist has had many patients tell him that they were getting professional counseling concerning their hearing loss, when in fact the "professionals" were salesmen operating on temporary permits and trained only in the sale and fitting of hearing aids. He believes that this type of consumer misunderstanding of dealers' limitations and of the roles of the otolaryngologist or audiologist is widespread and crosses educational and social boundaries.[68]

Mike Pasiewicz, an independent witness with a bilateral hearing loss and former sales-trainee, agreed that the use of the terms "consultant" or "counselor" when applied to a salesman is very deceiving; people who seek advice about hearing loss rehabilitation may be victimized by salesmen using such titles. Tr. 8911.

Section 440.8(e) of the proposed rule would eliminate this confusion by restricting the use of the terms as follows:

> No seller shall represent that it or any of its employees' agents, salespersons and/or representatives is a "counselor" or a "consultant."

ASHA, in its support for Section 440.8(e), cites Webster's Seventh New Collegiate Dictionary's definition of consultant, which reads:

> 1: one who consults another 2: one who gives professional advice or services: EXPERT

as implying, connoting, or indicating that the persons to whom the terms "counselor" and "consultant" are applied are experts; thus, the dealer who holds himself out as such is representing that he is an expert. In reality, medical and health services

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68 Frank M. Butts, M.Ed., audiologist, Williams Otology Clinic, Richmond, Virginia, part-time employee, Veterans Hospital, Tr. 4166; see also Mary Ruth Whitman, Note 46, supra at 8594; Robert C. Beiter, audiologist representing the Association of Clinical Programs in Speech Pathology and Audiology of Metropolitan Chicago, Tr. 9074; Lloyd Mosley, Supervisor of Speech and Hearing Services, University of Illinois, Division of Services for Crippled Children, Tr. 7749-50.

in the hearing care field are provided by two professional groups--physicians and audiologists. These true "experts" usually are characterized as maintaining objective, unbiased views that are unaffected by any financial interests. According to ASHA, the dealer does not fit this definition of expert. R-10-1781. Mary Ruth Whitman, audiologist, Illinois Department of Public Health, believes the profit motive figures heavily in the dealer's public contact; for example, it would act to make him reluctant to give advice about certain disadvantages of a hearing aid for fear that he would discourage a sale. Tr. 8593-94. She also does not believe the average dealer is capable of providing realistic guidance, counselling, and instructions that will enable the hearing aid wearer to obtain satisfactory benefits from amplification. Tr. 8593.

HAIC, opposed to these arguments, contends that hearing aid dealers do engage in counselling and consultation within the meaning of the dictionary definition of those terms. In fact, they advise purchasers concerning a variety of areas and problems having to do with hearing aids and hearing aid uses, and they provide other valuable services which fairly qualify them to be described as counselors or consultants. R-3-3964.

The Payne and Payne survey demonstrates that the significant amount of time the dealer invests in customer counselling is the "key" to his unique role in the hearing aid delivery system. The survey results indicate that the sale of a hearing aid in most cases is only the beginning of a personal involvement between the dealer and the customer that may last for many years; dealers are generally the only ones in the system who are willing to expend the necessary amount of time in counselling needed to ensure the user's optimum satisfaction with his hearing aid.[69] The survey also indicated that most users, in turn, look almost entirely to their dealers for such counselling, services, and encouragement.[70] A majority of medical ear specialists (17 out of 21) interviewed, too, indicated that they referred patients to dealers mainly because of dealers' willingness to provide unlimited counselling and services; they further felt that dealers should be encouraged in their assumption of counselling responsibilities.[71]

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69 A National Survey of the Hearing Aid Delivery System in the United States, Payne & Payne Consultants, 1974, R-8-D238-55.

70 Id. at 9; see also Herbert E. Richenberg, Note 50, supra at 3547.

71 Payne and Payne, Note 69, supra at 33, 37.

In view of the survey results, HAIC believes that hearing aid dealers must engage in customer counselling and that, accordingly, their use of the terms "consultant" and "counselor" in referring to themselves is not misleading or deceptive and should not be prohibited as now proposed. R-3-3965-66.[72]

b. The findings. The terms, "counselor" and "consultant" as those terms are used by hearing aid dealers and salesmen, could indicate to consumers generally that the bearer has some special medical expertise or professional skills. The industry, dealers themselves, many consumers, and other rule opponents believe that dealers do have the expertise and skills coming from their constant counselling of customers that would permit them to truthfully call themselves "consultants," etc. Specifically regarding counselling pertaining to the hearing aid and its related problems and to the user and his adjustment and use problems, it appears that some dealers (but not many salesmen) may have more experience of this nature, particularly in regard to common hearing problems, than do professionals. In view of this amount of practical counselling, then, the proscribed terms although potentially confusing, would seem to be less so than some other expressions currently used by some dealers to carry far more seriously misleading connotations. Such expressions include the terms "professional," "otometrists," and "audioprosthologist." Perhaps "specialist" should also be added to this list.

c. Conclusions. As the expressions "counselor" and "consultant" are shown by the evidence in the record as a whole to carry the connotation of specialization and to be generally accepted as referring to expertly trained medical personnel, dealers should probably be prohibited from using such terms to refer to themselves. This should prevent consumers from believing that a dealer's expertise was acquired in a fashion or manner other than in the course of the conduct of his trade or business.

The record indication that such other words implying expertise as "professional," "otometrist," and "audioprosthologist," are currently being used to some extent by dealers is just cause for serious concern.

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72 See also NHAS, R-3-3604; John Payne, hearing aid professional private dispenser, Tr. 9252-53.

PART VI. PROHIBITED REPRESENTATIONS CONCERNING HEARING AIDS

A. General. Impaired hearing continues to be regarded by many persons as a defect that is to be hidden and of which one must be ashamed. A number of individuals with decreased hearing are, therefore, reluctant to admit their loss and seek remedial amplification when it is appropriate. Although hearing devices are more readily accepted today than they were 10-20 years ago, they still do not meet with the degree of social approval that eyeglasses have acquired. Doctors, audiologists, and dealers constantly face consumer questions that are prompted by the "need" to disguise both the defect and the hearing aid necessitated by it.[1] Concealment of hearing problems and devices may assume abnormal importance if the person involved is a child; some parents are motivated to select hearing instruments for cosmetic reasons rather than for the benefits that the child will be able to receive,[2] although the desire to remove the young person from a "silent world" is also present.[3]

The quality and range of reproduction of sound is also important, and for some individuals, this is the most important consideration in a hearing aid purchase decision. But here, the first time user is generally handicapped by a lack of understanding on his part of the nature and meaning of hearing losses and what types of remedies, including amplification, are available to help him; if he relies upon sales representations, he may well set out to locate the instrument that will return his normal hearing to him, seeing such a device as the end to all of his hearing problems.[4] Even many long-time hearing aid users (or at least not novices) who know the limitations of their current instruments, continue to search for something better, being under somewhat of the same handicap. They, too, look for the "ultimate answer"--the breakthrough that will enable them to improve the quantity and quality of their hearing. Thus when a new model or a new system is advertised, these people flock to the seller's door in what is

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1 James M. Anthony, M.D., Dallas, Texas, Tr. 8496.

2 Fern Feder, Coordinator, Regional Program for Deaf Children and parent of a deaf child, Lombard, Illinois, Tr. 8510-12.

3 Id. at 8522-23.

4 Mark McShane, certified clinical audiologist, Department of Communicative Disorders, Memorial Medical Center, Springfield, Illinois, Tr. 8121.

sometimes a vain hope that he will have something useful to offer them.[5]

In a significant number of cases, as the discussion below will indicate, claims made regarding these and other desirable aspects of hearing instruments are frequently untrue, misleading, or, at best, turn out not to mean what the responding individual thought they meant. Thus, whether by design or otherwise, such advertising and sales representations may mislead potential purchasers through false encouragement.[6]

B. Specific issues.

1. Issue 19.

Will any hearing aid restore or help restore normal or natural hearing, or enable wearers to hear sounds normally or naturally?

a. The evidence. When those with suspected hearing losses begin to explore the hearing health care delivery system, they generally know little, if anything, about the nature, variety, and causes of hearing impairments or the operational techniques and limitations of mechanized devices available to help them if other medical treatment or surgery is inappropriate or impractical in their case. Quite often they are motivated to purchase a hearing aid in the belief that through its use, they will again regain their natural or normal hearing facility.[7] While hearing aids are one of the better rehabilitative tools that have been devised through the use of modern scientific and technological knowledge, they are neither the answer to everybody's problems, nor necessarily the answer for any particular individual's problem.[8] They assist the wearer in picking up many sounds, but with a slight mechanical or electronic effect. However, they cannot give back or restore normal, physical hearing.[9] Neither do they have the ability to restore the natural ability

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5 James Langford, Associate Professor of Audiology, Northern Illinois University, DeKalb, Illinois, representing the Illinois Speech and Hearing Association, Tr. 8062.

6 Id.

7 Ray Stallons, clinical audiologist, Peoria, Illinois, representing the National Hearing Aid Society, Tr. 7868-69.

8 McShane, Note 4, supra at 8121.

9 Lou Jungheim, Chairman, Board of Directors, Chicago Metropolitan Area Senior Citizens Senate, Tr. 8879.

to discriminate sounds and words normally, once that facility has been lost or impaired.[10]

In evaluating amplification devices, each system's electroacoustical qualities must be considered: the system normally contains internal noise and distortion and it reproduces sounds only within a limited frequency range. Considering such factors that are inherent in the technical design of all presently marketed hearing aids, one must question, on this basis alone, whether any device can lay claim to the reproduction of normal or natural hearing.[11] Yet, the results of an instrument's performance cannot really be judged on the basis of its technical limitations; rather, factors external to the system itself also figure importantly in the normalcy or naturalness of the sound received by the wearer. These external factors include the nature and severity of the individual's hearing loss, the situational environment in which the individual is attempting to use the aid, and the appropriateness of the particular aid for the user.[12] Under these circumstances, a device which only amplifies a limited sound spectrum should not realistically be expected to restore or create normal hearing, but it must constantly be borne in mind that most hearing aid purchasers and users do not understand the device's true function, i.e. increasing the "loudness" of the sounds received. They understand only that they do not have the hearing they once had and they hope that, through use of a hearing aid, they will regain the auditory world they once

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10 Mike Pasiewicz, consumer witness, Antioch, Illinois, Tr. 8911; David Rompala, clinical audiologist, Schwab Rehabilitation Hospital, Chicago, Illinois, Tr. 9097-98; Donald E. Morgan, Ph.D., Chairman, Audiology Task Force of the Commission on Legislation, California Speech and Hearing Association, Los Angeles, California, Tr. 9554; Lee Wilson, clinical audiologist and President, Society of Medical Audiology, St. Paul, Minnesota, Tr. 10080; Hubert L. Gerstram, Chief, Hearing and Language Center, New England Medical Center Hospital, Boston, Massachusetts, Tr. 2466; Paul Burris, Manager, Professional Services, Dahlberg Electronics, Minneapolis, Minnesota, Tr. 2560; Luke Fortner, President, National Hearing Aid Society, and private hearing aid dispenser, Memphis, Tennessee, Tr. 2964; Stephen Epstein, M.D., representing the National Council of Senior Citizens, Tr. 4569.

11 Kenneth O. Johnson, Ph.D., Executive Secretary, American Speech and Hearing Association, R-10-1787.

12 Angela Loavenbruck, Ed.D., audiologist-speech pathologist, Teachers College, Columbia University, New York, New York, Tr. 1560.

knew. With the prevailing technological situation, their search is doomed to failure. Though not all parties agree with the American Speech and Hearing Association (ASHA) in its branding of advertising that instills such unrealistic impressions of expected results in consumers as per se deceptive and misleading.[13] Many do agree that the beholder of such statements is likely to have hopes raised that are cruelly disappointed upon the consumer's first actual experience with a hearing device. In some instances, this experience is so disillusioning and dissatisfying to the hearing-impaired individuals that it will cause them to fail to adjust to the use of the device entirely, thus depriving them of whatever benefits they might have obtained had they approached the matter more realistically.[14]

Evidence produced during the proceeding pointed to the frequent occurrence of sales representations that do convey to recipients confusing and misleading, if not downright deceptive notions regarding the potential restoration of normal hearing by amplification. Mary Ruth Whitman, Illinois Department of Public Health audiologist, often comes into contact with elderly persons who have put away their hearing devices in disgust after learning that their restored hearing was nowhere near "normal," as they had been led to believe it would be. Ms. Whitman feels that, had these people initially been given performance expectations that were realistic, many of them would have satisfactorily adjusted to amplification and would have been benefited thereby. Tr. 8558. She noted that her mother-in-law, a victim of such unreal expectations, was sold binaural aids with the seller's assurance that the system, if regularly used, would gradually restore her normal hearing. Of course, this promised condition has not materialized, yet this hearing aid user, more optimistic than most, continues to faithfully use her devices in the hope that the dealer's prediction will eventually be fulfilled. Tr. 8562-63.

Frederick Schreiber testified that in his capacity of Executive Secretary of the National Association of the Deaf, he frequently receives complaints that consumers do not get the benefits for which their hearing aid dollars have been spent: the failure of hearing aids to deliver to their wearers the "cure" that each

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13 ASHA, R-10-1786-87.

14 Frederick Schreiber, Executive Secretary, National Association of the Deaf, Tr. 4072; Stephen Epstein, Note 10, supra at 4569; David M. Resnick, Ph.D., National Council of Senior Citizens, Tr. 5389; Mary Burke, audiologist, Hearing Clinic, Northwestern University, Evanston, Illinois, Tr. 6411, 6414; Mary Ruth Whitman, audiologist, Illinois Department of Public Health, Springfield, Illinois, Tr. 8558, 8583-84; David Rompala, Note 10, supra at 9097-98.

individual seeks appears to be at the roots of such discontent--when the "cure" does not materialize, consumers feel they have been victimized and are unhappy. Tr. 4072.

Dr. Thomas W. Norris, Director of the University of Nebraska Medical Center's Division of Audiology and Speech Pathology, in Omaha, Nebraska, characterized many people as "naive" regarding hearing defects; lacking even general information concerning hearing impairment, they can and do believe that a return to normal hearing is possible. He is often approached by individuals with newspaper articles in hand, regarding "new developments" and "cures" for their problems. R-10-6497.

Specific examples of sales representations were discussed in record submissions:

> Does it make sense to throw away the God-Given and designed, 'Million Dollar' Ears you were born with and try to replace them with a crude, man-made mass-produced device, when it is now possible to have your very own, guaranteed, personal prescription 'Booster' made to fit entirely inside your own 'million dollar' ears to catch, separate, and clarify sounds*** Naturally? - Naturally!
>
> ASHA, R-10-1789, referring to R-8-D314-15.
>
> Natural Level Hearing
>
> ASHA, R-10-1789 citing R-8-D303.
>
> They produce a natural, almost hi-fi sound.
>
> ASHA, R-10-1789 citing R-8-D472.
>
> With HEAROLA you hear naturally.
>
> ASHA, R-10-1789 citing D10-57, Exh. 100-LL(6).
>
> '(just as it is in normal hearing),' '(Just like a person with normal hearing can.)' and 'In normal hearing, the concha is shaped so that it can distinguish between sounds from the rear and sounds from the front. Rear noises are weaker. Muted. Muffled. Front noises are louder. Sharper. Clearer.*** In our 568 series, this capability has been reproduced****'

ASHA, R-10-1789 citing D10-57, Exh. 100-YY/2, 5(a), (b), and (c)-(d).

Completely natural sound.

ASHA, R-10-1789 citing D10-57, Exh. 100-A(4).

TELectret - the microphone that makes hearing a natural experience.

ASHA, R-10-1789, citing D10-57, Exh. 100-AR.

The number of hearing aids that do go unused following their purchase and the number of consumers who have recounted their sufferings from the so-called "dresser drawer syndrome" are seen by rule proponents as proof enough that no hearing aid currently on the market can deliver on promises of normal or natural hearing.[15]

To eliminate the use of such sales representations, Section 440.9(a) of the proposed rule has been drafted to read as follows:

> (a) No seller shall represent that any hearing aid will restore or help restore normal or natural hearing or will enable or help enable wearers to hear sounds normally or naturally.

The industry, as represented by the Hearing Aid Industry Conference (HAIC) forcefully takes issue with the scope of this proposed provision, raising the question of exactly what claims it would operate to proscribe. Noting that the prohibition specifically extends to representations that a hearing aid "will***help restore***or help wearers to hear sounds normally or naturally," it asserts that hearing aids do help restore normal or natural hearing and will help to enable wearers to hear sounds normally or naturally. Indeed, the major function of the hearing system is to make possible the reception of sounds as normally and naturally as the residual hearing will permit.[16] A prohibition that would eliminate such representations would not only constitute a proscription of truthful and accurate advertising, but would also dry up an important source of consumer information regarding the function of amplification.[17]

ASHA, on the other hand, contends that, since there are no known, presently marketed wearable hearing aids which will restore or help to restore normal hearing, Section 440.9(a) will be a

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[15] ASHA, R-10-1786-87.

[16] Hearing Aid Industry Conference (HAIC), R-3-3966.

[17] Id.

"viable" means of eliminating the kind of misrepresentation that flows from statements that contain such indications or make such implications. It sees no particular difficulties arising from the fact that compliance with this rule section would see to it that the consumer no longer has before him such statements, including those that mention only "help" in hearing sounds normally.[18]

Speaking against the rule section, some witnesses made much of the anticipated negative effect that this section and those subsequent to it might have in terms of discouragement of an already negatively inclined hearing-impaired person toward attempting to wear a hearing aid.[19] Luke Fortner, a Memphis, Tennessee, hearing aid dealer and President of NHAS, presented his personal method of dealing with customer expectations of hearing improvement from amplification, including holding performance ideas to a minimum until the hearing device is applied and then letting the customer see for himself what benefits are to be gained. Using this method, he has had very little difficulty with consumers' overblown, unrealistic expectations of normal hearing. Nonetheless, he felt that, if he were required to advertise negatively as he believes the proposed rule requires, potential customers would be so discouraged that many of them would never even come into his shop to investigate. Tr. 2965.

Again switching to the opposite side of the issue, proponents reiterate their view of the importance of the consumer's understanding that hearing aids will not restore normal hearing. Noting that hearing-impaired individuals are ready to believe even the most outrageous claims,[20] they point out that advertising has led some consumers to the purchase of one device after another in their search for the "perfect" instrument they believe they have seen or heard advertised. This is particularly true of the elderly who have demonstrated in the past a high degree of vulnerability to vacant promises that suggest unattainable results.[21] Through such claims the first-time user may be indirectly led to believe that his hearing aid will solve all of his problems; in reality, he may find that it even creates some new ones. For instance, consumers are often unpleasantly surprised at the amplification of unnatural (in their view) environmental sounds, or

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18 ASHA, R-10-1786-88.

19 James Keyes, Executive Vice President, Audiotone Division/ Royal Industries, Tr. 10695.

20 Stephen Epstein, Note 10, supra at 4569.

21 David M. Resnick, Note 14, supra at 5389.

to learn that in addition to such sounds, their speech discrimination ability has not been improved.[22] Adjustment is difficult enough for those who face the facts; the hope was expressed in favor of the rule that 440.9(a) would see that more of the true facts and fewer self-defeating notions reach consumers.[23]

b. The findings. Hearing-impaired individuals are strongly motivated by the desire to regain normal hearing, therefore, a claim made in advertising that a particular hearing device will restore natural hearing ability is a definite attraction for them to at least inquire, if not also purchase, the advertised amplification system. Yet, there is no hearing aid on the market that can live up to this claim; the wearer instead receives internal noise and distortion inherent in the hearing device and hears amplified sounds only within a limited frequency range. The result of consumer action motivated by such representations is often extreme dissatisfaction and disappointment with amplification in many instances culminating eventually in the "dresser drawer" phenomenon in which the purchaser discards his hearing device. Although the industry contends that the device will help restore natural hearing, the sound received falls far short of what the consumer considers to be "normal."

c. Conclusions. Due to the nature of currently available amplification, representations that hearing aids will either restore normal hearing or will help to do so, are confusing, misleading, false, and per se deceptive. To prevent consumers from being literally "taken in" by such claims, to their financial and frequently also emotional detriment, claims of this nature should be eliminated. The negative impact upon the consumer stemming from the advertiser's inability to make such claims would seem to be less of a discouragement than the negative impact experienced when consumers learn that the unrealistic promises they have been given about restoration of normal or natural hearing are untrue. Section 440.9(a) will be beneficial in this area.

2. Issue 20

Do the expressions set forth by way of example in Section 440.9(b) have the capacity or tendency to lead consumers to believe that any

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22 Judith A. Rassi, audiologist, Northwestern University, Evanston, Illinois, Tr. 5732-33, 5736-37.

23 Mary Ruth Whitman, Note 14, supra at 8573; Angela Loavenbruck, Note 12, supra at 1560; Robert I. Oberhand, M.D., Westfield, New Jersey, Tr. 3039-40.

hearing aid will reverse, halt or retard the progression of hearing loss, or will help to do so?

a. The evidence. While examples cited, such as "Act now before it's too late," "Delay may be harmful," and "I caught your hearing loss just in time," not only carry the meaning to consumers that a hearing aid will reverse, stop, or slow down the progression of hearing deterioration, they even more importantly imply that if the consumer doesn't act now (by buying a hearing aid) his hearing condition will most certainly and immediately worsen until he will perhaps lose his hearing altogether. To those persons, uneducated in the etiology and pathology of ear diseases and conditions, who have already suffered hearing losses to some degree (or at least think there's a loss), these statements can be and are often powerful incentives for immediate purchases. Testimony indicates that some of these types of representations are so misleading as to be outrageous. Dr. Donald E. Morgan, chairman of the Audiology Task Force of the Commission on Legislation, California Speech and Hearing Association, discussed a document entitled "Presentation," which is used for instructing sales personnel on what to say to prospective customers. At one point, after a good deal of harangue has already taken place and the customer is at least wavering on the brink of a purchase, the salesman is instructed to "agree" to "take the case" and to guarantee that the customer will hear if he wears the hearing device for at least 2 hours per day. This "procedure" is represented as being designed to exercise the nerve center in the inner ear with sound. The salesman goes on to point out that the beginning of this calisthenic program immediately is imperative as a hearing loss is no different than any other body ailment--it won't get better by itself. The customer is warned "***[I]f you don't take care of this, there is only one place it's going to go." That "place" leaves little to the imagination! Tr. 9512, 9557-58.

Dr. Morgan hears with some frequency from patients who have been told they must purchase an amplification system in order to stave off the complete deterioration of their hearing; some have quoted sellers to the effect that, if the nerve endings are not exercised, they would die out completely. Tr. 9515. He noted that if he were personally confronted with a statement, such as "Thank God we got to you in time," his layman's interpretation would be, not only that the hearing aid would stop the deterioration, but that had the salesman not called today, something dire would have quickly happened. Tr. 9560-61. He noted that salesmen make such statements despite the fact that not all hearing losses are progressive in nature anyway. Some losses do get better with medical treatment or surgery although sensorineural losses often do get poorer with time. But, on the other hand, cases may also fluctuate, improving as well as deteriorating, (Tr. 9552) and the use of a hearing aid has nothing at all to do

with such changes.[24] Yet, it seems that statements saying or implying this much are made regularly, causing the hearing-impaired individual to at least wonder whether he should act immediately, if not actually impelling him into action. Other ambiguous statements may produce the same results.[25]

Much of the evidence that such statements have been made to prospective customers comes from reports of such happenings made to audiologists by their patients. The Minnesota Public Interest Research Group of Minneapolis, however, found that their survey volunteers were given similarly misleading information. In the MPIRG survey three subjects were sent for hearing examinations and recommendations to various dealers in Minneapolis and St. Cloud, Minnesota. Each subject had been previously tested and found to have (1) normal hearing, (2) a mild hearing loss for which the value of hearing aid use would be questionable, or (3) a severe hearing loss for which routine amplification would not be beneficial. Tr. 7572-7574. In spite of their varying auditory abilities, the subjects returned to report the common misrepresentation made to each of them by some dealers of the efficacy of hearing aid use in preventing their hearing from becoming worse. They were also advised of the need to stimulate the nerve to keep it alive. A Beltone representative informed one subject "It is lucky you came when you did, otherwise your hearing would have gotten worse." A Maico dealer stated that the subject's hearing would get worse without an aid while a Telex dealer noted that an aid might help the nerve in the ear from "getting worse"; Dahlberg's dealer informed the subject with the severe hearing loss that the nerve in his bad ear would continue to deteriorate without an aid and that the continued "overworking"

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24 Paul Burris, Note 10, supra at 2560; Joseph C. Elia, M.D. (otolarynologist), Reno, Nevada, Tr. 7471-72; Kenneth O. Johnson, Note 11 supra at 1793, to the effect that noncorrectable conductive loss and sensorineural loss are permanent and irreversible etiologies for which no hearing aid can provide reversal, retardation of incremental deterioration, or stablization.

25 Mrs. Irene Bowen, Student Director, National Center for Law and the Deaf, Tr. 1941; Betty K. Hamburger, National Council of Senior Citizens, Baltimore, Maryland, who was informed that the little hairs in her ear needed stimulating and that if she did not get a hearing aid, her condition would worsen while the aid would prevent such progression, Tr. 5355-56; Michael Stahl, Director, Clinical Services, Hearing and Speech Center, Grand Rapids, Michigan, who noted that the clinic's patients often inform staff members that dealer sales personnel have told them that failure to buy a hearing aid involved running the risk of further hearing loss, Tr. 5535; and Mary Ruth Whitman, Note 14, supra at 8562-63.

of his good ear would lead to problems later in life. This same subject was given similar information at the Audibel Hearing Center. Tr. 7579-80.

The use of such statements or statements similar thereto seems to be commonly found in oral representations made to potential customers; this view is supported by the fact that at least some manufacturers utilize such "information" in training materials provided to their independent dealers. ASHA pointed out as an example various excerpts from the BELTONE CONSULTANT'S MANUAL:

> And this is about what you can easily hear--but you are missing all of this out here. HEARING DOESN'T REMAIN THE SAME, YOU KNOW. YOURS IS GETTING WORSE. IT IS DIFFICULT ENOUGH NOW FOR YOU, *** (Emphasis added by ASHA) at R-1791.
>
> ASHA, R-10-1791, referring to R-8-D250-IV-28.
>
> Beltone doesn't stop your deafness. It does PUT THE BRAKES ON THE PROGRESS of your misunderstanding. (Emphasis added by ASHA).
>
> ASHA, R-10-1791, referring to R-8-D250-IV-29.
>
> Beltone CAN REVERSE MISUNDERSTANDING. (Emphasis added by ASHA).
>
> ASHA, R-10-1791, referring to R-8-D250-IV-29.

b. The findings. Representations that a hearing aid will reverse, halt, or retard the progression of hearing loss, or will help to do so are sometimes allied with statements which suggest to the prospective buyer that, without immediate purchase (and use) of amplification, he faces disasterous consequences for his hearing in the near future. While various interpretations may be assigned to such statements, the consumer could easily believe they carry the threat of total deafness. Some representations have been so misleading in their claims or implications regarding the impact of amplification on hearing losses and their thinly-veiled threats of worse to come if a purchase is not made, that they may properly be termed "outrageous." The fact is that no hearing aid acts to correct, stabilize, or reverse hearing deterioration.

c. Conclusions. Representations that amplification will reverse, retard, or halt the progression of a hearing loss or that the failure to immediately purchase and use a hearing

device may result in rapid deterioration of an already impaired hearing condition are deceptive and should be prohibited to prevent consumers from being led, bullied, or threatened into making snap-judgment hearing aid purchases that are often unwise. Indicated or implied claims that suggest the immediate consequences of failure to act may be a complete loss of hearing or a deterioration to a degree that cannot be helped by amplification are particularly pernicious. Section 440.9(b) of the proposed rule should go far toward preventing such representations.

3. Issue 21.

Does the word "new" when used to describe hearing aid models, or features thereof, which have been on the market for more than 1 year, have the capacity or tendency to mislead consumers?

Issue 24.

Do representations that a hearing aid model is unique, special, or revolutionary, with respect to some particular characteristic, have the capacity or tendency to lead consumers to believe that the advertised model is being compared to all other hearing aid models with respect to such characteristic?

a. The evidence. Hearing-impaired individuals are always anxious to hear about improvements which might help them to hear better than they currently do, and about systems that are less difficult to conceal.[26] Representations concerning the "newness" of a hearing aid or its features or playing up the revolutionary or unique concepts incorporated in its technology may

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26 Ruth Lesko, President, Lesko, Inc. (Pittsburgh, Pennsylvania ad agency), Tr. 7227; William H. Plotkin, Executive Director, Chicago Hearing Aid Society, Tr. 5987; James Langford, Note 5, supra at 8002, 8062; Dr. Roger Kasten, former Director of the Veterans Administration Hearing Aid Program, Tr. 745; and Laszlo Stein, Director of Audiology, David T. Siegel Institute of Communicative Disorders, Michael Reese Hospital, Chicago, Illinois, noted the particular susceptibility of parents of hearing-impaired children to advertisements of this type implying or saying that the "miracle cure" they have been seeking has appeared in a space-age electronic gadget--such people being neither ignorant nor irrational are rather experiencing intense emotional upset over the health and well-being of a loved one, Tr. 8977-79.

often be the deciding factor in the consumer's selection of a hearing aid. There have been some truly revolutionary breakthroughs in past years, for example, transistors, integrated circuits, the CROS and BI-CROS systems, but many ads appear today announcing or implying technological advancements that are neither "new" nor "revolutionary" in the sense that such words are familiar to the consumer. ASHA has pointed out in this connection that consumers are not the only population segment misled by such terms: dealers also fall prey to statements channeled to them by suppliers. R-10-1812. Some say that quite a number of these new, unique, revolutionary, or breakthrough statements cannot be substantiated by scientific or medical evidence. ASHA stated that substantiation shortcomings are especially magnified when such advertising induces the replacement of a consumer's current amplification device with an instrument that may not be able to deliver the superior experience he is led to expect. The consumer and some dealers, when confronted by such "puffing" terms as "sensational" may also be confused, if not downright deceived with respect to the relative merit of the aid's "revolutionary" benefits.[27]

A quantum or time measurement is implicit in the use of "new" and the record indicates that this "time-factored" term is at best vaguely defined in the public's mind and may substantially vary in meaning from one interpreter to another. John Kojis, President of Maico Hearing Instrument Company, believes that a device might properly be considered "new" for the entire 17-year life of its patent. The Maico Mark 100, advertised as "unique" in 1974, had the same "unique" features then as it did when it was first put out in 1971, according to Mr. Kojis. Tr. 2029, 2035. Ruth Lesko, President, Lesko, Inc., a Pittsburgh, Pennsylvania, advertising firm, stated she would describe an instrument or product as "new" until a subsequent improvement comes along or so long as the concept is "unique" to some people. Tr. 7205. Dr. Laura Ann Wilber, Associate Professor of Otorhinolaryngology, Albert Einstein College of Medicine, Yeshiva University, interprets "new" to mean that the referred-to model is very recent and has not previously been on the market. She noted, too, that she finds occasionally some items are 6 months old or older before she even knows they exist as she normally sees manufacturers' agents only every 6 months to a year. Tr. 1383. Dr. Darrell L. Teter, a speech pathologist and audiologist, testified that, in some areas of the hearing aid industry, an instrument that has been available for 2 years would be considered very old, but that in other areas, an instrument which has been available for that same amount of time would be considered very, very new. Tr. 10303. Consumer

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27 Kenneth O. Johnson, Note 11, supra at 1801-02; and Patricia G. Mastricola, audiologist with Otologic Professional Associates, Chicago, Illinois, Tr. 8620.

witness, Mike Pasiewicz of Antioch, Illinois, would regard a hearing aid described in an ad containing the statement, "this is new" or "never been available," or words to that effect, as a product "to look into." Tr. 8959-60.

The following examples of potentially misleading advertisements for "new," "unique," and "revolutionary" products were placed on the record for Commission consideration by ASHA:

> The New ANALOG COMPUTER HEARING AID
>
> ASHA, R-10-D57, Exh. 100-C(1)
>
> with the introduction of the Miracle-Ear JY1221
>
> ASHA, R-10-D57, Exh. 100-I(2)
>
> Dahlberg's new energy saving
>
> ASHA, R-10-D57, Exh. 100-J(1)
>
> with the new Danavox body aid 727 PPX
>
> ASHA, R-10-D57, Exh. 100-O(3)
>
> The new Danavox Directional Aid
>
> ASHA, R-10-D57, Exh. 100-Q(2)
>
> This is Oticon's new 568
>
> ASHA, R-10-D57, Exh. 100-YY/2(1)
>
> New from Radioear
>
> ASHA, R-10-D57, Exh. 100-AI/1(1)
>
> Telex is proud to introduce an unusual hearing aid
>
> ASHA, R-10-D57, Exh. 100-AT(1)
>
> a number one in all-in-the-ear (hearing aids):, 'Unique features,' 'to prevent ear wax and other material from clogging the receiver,' 'most easily fitted, most economical Dahlberg in-the-ear hearing aid available today.'
>
> ASHA, R-10-D57, Exh. 100-I(1), (3), (4), and (6) respectively.

> have advanced features that make them easier to use*** and the trusted name that makes them easier to sell,
>
> ASHA, R-10-D57, Exh. 100-VV(1)

To deal with the problem of defining "new," proposed Section 440.9(c) would place a time limitation on the use of the word:

> (c) No seller shall represent that a hearing aid model or feature is new for a period greater than one year from the date on which it was first marketed in the United States.

To deal with the more nebulous problems that stem from the use in advertising of words implying "breakthroughs" or the existence of a product truly unique and revolutionary in its characteristics, Section 440.9(f), provides that:

> (f) *** a general or unqualified representation that a hearing aid is unique, revolutionary or special will be deemed to be a comparison to all other hearing aid brands and models****

This section in conjunction with Section 440.9(e)(6) requires the advertising seller to disclose the identity of the hearing aids with which such advertised product is being compared (440.9(e)-(6)(i)), and each particular characteristic with respect to which such comparison is being made (440.9(e)(6)(ii)). Additionally Section 440.9(e)(6)(iii) requires that each such compared characteristic must provide a significantly greater benefit than that provided by the comparable characteristic in the identified hearing aid brand(s) and/or model(s) while Section 440.9(e)(6)(iv) requires the seller to possess and rely upon competent and reliable scientific or medical evidence fully establishing that each compared characteristic does provide the required significantly greater benefit at the time he makes any such representations, with certain less stringent requirements if he is not the manufacturer of the instrument advertised.

ASHA favors advertising which represents products or features which are "new" or are being "introduced" for the first time, if such statements are true and it sees proposed Section 440.9(c) as going far in seeing that this is the case. In organizing its exhibits for submission to the record, it found that Norelco advertised its models 6724 and 8249 as "new" for a period of 13 months. Advertisements of V.T.A., concerning a new venting system, appeared over a 9-month period. Of the remaining advertisements compiled, a 3-to-5 month advertising period announcing "newness" was found to be common. ASHA concluded from this fact that hearing aid manufacturers should and can live comfortably with the 12-month requirement imposed by the proposed rule section. R-10-1797.

It also concluded, in regard to the subject matter of proposed Section 440.9(f), that when an advertiser makes a general statement about a characteristic common to an array of products of the same general kind, the comparison can be and is understood to relate to all such products; indeed, after reviewing the advertisements gathered for submission, it believes the representations regarding uniqueness and revolutionary characteristics were intended by the advertisers to apply to all hearing aids. If the consumer confronting such representations does not have the knowledge necessary to make valid distinguishing comparisons among the hearing aids having similar characteristics, (which is usually the case) ASHA contends that such statements and claims definitely then have the capacity to deceive. Therefore, it supports proposed Section 440.9(f) as taken in conjunction with proposed Section 440.9(e)(6), in the belief that they will compel the seller to provide the consumer with information that will enable him to make more meaningful comparisons of products. R-10-1823, 1803.

The National Hearing Aid Society (NHAS) vigorously takes issue with the proposed definition of "new": it feels that the 1-year period specified is much too short considering the nature of the instruments involved and the market therefor. R-3-3605. Furthermore, it believes that the magnitude of change required to support the advertising of a "major improvement" is too large. Noting that, although the proposed rule section purports to regulate the use of "new," it does not define its precise meaning; therefore, NHAS has drawn its definition from Advisory Opinions Nos. 120 and 146 wherein the Commission defined the term as "either entirely new or . . . changed in a functionally significant respect." R-3-3605-06. Assuming that this definition must be applied also in the case of the proposed rule section, it goes on to point out the nature and frequency of major technological improvements which have occurred in recent years: the introduction of the transistor and of integrated circuits, both greatly improving the size and quality of hearing devices, occurred roughly 15 to 20 years apart and constitute two of the most significant advancements in the history of hearing systems.

Neither, however, arrived in "quantum jumps;" for example, the introduction of the transistor was not so rapid that, at any given point in time, any one hearing device could be said to be "entirely new or***changed in a functionally significant respect." Thus, it is inherent in the nature of industry advances that incorporation of such improvements into the actual product has proceeded at so slow a pace that it would be unrealistic and unnecessarily harsh to require that the product be either entirely new or significantly changed in order be characterized as "new." R-3-3606-07. Furthermore, the market setup is such that a significant portion of a year may have passed in product manufacture, distribution through wholesalers to retailers, and ultimate placement of the device on the retailer's shelf for sale. Considering also that only a few models will be appropriate for any given person, the time

between manufacture of a hearing aid and its sale to the consumer may occupy a very significant portion of the allowed 12-month period. Such an inflexible cutoff is viewed as inadequate and unfair under such circumstances. R-3-3608.

The matter of test marketing periods was also broached; given the subjective preferences of consumers in hearing device selection, a test marketing period is often essential to national marketing, yet the proposed rule fails to make any reference to such a period or to define the term, "marketed in the United States." This period cannot be too short since it must include not only product promotion, but also evaluation of consumer reactions. R-3-3608-09.

Beyond even these points, NHAS says the Commission has failed to show that any consumer harm has arisen due to the use of the word "new" in connection with the promotion of a product for more than 1 year. Certainly if it can be assumed that consumers equate "new" with "latest" or "best," the proposed rule fails to insure to the consumer that such an equation is accurate; in fact, a hearing aid that has been on the market for less than a year, thus qualifying as "new" under the proposed section's limitation, may not be the "latest" model on the market. So, to impose such an arbitrary and inflexible industrywide standard upon those who deal with and in hearing aids would be inappropriate and improper. R-3-3609-10.

Turning to proposed Section 440.9(f) and to proposed Section 440.9(e)(6) to which the former section refers, the industry, through NHAS, questions the nature of the effects and final results that will be produced by these sections' requirements and in particular, by subclauses (iii) and (iv) of 440.9(e)(6) which deal with the "significantly greater benefits" that must be disclosed in connection with comparisons and with the competent and reliable scientific or medical evidence establishing such benefits, upon which the seller must rely in making claims. Initially noting that many representations are, by their nature, not subject to verification by scientific testing, NHAS interprets the proposed rule sections as applying the same standard of substantiation to all representations of characteristics without showing the need for all such representations to be treated in the same manner. Accordingly, NHAS believes that an assertion that a hearing aid is blue will be subject to the same standard of substantiation as an assertion regarding a certain amount of gain in a specified frequency range. Other unspecified aspects of the substantiation requirement are termed "too vague to permit sellers to properly and reasonably be apprised in advance of what representations they can and cannot make." R-3-3614-15. The definition of "characteristic" is challenged as being obviously so broad that nothing about a hearing aid is excluded; drawn to its logical conclusion, use of the word "hearing aid" itself may require that the seller possess competent and reliable scientific or medical evidence fully establishing that the item advertised

will significantly aid the hearing of a significant number of buyers. R-3-3615-16. NHAS argues that "this clearly ridiculous result does not stem from illogical or stretched construction; [rather] it results from the fact that the proposed rule is so poorly worded and conceived that even a reasonable construction of its provisions easily leads to absurdities." R-3-3616.

Use of the word "significant" in proposed rule Section 440.9(e)(6) comes in for its share of criticism from NHAS which finds that, as a threshold matter, there is no established standard upon which to make a determination that a given benefit is "significant." A hearing aid which renders an objective benefit by increasing the wearer's ability to hear may, at the same time, produce subjective dissatisfaction to the consumer who has grown accustomed to not hearing many sounds. The proposed section must, therefore, call for some form of objective test that will make compliance feasible, but that test has not been yet specified. R-3-3617-18.

There is further a question of which words raise a comparison. "Smaller" and "smallest" are clearly comparative adjectives, but what about "small" which may also be taken in particular context as comparative? In effect, NHAS contends that almost any statement about a characteristic may create a comparison problem so that the list of terms which are subject to the comparison ambiguity built into the rule becomes endless, and the section becomes more vague and imprecise. R-3-3619. NHAS summarizes its prediction of the proposed sections' effects in this way:

> By prohibiting representations except as to characteristics for which a significant benefit can be shown to exist for a significant number of buyers, the proposed rule, in practical effect, will prohibit most representations about hearing aids and will, in practice, effectively reduce the variety of aids which can be offered for sale. R-3-3624.

Furthermore, while advertisements containing the type of information required will present fewer opportunities for deception, such disclosures alone will be essentially useless to the average consumer. "Section 440.9(e), in its entirety, is unconscionably broad, counterproductive and unreasonable as a matter of law." R-3-3623.

b. The findings. Hearing instruments are advertised as "new," "unique," "special," or "revolutionary" even though they may have already been on the market for a substantial period of time and even though their "new" and "unique" features may be shared by most or all of the other competing brands of hearing aids available. Since the truly significant breakthroughs in amplification systems have been limited in number and have, at

the same time, been not too rapidly incorporated into the technologies of the instruments themselves, there is little likelihood that one absolutely "revolutionary" device will be on the market at any one time, in comparison to its competitors. Although, based on the record, both Issues 21 and 24 should be answered in the affirmative, the real difficulty for the rulemaker comes in the attempt to qualify and quantify (in time measures) the meaning of the terms used in advertising claims. In fact, all statements pertaining to newness and uniqueness may well be true if they were to be "correctly interpreted," but consumers, hearing care professionals, sellers, advertisers, engineers, and others assign different meanings to the same claims. An engineer may recognize a hearing aid operating on integrated circuits as a "breakthrough" and as the "latest thing" on the market in amplification systems even though such a device has been available for several years; yet, when he refers to the instrument in these terms without disclosing his frame of reference or his universe of comparison, the consumer is apt to interpret these adjectives in true layman's terms, i.e., that the hearing aid is really something brand new--absolutely the latest "word" in very recent technological breakthroughs and, as such, is superior in its features to all other hearing aids then on the market--this is not very often the case. Therefore, since "newness," "uniqueness," and "superior technology" are all material selling points for hearing aids, such consumer misinterpretations may lead to unwise purchase decisions, including the inducement of consumers to discard the hearing devices they are already wearing in favor of new ones that are really no significant improvement over the old ones.

c. Conclusions. Based on the foregoing findings, it may be concluded that proposed Sections 440.9(f) and 440.9(e)(6) do deal with their subject problem areas in very specific terms: statements that indicate or imply hearing aid innovations will be taken to be comparisons with other hearing aid products on the market, and the making of claims involving such representations will require that the compared products be identified and that the advertised product's superior qualities be scientifically and medically supported. Under strict and continuous enforcement, these provisions should eliminate many possible misunderstandings while seeing that consumers get the information they need to make more informed hearing aid purchase decisions. The industry's argument that the lack of definitional precision in certain important disclosure and substantiation terms will produce chaos in compliance efforts is noted, but must be discounted by the assumption that enforcement (and compliance) will take place in accordance with "reasonable" interpretations of such terms, rather than in accordance with their most far-out, albeit logically concluded, meanings. It is certainly questionable whether any meaningful and informative advertising will be curtailed or prohibited by the operation of these conjunctive sections, as industry fears; rather, it is more likely that the

advertising which will disappear is that which cannot be adequately substantiated--precisely the desired objective.

On the other hand, it is doubtful whether Section 440.9(c) will assist consumers in accurately understanding the meaning of the term "new" or the concept of newness. Because of myriad interpretations of such expressions, they may not be "quantifiable" by such a simplistic approach as the assignment of a hard-and-fast time limitation upon their use. Perhaps the proposed section will eliminate some deception which has occurred in the past, but at the same time, it may be creating interpretation problems in the future. It will be possible under the currently proposed time restrictions to have a definitionally new instrument on the market (and advertised as such) when the device is neither the latest entry into the competition nor particularly representative of the most advanced technology available to consumers in then-marketable devices--this is a situation that may in itself confuse and mislead the public by imposing yet another artifically established definition of "new" upon an already confused situation. Matters become even more confused when one considers that the proposed rule section does not specify what is meant by the term, "United States market." It may be possible, taking this expression at face value, to have a technologically advanced product amounting to a genuine "breakthrough" enter the nationwide retail marketplace as definitionally "old" or "not new" because of previous extensive periods of test marketing--again, this is a potentially misleading situation for the consumer which leads one to question the overall value of the consumer benefits that the operation of Section 440.9(c) will provide.

4. Issue 22.

> Do representations that a hearing aid possesses a general or specific feature or characteristic, or that it embodies any particular concept or principle, have the capacity or tendency to lead consumers to believe that (with respect to such feature, characteristic, concept, or principle) the advertised hearing aid will (a) provide some significant benefits to the wearer (b) regardless of the wearer's particular type of hearing impairment?

a. The evidence. Sales representations appear with some frequency indicating or implying that a particular brand-name product can improve the prospective customer's hearing significantly without any further qualifications or disclosures. Although these representations may not always be intended to convey erroneous notions, the often unsophisticated consumer may nonetheless get a misleading impression from them. In some other cases, however, it appears that such claims are made with the intention of drawing in as many prospective customers as possible. The following examples illustrate the problem:

> "New from Maico a unique concept of directional hearing that reduces background noise and helps you hear cleaner, clearer sounds in most situations." R-8-D356.

Another Maico ad mentions their remarkable new hearing aid with an exclusive type of microphone called the linear array dephaser which suppresses bothersome background noises and allows the user to hear more clearly than ever before. "Experienced hearing aid wearers are amazed at the improvement." R-8-D368. Again, Maico in a Yellow Pages advertisement submitted by ASHA, seems to be holding out to the consumer the promise that the Maico line has benefits generally for all hearing losses:

> "quality hearing aids for every type of hearing loss and wearing preference." R-10-D57, Exh. 102-D(1), I(2), U(3), and FF(6).

Another Yellow Pages advertisement for "Custom-Aid," submitted by ASHA claims to the reader:

> "Again enjoy clear understanding and hearing." "You hear with clarity because the tiny speaker is deep in the ear canal close to your eardrum." R-10-D57, Exh. 102-cc(5) and (6) respectively.

The following "announcement" was sent by a seller to physicians, audiologists, and dealers thus illustrating, in the view of ASHA, which collected this example for the record, how the industry representations may be placed in the hands of professionals and dealers and thence passed to prospective hearing aid consumers:

> "There has been a dramatic break-through in the field of electronic hearing correction and today, MOST HEARING LOSSES CAN BE CORRECTED ELECTRONICALLY." "Now available in Dahlberg 'Contour' and Starkey 'CE' all-in-the-ear models, are hearing aids capable of correcting both conductive and nerve type hearing loss, even in moderately severe cases," "not possible in previous models." R-10-D57, Exh. 103(1),(2) and (4), respectively.

The problems consumers have in deciphering the true meaning of such statements stems to a large degree from their ignorance of the physiological characteristics of hearing losses and the mechanical principles of hearing aid operation. While it might generally be said that most hearing-impaired individuals can receive some degree of benefit from a hearing aid, the matter

is not so simple as such a statement would lead one to believe. The qualifications that follow will indicate why this is true. There are types of hearing problems that will not be helped by amplification. For instance, presbycusis, the kind of hearing loss common to the elderly, affects first the higher frequency range and then moves down the scale with age; in many cases, hearing aids will not help those so afflicted since aids are generally most beneficial to those with impairments not associated with frequency.[28] A majority of individuals with discrimination problems will not be helped by hearing aids, and this, once again, is particularly true of the geriatric portion of the population.[29] Profound hearing losses preclude the use of amplification as a means for improved aural communication although it may still serve to give the wearer some of the sounds of the everyday world, such as general environmental background noises.[30] The group of aphasic nonorganic losses also do not benefit from hearing aids, yet, James Langford, Assistant Professor of Audiology, Northern Illinois University, DeKalb, Illinois, has found some of these hearing-impaired individuals wearing amplification devices. Tr. 8008.

Others may be unable to wear hearing aids because of headaches and pain resulting from extraneous noise transmitted by the device; such people cannot be helped by an instrument regardless of its features or the type of loss involved.[31] Patricia G. Mastricola, an audiologist for Otologic Professional Associates of Chicago, Illinois, reported that some 5-10% of the patients seen in their offices are told that they should not get hearing aids for their problems. Tr. 8653.

Taking the much broader view of the benefits of amplification, Dr. Austin T. Smith, M.D., (otolarynology), of Philadelphia, Pennsylvania, former instructor at Jefferson Medical College, testified that he is unaware of anyone among the hearing handicapped who cannot get some benefit from a hearing aid unless he

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[28] David M. Resnick, Note 14, supra at 5399; see also Wynnette Moneka, audiologist, Chicago Campus of Northwestern University, at Tr. 6150, where she describes a case of high-frequency loss in a young person who was not benefited by a hearing aid.

[29] Michael Stahl, Note 25, supra at 5541.

[30] Richard Fechheimer, Senior Vice President, Chicago Office of Grey-North Advertising, Inc., Tr. 6967; Lily Corbett, Program Supervisor, Virginia Department of Vocational Rehabilitation, Tr. 188-89.

[31] Helen Kelly, Special Assistant Attorney General, Minnesota, Tr. 7527.

has suffered such an extreme hearing loss that he cannot hear at all and must accordingly resort to lipreading. Tr. 8161. Other testimony along these lines indicated that the majority of the sensorineurally impaired can benefit from an aid, and as the number of hearing-impaired with this type of loss is great, the odds are in favor of an individual with a hearing loss being a prime candidate for amplification.[32] David Vreeland, a Florida hearing aid specialist, reported that 90% of his patients suffer from sensorineural losses, so that he almost never sees a customer who cannot be helped by amplification to hear with more clarity. Tr. 3833-34.

Not only may specific types of hearing losses not be improved by the use of a hearing aid, but specific hearing aids, acclaimed for particular features and characteristics may not be appropriate to or useful in the case of all hearing losses or may provide questionable benefits in a particular case of hearing impairment. Thus, descriptions of hearing aids that are "always perfect for understanding" encourage the public to expect results that are not forthcoming.[33] As a specific example, advertisements for the "directional microphone" are often unrealistic in their suggestions that such component will eliminate all background noise--a benefit for which all hearing aid wearers are constantly searching--when actually the benefits delivered by the instrument so advertised may be very little greater than the ones they receive from the instruments they're already wearing since directional devices do not reduce background noise in all cases and in all situations.[34] Other hearing aid ads may state that the instrument is designed for persons who can hear but cannot understand, but in reality, amplification alone will not improve clarity.[35]

But perhaps the most confusing or misleading advertising frequently encountered is that for the "all-in-the-ear hearing aid." Ads for this cosmetically very desirable instrument generally fail to state that for the vast majority of hearing losses

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[32] Richard Iliff, Overland Park, Kansas, speaking on behalf of hearing aid dealers, Tr. 3887.

[33] Dorothy A. Shannon, audiologist, Chief of The Speech and Hearing Section, Sinai Hospital, Baltimore, Md., Tr. 1861.

[34] Patricia G. Mastricola, Note 27, supra at 8640; William Lentz, Director of the Colorado State University Hearing Clinic, questioned whether the directional device provided any superior listening capability in a noisy situation vis-a-vis the omni-directional device, Tr 11194.

[35] David Ro[illegible]ala, Note 10, supra at 9097-98.

this type of hearing aid is not appropriate.[36] Patricia G. Mastricola's experience shows that this so-called "invisible" aid is useful only in a very small percentage of her patients' cases because normal bone-conduction ability must be present for use of a device placed in the ear.[37] David Rompala, clinical audiologist at the Schwab Rehabilitation Hospital in Chicago, Illinois, also indicated that he would not recommend an in-the-ear model in cases of a mild hearing loss or greater; in his view, such an instrument would be appropriate only for a "minimal" hearing loss. Tr. 9096-97, 9132-33.

Parents of deaf children seem to be particularly susceptible to unqualified advertising of "ear-level" aids: these devices, too, are more acceptable than body aids for cosmetic reasons, but they may not do the child any good in terms of hearing improvement. Fern Feder, coordinator of a regional program for deaf children in the Lombard, Illinois, area and the mother of a deaf son, recounted her own personal experience some years ago with a salesman who called at her home. He attempted to sell her an ear-level aid for the profoundly deaf boy following a discrimination test, conducted with a binaural system. With a small amount of training in audiology, Mrs. Feder recognized the test as being ill-conducted and yielding erroneous results. To this day in her work with the regional program, however, she often encounters parents who have purchased such ear-level systems which they have been led to believe are more desirable (and cosmetically they are), but in subsequent clinical testing, have learned that their children were not getting the gain from the instruments that they should get.[38]

To eliminate the presently existing potential for consumer confusion, misunderstanding, and deception, Section 440.9(e) of the proposed rule has been fashioned to proscribe from sales representations the use of certain claims regarding various features, characteristics, principles, and concepts of hearing aids unless the seller clearly and conspicuously discloses the specific and significant benefits to which he is referring (subsections (e)(1), (2), and (3)), in conjunction with the disclosure of the specific condition(s) under which or the category or categories of hearing aid wearers by which each such disclosed benefit will be received (subsection (e)(4)). He must also possess and rely upon competent

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36 Lloyd Mosley, Supervisor of Speech and Hearing Services, Division of Services for Crippled Children, University of Illinois, Tr. 7740.

37 Mastricola, Note 27, supra at 8667.

38 Fern Feder, Note 2, supra at 8519-20, 8510-12; see also Laszlo Stein, Note 26, supra at 8977-79.

and reliable scientific or medical evidence supporting the existence of each claimed significant benefit and the receipt of such benefit by a significant number of wearers in the category specified or under the conditions indicated at the time he makes such claims, (subsection (e)(4)). If he is not also the product's manufacturer, he will be required only to believe that his claims are supported by materials he has received from the manufacturer, unless he has reason to know that the manufacturer does not possess such evidence, that the alleged evidence is false or that the representations are unsubstantiated, or has reason to inquire about such information (subsection (e)(5)(i), (ii), and (iii)). (Subsection (e)(6) has been discussed under Issues 21 and 24 supra and will not be discussed again at this point.)

Once again, the industry, this time speaking through HAIC, finds the prohibitive requirements imposed upon advertising by these proposed rule sections to be "incredible." R-3-3968. Section 440.9(e)(5), requiring the seller to rely upon competent and reliable scientific or medical evidence of benefits to a significant number of buyers under the conditions specified, is particularly onerous since it deals with conditions of satisfaction or dissatisfaction subjectively derived, which cannot be substantiated or supported by objective scientific testing. R-3-3968-69. All in all, HAIC views the proposed section's requirements as "incredibly confused" and "tantamount to a complete prohibition upon the advertising of hearing aids." It feels that such requirements cannot be reasonably imposed upon the hearing aid industry. R-3-3969.

NHAS emphasized and reiterated HAIC's concern over the need to limit substantiation requirements to objectively determinable and verifiable characteristics. R-3-3614, 3622-23. It, too, notes that the substantiation requirements contain vague aspects which will prevent sellers from being properly and reasonably apprised in advance of what representations they can and cannot make. R-3-3615. Within this "vague" category, NHAS points specifically to the expressions "characteristic," "significant benefit," and "significant number of buyers." R-3-3615-18. It also terms "unclear" the extent, nature, and quality of the research and testing required by the proposed section. Hearing aid sellers cannot generally tell with any degree of certainty whether evidence that establishes the significance of a benefit to a significant number of buyers also constitutes "competent and reliable" evidence which fully establish such significance, as required by the proposed rule. R-3-3621-22. Furthermore, newly introduced characteristics may not even be capable of such substantiation until a significant number of buyers have actually worn them for a period of time and have indicated whether the benefits derived are significant." R-3-3622. Again, industry asks what benefit the proposed section will provide if, in eliminating some of the opportunities for deception, its disclosure provisions give consumers only essentially useless information. R-3-3623.

In explaining her opposition to the section, ad agency executive, Ruth Lesko of Lesko, Inc., Pittsburgh, Pennsylvania, notes that she doesn't think an ad which states that hearing aids will help hearing-impaired persons could or would possibly be interpreted by readers as meaning that the same hearing aid will help every person regardless of his particular type of hearing problem. If some readers do make such interpretations, Ms. Lesko feels they are literally hunting for material to misinterpret. Tr. 7209-10.

In its support of these proposed rule provisions, ASHA notes that the objective of any consumer protection effort is to see that the consumer is provided with information he needs to decide whether he should make a "material change in his position." If the important conduit of information via sellers' advertising fails to fully and fairly inform him of relative advantages and disadvantages of a hearing aid, an informed decision cannot be made, the hearing aid has accordingly been misrepresented, and the consumer has been denied "due process." The dispensing of a health-related device, such as a hearing aid, cannot be considered, in ASHA's opinion, to fall within the realm of the doctrine of caveat emptor. R-10-1799-1800. Other witnesses expressed a somewhat similar view, based mainly on their encounters with consumers wearing inappropriate hearing aids or refusing the help that amplification could give them because of prior disappointing experiences.[39]

b. The findings. Advertising statements often note specific features or general characteristics of a brand-name product, such as, directional hearing, all-in-the-ear wearing capability, etc., without disclosing the fact that the product may not be suitable for all types of hearing impairment or for one reason or another for all hearing-impaired individuals. Deception may be expected to occur in this area when consumers' ignorance is coupled with consumers' eager belief that the hearing aid with the characteristics they want is an instrument that will benefit all persons with hearing losses, across-the-board and without regard to the etiology or pathology of the loss. Hearing aids, however, are not so versatile. For certain hearing problems, such as presbycusis and the inability to discriminate, amplification does not help in a majority of cases, and even when benefits are received they may not be of the magnitude consumers hoped to find. The most cosmetically desirable instrument of all, the in-the-ear hearing aid is totally inappropriate for use by the vast majority of the hearing-impaired. Finally, there are also some

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39 Resnick, Note 14, supra at 5399; Moneka, Note 28, supra at 6150; Stahl, Note 25, supra at 5541; Shannon, Note 33, supra at 1861; Rompala, Note 10, supra at 9097-98; and Feder, Note 2, supra at 8519-20, 8510-12.

individuals who, for emotional or physical reasons, will not be able to use amplification, even though a suitable instrument is available. Unaware of these facts, however, consumers rush to experiment with advertised products, frequently to their financial or emotional detriment.

c. Conclusions. Section 440.9(e), as proposed, should put an end to unqualified advertising that has misled consumers into believing that a device with certain features will significantly benefit them regardless of their particular type of hearing impairment. The required disclosures of specific, significant benefits to be gained from an advertised product, the conditions under which such benefits may be received, and the categories of disability that can be benefited, all supported by reliable, competent evidence should either realistically encourage or warn away certain consumers. Of course, it is beneficial to have consumers inquire about aids that reasonably can be expected to improve their hearing. However, to make unqualified statements that mislead the hearing-impaired and result in disppointing experiences and sometimes purchases of instruments that are useless to them is unfair, deceptive, and unfortunate; when such claims are made with that specific intent, they are little less than "bilking."

5. Issue 23

> Do representations in which a particular hearing aid is being compared to any other hearing aid(s) have the capacity or tendency to (a) mislead consumers as to what hearing aid(s) the particular hearing aid is being compared to when the representation is in the form of a dangling (incomplete) comparison; or (b) lead consumers to believe that the particular hearing aid is superior with respect to any characteristic being compared?

a. The evidence. Misled by claims asserting or implying that the product is "better," "best," "improved," etc., some people shop from one dealer or clinic to another seeking the perfect aid: one that is invisible and has high fidelity amplification for speech.[40] Many ads merely "suggest" that the instrument is somehow different, an "innovation," or something "better," when in reality, it may be very little different from the aid the wearer is using.[41] "Weasel words" are the ready and willing tool of those sellers who wish to convey this type of impression. Ruth Lesko, of Lesko, Inc. (an advertising agency), an opponent

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40 Mary Burke, Note 14, supra at 6410.

41 Patricia G. Mastricola, Note 27, supra at 8620.

of the proposed rule, explained how this semantic creature operates: advertising headlines announce, "My hearing aid is better." Without more, the ad, which might be true depending on the available substantiation, fails to direct the consumer's mind to the next logical and often extremely important question of "better than what?" Taking this into account, the capacity to mislead becomes apparent. Tr. 7228. Ms. Lesko notes that the effect of ads using weasel words is particularly bad as they are directed to those hearing aid users who are particularly anxious to hear about an improvement which may help them to hear better than their current aids do. Tr. 7227. Her firm very carefully avoids this type of advertising, especially when addressing the elderly who are not only in this group but who are also often living on fixed incomes and many additionally have a "chip" on their shoulder about their disability. Tr. 7213. James Langford, Associate Professor of Audiology, Northern Illinois University, DeKalb, Illinois, finds advertising which implies that innovations have been made to create particular instruments that are better than the others, without saying more, misleading if for no other reason than that they encourage those who seek ultimate answers to their hearing problems to continue their often fruitless and expensive searches. Tr. 8062.

ASHA notes that the hearing aid purchaser is not a comparison shopper in the sense that he would be when looking for a car, furniture, or other consumer goods; also his comparison shopping problem may be compounded by the fact that his area may have only a regional dealer representing one manufacturer or several visiting dealers who promote the products of but one company. R-10-1800-01. If the advertised product is clearly compared with another specified device, even if the latter is unavailable to him for trial, he at least is aware that other hearing aids exist. If the comparison is incomplete or cites the unique and revolutionary characteristics of the advertised aid without indicating either why these claims are so or with what other devices the advertised product is being compared, he may purchase an available aid in the belief that he has no other choice if he is to receive benefits at all from amplification. In the former case, he is merely disadvantaged; in the latter he is misled. R-10-1801.

These examples submitted by ASHA, give cause for concern:

> "Now 'mission-impossible' with our TRUE-LOG COMPRESSION hearing aids." R-10-1803, referring to R-10-D57, Exh. 100-B(2).
>
> "[permits users to] CONCENTRATE THEIR HEARING DIRECTIONALLY TO THE FRONT," "ENJOY THE ASSURANCE OF ALL-ROUND RECEPTION," "truly revolutionary." Id., referring to R-10-D57, Exh. 100-D/1(1), (2), and (4) respectively.

"excellent sound reproduction," "The battery economy, however, is remarkable." Id., at R-10-1809, referring to R-10-D57, Exh. 100-S(3) and (5) respectively.

Excellent sound reproduction may very well be available through the aids advertised, but notes ASHA, claims of this nature fail to disclose just what "excellent sound reproduction is"--what it is "excellent" in comparison to. R-10-1809. Terms such as "truly revolutionary" raise similar unanswered questions about what other hearing aids on the market have been involved in the comparisons. R-10-1804.

The following ASHA-compiled examples of ads with incomplete comparisons clearly assert superiority of the advertised product over other unnamed products:

> "more than in other types of hearing aid spectacles," "uniquely wide frequency range," "improves the intelligibility considerably." R-10-1809, referring to R-10-D57, Exh. 100-W (2), (4), and (5) respectively.
>
> "The BEST PERFORMER at its PRICE" R-10-1811, referring to R-10-D57, Exh. 100-FF(2).
>
> "Largo, by Beltone, is the effective aid for really severe hearing losses . . . . It actually delivers pure hearing power with remarkable clarity." R-10-1816, referring to R-8-D459-3077.

Proposed rule Section 440.9(e)(6) would compel an advertiser or seller who is comparing, or representing that he is comparing, characteristics of an advertised product with comparable characteristics possessed by other hearing aid brands or models to comply with these requirements:

> 440.9(e)(6)(i) Clearly and conspicuously disclose the names of the hearing aids with which such comparisons are made so that the comparison is not in the form of a dangling comparison;
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> 440.9(e)(6)(ii) Clearly and conspicuously disclose each particular characteristic with respect to which each such comparison is being made;
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> 440.9(e)(6)(iii) Advertise such compared characteristics that provide a significantly greater benefit than the benefit provided by

the comparable characteristic in the disclosed hearing aid brand(s) and/or model(s) to which the advertised brand is being compared;

440.9(e)(6)(iv) To possess and rely upon competent and reliable scientific or medical evidence fully establishing that each compared characteristic of the advertised brand renders significantly more benefit to the buyer than that (those) of the compared brand, and to possess such evidence at the time of making such representations except in the case that, not being the manufacturer, he has determined that the representation he makes is contained in materials given to him by the manufacturer and he has no reason to know that the manufacturer has no such evidence, has false evidence, or has evidence that does not constitute substantiation.

Once again the industry is disturbed by what it sees as a lack of finite definitions for some of the most important terms contained in this proposed section. As its position has already been set out in section 3 of this part pertaining to Issues 21 and 24, above, it will not be discussed again here except to note the continuing objection to what it views as the vagueness and ambiguity of expressions such as "significantly greater benefits," "characteristics," and "significant," which will effectively prevent sellers from knowing exactly what is required of them and when it is required, if the rule is promulgated in its present form. R-3-3619. Again it sees this section as providing consumers with useless information (R-3-3623), if, in fact, most hearing aid advertisements containing representations are not in effect prohibited altogether. R-3-3624, 3628.

ASHA, on the other hand, views the entire Section 440.9(e), including the subsections dealing with substantiation and comparisons, potentially of great benefit to hearing-impaired individuals, sellers and industry as well through its elimination of dangling and incomplete comparisons. ASHA contends that advertised aids must be compared with reasonably comparable benefits of other hearing aids, (R-10-1804) and it does not expect the industry to object on cost grounds to disclosing the information which will assure that consumers receive informative and truthful advertising, especially when the retail price of hearing aids is taken into account. Furthermore, it knows of no documentation that supports any claim that different wording in ads will result in cost

increases. R-10-1822.[42] However, under all circumstances, advertisers must be compelled to substantiate the claims applying to the advertised product and the explicit or implicit comparisons of such product with all other industry products. R-10-1803.

b. The findings. Comparisons involved in hearing aid advertising often are made through "suggestions," rather than through flat statements. By means of dangling or incomplete comparisons and weasel words, the consumer is often led to mentally compare advertised items with their competitors, by utilization of the logical process in which certain words are used to trigger a chain of thought, ultimately concluded, and perhaps erroneously so, in the consumer's mind. Such representations might, of course, be true, but without qualifications, disclosures of what superior qualities are being referred to, and indications of how or why such qualities are superior in terms of significant consumer benefits rendered over those offered by competing products, the consumer, usually without even knowing the identity of competitors, is at a loss to make meaningful use of what information is given to him. He may, therefore, often accept or be forced to accept the advertisement he sees and hears at face value or on faith, and accordingly he may also end up with a hearing aid that is no better than its competitors; no better even than the hearing aid he may already have been wearing; and possibly not even appropriate to his type of hearing loss.

c. Conclusions. Dangling and incomplete comparisons (including "weasel" words) necessarily assert the superiority of the advertised product and imply its comparison with unidentified competitors, while leaving the consumer to figure out for himself just who the competition is and how and why the advertised item is "better" or "the best." The more subtle the "weasel," the more insidious it is, as consumers may not realize that they are subconsciously being induced to conclude that valid comparisons have been made. Proposed rule Section 440.9(e) would seem to compel adequate disclosure of the "whole" story to the consumer's benefit. This proposed section may have the most far-reaching effect on the advertising industry of any other contained in the rule since it will virtually eliminate from hearing aid ads a format common to that advertising in general.

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[42] The Hearing Aid Industry Conference nonetheless does make this argument contending that, taken altogether, the disclosure requirements mandated by 440.9(e)(1) through 440.9(g)(2) will constitute a massive burden upon the industry's advertisers in terms of cost and ad copy preparation, R-3-3971.

6. Issue 25.

> When a hearing aid is represented as being "smaller" than other hearing aids, would the fact that it produces sound of less quality and range than those with which it is being compared be a material fact which might influence the potential purchaser's decision of whether to purchase it?

a. The evidence. The following ads illustrate the type of representations that are the subject of this issue:

> "a unique combination of features," "one of the smallest*** on the market."
>
> ASHA, R-10-D57, Exh. 100-H(1) and (3), respectively.
>
> "world's smallest hearing aid," "one of the world's smallest."
>
> ASHA, R-10-D57, Exh. 100-K(1) and (2), respectively.

The questions posed in Issue 25 involve the relationship of size to quality and range of performance and whether, if it is true that smaller hearing aids exhibit inferior performance, this would be a material factor in a consumer's purchase decision. "Smallness," according to ASHA, is not synonymous with quality of amplification and range of sounds produced. ASHA believes that a person with a severe or profound hearing loss may not benefit as significantly from a smaller instrument with limited gain as he might from a larger instrument with an appreciably higher gain. R-10-1824. Most experts today agree: A few years ago, hearing aids were cumbersome units with large components and heavy batteries. Today, tiny "solid state" electronic devices such as transistors have reduced the instrument and its power source to a fraction of their former size and weight. If your hearing loss is mild, you may get satisfactory performance from a device so small that it fits directly in your ear. If you have a severe impairment, you will need a larger, more powerful system; but even in the largest models, size and weight are not a serious problem. "In-the-ear" aids fit directly in the ear canal, supported by the ear shell, itself. These models have no external wires or tubes, and are very light in weight. They

have a volume control, but may have no tone control. Generally speaking, they are useful only if the hearing loss is mild.[43]

In-the-ear aids are the smallest and generally least powerful of today's aids. They are cosmetically desirable but not yet appropriate for more than a mild or moderate loss.[44] There are still many serious problems to be solved before in-the-ear aids will be comparable in quality of sound reproduction to behind-the-ear or body aids.[45]

Dorothy A. Shannon, Ph.D., audiologist, Chief of Speech and Hearing Section, Sinai Hospital, Baltimore, Maryland, testified that an advertisement in the then current telephone directory for Baltimore contained a conspicuous picture of an in-the-ear aid, leading consumers to expect that any hearing loss can be aided with in-the-ear amplification. Tr. 1861-62. She would not recommend such aids for most users because they generally have less power yet she knew that ads mislead consumers to expect to be able to use in-the-ear aids. Tr. 1870-73.

Angela Loavenbruck, an audiologist and speech pathologist, Teachers College, Columbia University, believes that changes in amplification necessarily accompany changes in the size of the hearing instrument. Tr. 1561. Typically, all-in-the-ear smaller (smallest) models are not as powerful as behind-the-ear (small) ear models or (large) body aids, according to Wynnette Moneka,

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43 Edith Corliss, Facts About Hearing and Hearing Aids, A Consumer's Guide, NBC Consumer Information Series 4, ed., James E. Payne, National Bureau of Standards, U.S. Dept. of Commerce, November, 1971, R-8-D222-14. See also Earl R. Harford, Ph.D., Professor of Audiology, Vanderbilt University, Tr. 49-50; Darrel E. Rose, Ph.D., Mayo Clinic, R-8-4186; William C. Lentz, Ph.D., R-8-8000. James Jerger, Ph.D., Professor of Audiology, Baylor College of Medicine, Texas Medical Center, Houston, Texas, R-8-D604-12.

44 Michael C. Pollack, "Electroacoustic Characteristics," in Amplification for the Hearing-Impaired, Grune & Stratton, Inc., 1975, R-8-Exh. B-25. See also Kenneth W. Berger, "Hearing Aids Today and Tomorrow," in The Hearing Aid: Its Operation and Development, NHAS, 1974, R-8-D637-88-89; Ernest Zelnick, Ph.D., audiologist and dealer, Brooklyn, New York, Tr. 428.

45 The Hearing Aid: Its Operation and Development, id.

an audiologist at the Chicago Campus of Northwestern University. Tr. 6183). Elma L. Griesel, formerly Project Coordinator with the Retired Professional Action Group (RPAG), noted that in RPAG's contact with industry in the course of conducting its survey activities, the surveyors were told that it was not possible to get the same kind of performance in a "miniaturized" instrument. In the study entitled "Paying Through the Ear, A Report on Hearing Health Care Problems," RPAG accordingly noted that "Tiny units cannot effectively amplify lower frequency or base sounds without considerable distortion." The account continues by citing the problem of "feedback" in the miniature aids caused when sound leaks around earmolds and impinges back onto the microphone which recycles the stimuli through the amplifier--the problem is characterized as "difficult, if not impossible, to solve" in miniaturized instruments where components are so close together. The report then proceeds to note that not only is sound more distorted in smaller aids but the smaller instruments are more difficult for older and arthritic people to operate. R-8-D421-XI-2-3. However, in the cross-examination portion of her testimony, Ms. Griesel acknowledged that the fact one hearing aid is smaller than another doesn't necessarily mean that the smaller aid is of inferior quality; rather the quality factor would be determined by the different hearing aid characteristics. In her research, she had even found that for certain types of hearing loss, the ear-level aid would be preferable to other types. She clarified her statement against miniaturization by indicating that they had intended to point out particularly the difficulties experienced by elderly hearing-impaired persons in manipulating the controls of behind-the-ear devices. Tr. 9433-35.

Sandlin and Krebs noted that, in regard to all-in-the-ear hearing devices, the wearer must be willing to accept the compromises which are imposed: a smaller microphone, a smaller receiver, and an amplifier which has limited gain and output response. They find that gain, maximum power output, and frequency response are all limited when compared with those that can be achieved in the post-articular, eyeglass, or body-worn hearing instruments, noting, too, that greater acoustic gain and maximum output values can be generated in a body-worn aid because it is larger and much more sophisticated circuitry can be utilized to modify the shape of the output envelope. However, body instruments are generally recommended for those who have severe or profound hearing losses and who require greater maximum power output and acoustic gain than can be achieved today in an ear-worn device.[46] In summarizing the technological achievements in the hearing aid industry, though, Sandlin and Krebs note that

46 Robert Sandlin and Donald Krebs, "Audiometers and Hearing Aids," Chapter IV in Introductory Hearing Science, S. E. Gerber, 1974, R-13-D29-914-15.

the miniaturization of components has occurred without unreasonable sacrifice of quality and their acoustic characteristics. Though somewhat reduced in gain and power output, all-in-the-ear aids have been successfully utilized by a number of hearing-impaired persons. R-13-D29-943.

Many instances in which consumers purchased smaller aids only to find their hearing aoility decreased, were cited. Mark McShane, a certified clinical audiologist with Memorial Medical Center's Department of Communicative Disorders, Springfield, Illinois, noted the case of a 6-year-old congenitally deaf patient, who was evaluated at the clinic and found to have a moderate to severe sensorineural loss in the right ear and a profound sensorineural loss in the left ear. Upon recommendation of an audiologist, this patient was fitted with a body aid. Approximately 1 year later, the patient's family was contacted by a salesman who represented that the child would find an in-the-ear aid more comfortable to wear than the body aid; he did not mention the fact that the in-the-ear aid might not provide as much benefit as the body aid system then being worn. Rather, his recommendation was made solely on the basis of pure-tone thresholds established, and no aided or unaided tests were performed. The all-in-the ear aid, of course, did not provide benefits commensurate with the body aid. Tr. 8099-8100.

The propensity of the hearing-impaired individual to seek an instrument that is "smaller" and more concealable is well known.[47] Thus, advertising emphasizing "smallness" of an instrument may be used as a simple but effective means of getting the patient into the dealer's office where he may be given a high-pressure sales presentation, the end result of which may be the purchase of a completely inappropriate device.[48]

But on the other hand, there is some evidence that the quality and the range of sound from today's smaller hearing aid are not necessarily adversely affected by the decrease in instrument size. According to James Keyes, Executive Vice President of Audiotone Division, Royal Industries, 10 years ago, a smaller aid meant a decrease in performance ability, but size of behind-the-ear aids is no longer relative to quality of sound. Tr. 10745. However, Mr. Keyes did not profess that in-the-ear aids are comparable in range and quality of sound to other types of aids sold today. Tr. 10758-9.

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[47] William H. Plotkin, Executive Director, Chicago Hearing Society, Tr. 5987; Mary Burke, Note 14, supra at 6410-11.

[48] Patricia G. Mastricola, Note 27, supra at 8620-21.

Robert Briskey, audiologist for Beltone Electronics Corporation of Chicago, Illinois, testified that smaller hearing devices are comparable in quality, regardless of their size, to the very large instruments of some 20 years ago. Low frequency and quality have a direct relationship, and low frequency, he noted, is available now in very small packages. Conversely, the fact that one hearing aid is larger than another does not "necessarily" mean that the larger one produces any better quality of performance or sound. Reduction in instrument size has coincided with increased efficiency made possible by such technological advances as integrated circuitry and thin film production techniques, etc. Density can be increased through miniaturization so when an amplifier is reduced in size, its efficiency as an amplifier is not reduced. Tr. 7255-56, 7260-61. HAIC notes, too, that larger body-worn instruments do not necessarily have better fidelity than ear-level devices, although this may not have been true in the 1950's. Size is no longer a criterion of good performance and actually, some of today's body devices can be shown to have less acceptable acoustic performances than some ear-level aids. R-3-3866-67.

Ansel Kleiman, President of Telex Communications, Inc., stated, "There is not necessarily a correlation between size and sound reproduction," and that "many of today's ear level instruments can provide a wider frequency response, among other benefits, than some larger body style instruments." Tr. 6908-09. But when questioned about his use of the term "necessarily," he stated that he did not say there is "no correlation" between size and sound reproduction quality. He further explained that there "are certain things you can do in a larger physical configuration you cannot do in a smaller one." Tr. 6936-37. Donald Krebs, Ph.D., audiologist and Director of Speech, Hearing, and Neurosensory Center in San Diego, stated that in-the-ear aids "should have the same quality of sound" as behind-the-ear aids, but conceded that "The bigger the speaker system the better the quality of sound." Tr. 11901-02.

When asked whether small in-the-ear hearing aids would benefit everyone who could benefit from an aid, Mr. David Barnow, former chief marketing officer for Beltone Electronics Corporation, stated, "I know for a fact that the small in-the-ear aid cannot, and nobody pretends that it can."

As a solution to problems believed to exist in this area, Section 440.9(g) has been proposed:

> (g) No seller shall represent that a hearing aid model is smaller than other hearing aid models unless, in addition to making all disclosures prescribed by § 440.9(e):
>
> > (1) The quality and range of sounds produced by representative samples of such hearing aid models are at

least of substantially the same quality and range as the sounds produced by representative samples of each of the different brand(s) and/or model(s) of hearing aids with which it is being compared, and, at the time of making any such representation the seller possesses and relies upon competent and reliable scientific or medical evidence which fully establishes the relative quality and range of sounds produced by such hearing aids;

(a caveat provides that if the seller is not also the manufacturer, he will be held to a different standard of liability if he relies upon representations made to him in the manufacturer's materials which he has no reason to believe are false, inadquately substantiated or unsubstantiated)

or,

(2) It is clearly and conspicuously disclosed that such hearing aid does not produce sounds which are at least of substantially the same quality and range as the sounds produced by the hearing aid brand(s) and/or model(s) with which it is being compared.

If smallness is not synonymous with quality and if such an implication is or can be drawn from an advertising representation, Section 440.9(g) proponents' position, (forwarded by ASHA and others) is that the advertiser should make a reasonable effort to adequately point up whatever differences do exist. R-10-1824. The proposed section should, therefore, place such relevant information in consumers' hands for whatever use they choose to make of it. Those with the primary desire to wear an aid that is as inconspicuous as possible will be willing to forego quality and range considerations for a hearing aid that will permit the greatest cosmetic improvement. However, prospective buyers should be apprised prior to their purchases of "trade-offs" in electroacoustical characteristics affecting reproduction performance.

Opponents object to disclosing information regarding comparative ranges and qualities between small and large instruments on

the grounds that to do so would not provide any valuable information to the consumer.[49] Rather such required disclosures will result in overly long advertisements emphasizing matters that are not even of interest to those prospective purchasers who are looking for smaller, "more invisible" hearing aids.[50]

The Hearing Aid Industry Conference (HAIC) sees this section as but an additional requirement to be imposed upon the basically truthful representation that indicates simply that one hearing aid model is smaller than another hearing aid model. Taken together with the affirmative disclosures required by other proposed provisions, this section will contribute to the massive burden of required expanded representations and substantiation placed upon hearing aid advertisers, increasing their advertising costs and inhibiting their ability to feasibly prepare advertising copy. HAIC submits that the need for such requirements is totally without basis and will eventually result in a serious curtailment, if not a virtual prohibition, of hearing aid advertising. R-3-3970-71).

The National Hearing Aid Society incorporated generally its analysis of and arguments against Section 440.9(e) [above, Issues 21, 22, 23, and 24] into its arguments against promulgation of 440.9(g), and these will not be repeated here. R-3-3629.

b. The findings. If, in fact, smaller hearing aids produce sound of inferior quality and range than larger hearing aids do, this fact would be material to some hearing-impaired individuals. There is some dispute over what effect miniaturization has on the quality and range of sound. Testimony and submissions indicate strongly that, with today's improved technology, miniaturized devices operating with the latest microphones, transistors, and integrated circuitry, have superb quality and range reproduction ability equal to, if not actually superior to the performance capability of some larger aids. Most experts felt certain, that with in-the-ear aids, change in size generally involves a correlated change in response characteristics, changes involved are not necessarily adverse changes in all characteristics of performance, however. Thus, the perceived problem could be important to those persons seeking readily concealable devices and quality and range, etc. "Smaller" aids can involve "trade offs" in performance characteristics, and "smaller" aids have been sold to hearing-impaired persons who derived no significant benefits from them. The "wrong" type of aid has been found fitted to certain types of hearing losses and some "smaller"

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[49] James Keyes, Note 19, supra at 10745.

[50] Richard Fechheimer, Note 30, supra at 6970.

instruments have been found to be almost worthless in terms of beneficial gain to those with more serious hearing problems.

Kenneth W. Berger, in his book, The Hearing Aid, Its Operation and Development (NHAS, 1974), notes that the problems in using the in-the-ear aid in the case of persons with substantial hearing losses is not due to limitations in amplifying ability, but rather to other problems, such as feedback, etc. R-5-D637-38-89. Every amplifier has a maximum point beyond which an increase in the signal level cannot be made regardless of how much signal level is fed into the amplifier. Additionally, sounds reaching the ear at approximately 120 dB Sound Pressure Level begins to either become uncomfortable or produce some irritating sensation, such as tickling; and at higher levels, the sound becomes painful. (It is noted that Berger refers to thresholds that were established using listeners with normal hearing, but that for some types of hearing losses, the threshold of discomfort may be reached at a lesser sound pressure level in spite of the reduced threshold of hearing.) R-8-D637-75.

Michael C. Pollack traces the development of electroacoustic measurements used to express standardized performance parameters so that instruments can be compared with each other. The four characteristics most frequently obtained are acoustic gain, acoustic output, basic frequency response, and frequency range. Additionally, ANSI has described and identified five other important characteristics: comprehensive frequency response; harmonic distortion; gain control taper; effect of tone control on frequency response; and power supply voltage variation effects on gain. R-8-Physical Exhibit B, pp. 39-44. Also, Pollack notes that a considerable degree of inconsistency exists between the three common sets of hearing aid performance measurement standards, (ANSI, HAIC, and IEC) regarding what characteristics must be measured and how they are to be measured.[51]

c. Conclusions.

"Smaller" hearing aids sometimes produce inferior performances in terms of the specific characteristics cited in proposed Section 440.9(g), that is, in quality and range of performance. Persons seeking cosmetic advantages of smallness in a hearing device would very likely be interested in such disclosures. The group that may be most misled or deceived as to these characteristics (and others) would be those who rank sound quality and range as a matter of first magnitude in their purchase decisions.

The evidence indicates that, today, miniaturization of a hearing device does not necessarily detract from its quality of

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51 Michael C. Pollack, Note 44, supra at 64.

performance or the range of frequency reproduction, but with in-the-ear aids it generally does detract. While this conclusion has been disputed, the record does not contain clear and convincing evidence to the contrary. Consequently, there is little doubt as to whether hearing aid users are deceived or misled by ads for "smaller" in-the-ear instruments that fail to make performance disclosures regarding the two specifically mentioned performance characteristics--i.e., quality and range.

Turning to the other performance characteristics mentioned in the discussion above, it becomes readily apparent that significant "trade offs" in regards to them might have to be made in favor of greatly reduced size of the instrument. Perhaps most importantly, some smaller instruments have been found to lack sufficient power to provide significant benefits for those with more than mild hearing losses; in such cases, if the individual purchases such an aid with an eye only for its cosmetic advantages, he may consequently end up with a device that does him little or no good. The problem of feedback in the smaller types of aids may also be substantial and again, the cosmetic-value seeker may be forced to accept a less acceptable performance in the reproduction of sound in return for an aid that is more readily concealed. Certainly, whether the consumer is only cosmetically oriented or whether high-quality sound reproduction is his objective, he should be advised of such sacrifices before he makes his purchase decision.

However, although the proposed rule section focuses upon two basic types of characteristics that miniaturization may adversely affect to some degree, the discussion elicited by the section and its related designated issue points up the fact that similar "trade-offs" in other characteristics not specifically incorporated into the rule section may be involved with smaller aid use. Once again, the problems of feedback and power output seem to be matters of potentially paramount importance in consumers' decisions. If the rule section is promulgated in its present form containing such an omission, it can be expected that some manufacturers and dealers will "play" upon these omitted characteristics to their advantage and to the disadvantage of consumers and competitors.

As a final comment, it appears that Issue 25, and Section 440.9(g) which induced it, have led into a technological no-man's-land for the layman, and a semantical jungle for the rulemaker. But, with further expert exploration, it may still be possible to offer appropriate guidance to advertisers who imply that the smallest hearing aids perform as well as all others if such is not the fact.

7. Issue 26.

Do the terms "prescribe" and "prescription" when used in connection with hearing aids,

have the capacity or tendency to mislead consumers as to the extent to which hearing aids can correct hearing loss?

a. The evidence. A controversy exists concerning the "writing of prescriptions" for hearing aids in the meaning in which that expression is used in pharmacology and medicine. ASHA sees two possibly misleading aspects to the use of "prescription" and similar terms in recommending hearing devices: consumers may confuse the hearing aid dispensing industry with the medical and pharmaceutical dispensing professions and they may also get the impression from such statements that, because a hearing aid is "prescribed," it will correct hearing loss by restoring normal hearing. R-10-1826.

Hearola All-in-the-Ear prescription fitted.

AHSA, R-10-1827 referring to R-10-D57, Exh. 100-KK(6).

WORLD'S ONLY TOTALLY PRESCRIPTION (Rx.) INSTRUMENTS.

ASHA, R-10-1828, referring to R-10-D57, Exh. 100-AV(1B).

MADE TO PRESCRIPTION HEARING INSTRUMENTS, built to individual prescription requirements as determined by your doctor, audiologist, or by one of our firms qualified nonmedical technicians.

ASHA, R-10-1828 referring to R-8-D289.

The problem arises basically from the nonscientific nature of selecting and fitting a hearing instrument when this process is compared to the filling of a drug prescription. A recommendation may be made by either a hearing specialist professional or a dealer, following objective testing, for a specific instrument believed to fit the patient's needs, but in reality, it may not be the device actually ordered or it may be substantially adjusted from the recommendation's suggestions. Thus, hearing aid selection and fitting is not a precise science; indeed many witnesses referred to it as an "art," although the objective testing of the individual is itself scientific.[52]

Several witnesses compared the fitting of a hearing device with the fitting of a pair of glasses, finding the latter process

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[52] Luke Fortner, Note 10, supra at 2889.

to be far less complicated than the former; an optician can take a prescription for a pair of glasses and make it exactly in accordance with the specifications indicated, but there are "certain things" that come up in the process of selecting and fitting a hearing aid that make it impossible to follow the exact course of the audiogram.[53]

Hearing impairments involve variations; consequently there can be almost unbelievable variations in hearing losses. Then, too, the makeup of the hearing aid itself is complex and complicated; just a tiny movement of an almost microscopic part of the instrument can be the determining factor in whether the wearer hears clearly or gets instead a jumble of meaningless noise.[54] A doctor or an audiologist can tell what loss a patient has, but they do not necessarily know how to adjust an aid to compensate for that loss.[55] Therefore, there can be no certainty in predicting how well a person will function with the selected aid in his everyday listening situation, even though important information can be gained from manufacturers' specifications of gain, output, frequency-response and distortion characteristics, and from objective test results on individual performances with instruments having characteristics appropriate for a given hearing loss.[56] These variable factors have led a number of witnesses to conclude that a hearing aid cannot be "prescribed."[57]

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53 Dr. Sam Houston Sanders, Jr., National Hearing Aid Society, (trained audiologist), Tr. 3583.

54 Ima B. Payne, National Hearing Aid Society, Tr. 3602.

55 Id. at 3603.

56 Judith Rassi, Note 22, supra at 5734-35; David M. Resnick, Note 14, supra at 5431-33.

57 David Vreeland, Florida hearing aid specialist, Tr. 3847; Maurice A. Byrne, Jr., Assistant Director of Law and Legal Counsel, Department of Consumer Affairs for Mayor Harvey I. Sloane, Louisville, Kentucky, Tr. 1028; Vincent James Giglia, President, Audio Instrument Company, Philadelphia, Pennsylvania, Tr. 2758; Dr. John W. Heisse, Jr., member, Medical Advisory Board of the National Hearing Aid Society, Burlington, Vermont, who notes that, since two acoustically similar hearing aid models coming off the same production line will perform differently on two different patients, to describe the matching-up process of the patient with the appropriate hearing aid as following a "prescription" makes little or no sense, Tr. 3283; and Luke Fortner, Note 10, supra at 2889.

Still there are those who favor permitting the use of the word "prescription" and similar terms under certain circumstances or with certain qualifications. Angela Loavenbruck, an audiologist, speech pathologist, and Assistant Professor at Teachers College, Columbia University, believes that hearing aids can be prescribed for a particular individual in terms of a general category of hearing aid which is most appropriate in terms of general gain characteristics, general output character, the ear to which it is to be fitted, the kind of earmold to be used, and whether a rental period should be included. Tr. 1584. Barbara D. McGarry, a specialist in governmental relations, American Foundation for the Blind, Inc., recommends that the terms, "prescribe," "prescription," and "hearing tests" be used only with reference to written orders and procedures of an audiologist or a biophysician skilled in diseases of the ear (who is also independent of the hearing aid industry) Tr. 1267.

John C. Kenwood, President of J. C. Kenwood, Inc., a Chicago, Illinois, hearing aid dealer, does not favor use of the word "prescription" or using or referring to the fitting process as prescribing because this term carries the connotation that the dealer is filling a precise order, just as a druggist is filling a prescription; neither physician, audiologist, or dealer should be involved with such language. Tr. 9334-35. Lee Wilson, a clinical audiologist and President of the Society of Medical Audiology, on the other hand, doesn't think it matters what you call such a definite "recommendation" (Tr. 10044) while Hubert L. Gerstram, Chief of the Hearing and Language Center, New England Medical Center Hospital, Boston, Massachusetts, suggests that "recommendation" would be a much better word to use to describe the process. Tr. 2406-07.

On the other side of the controversy, James E. Payne, senior partner of Payne and Payne Consultants, Austin, Texas, found in a survey he conducted for the National Hearing Aid Society that four audiologists interviewed were "aggressive" in their claim that they could "prescribe" hearing aids with the same precision that an ophthalmologist could prescribe eye glasses although most medical ear specialists agreed that it is impossible. Tr. 2137.

John L. Holmes, President of the Hearing Health Group of Scottsdale, Arizona, felt that the word "prescription" should not be legislated out of the lexicon, but should be defined properly: his "more technically viable" definition of the term would be "a set of parameters in accordance with a patient requirement, including but not limited to gain, scope, compression, dynamic range and maximum power output, all as a function of frequency." Tr. 9584-85. Dr. Holmes, whose firm has perfected and is currently using two advanced master instruments, the OTOGRAF and the PRESCRIPTOR, for the testing and fitting of hearing instruments, believes that a "real prescription" is within the state of the art if this improved technology is used, and that, properly defined and professionally utilized, the term "prescription"

will not be a misrepresentation to the consuming public. Tr. 9586. He, therefore, opposes proposed Section 440.9(h), feeling that it may discourage or preclude the operation of professionals in a manner such as that common to the prescribing of other medical devices. Tr. 9584-85. John F. Fennema, of the Maryland Hearing Aid Service, Baltimore and Annapolis, Maryland, also has reservations about a ban on the use of the term as he believes it is becoming increasingly applicable to the selection process and, that while selection does still remain something of an "art," the technology and precision involved are being developed so that some day selection will be a science. Today, while the choice of an aid is subjective in the sense that some individuals simply cannot adapt to an aid, he believes that those evaluating and recommending aids come close enough to "precision" to justify the use of the term, "prescribe," and words of similar meaning. Tr. 1754. Although the National Hearing Aid Society agrees with those who state that it is not possible at the present time to write a "prescription" for a hearing aid, it also agrees with those who argue that the term should not be unqualifiedly prohibited since at some future point in time, prescribing may certainly be possible. R-3-3630.

To avoid any potential deception or misleading of the consumer on this point, the following subsection of 440.9 has been proposed:

> (h) No seller shall use the word "prescribe" or "prescription" or any other word(s) or expression(s) of similar import.

ASHA believes that hearing aid technology is rapidly approaching a time when a modified type of prescription may be appropriate for hearing aids; until then, the consumer should not be misled into believing that he is obtaining a hearing aid manufactured to meet specific standards for his individual hearing loss. Therefore, AHSA generally supports this section of the rule, but it would also like to see the terminology used restricted to "order" or "written recommendation." R-10-1825-26.

NHAS, as previously noted, opposes a total ban on the use of word "prescribe," feeling that, as presently written, the provision would even prohibit a seller from advising a consumer that a hearing aid cannot be prescribed. R-3-3630. The Hearing Aid Industry Conference makes a similar observation commenting that such a direct attempt to limit freedom of speech by flatly prohibiting the use of commonly used words cannot be tolerated. It notes the existence of various opinions about the use of "prescription" and agrees with those who believe that a ban on the use of the word is indeed a drastic measure. R-3-3971-72.

b. The findings. Because of improvements in the technology of instruments used to determine the most suitable hearing aid specifications and characteristics for a particular case, the day seems to be approaching when "recommendations" of specific

hearing instruments can be fairly precisely translated into the appropriate device. When a high degree of such precision is attained, the recommendation could then be appropriately referred to as a "prescription," and the process could be described as "prescribing." Such precision instrumentation is said to be available today but on an extremely limited scale. In the meantime, statements referring to hearing aid prescriptions cause consumers to confuse such "prescriptions" with the more familiar medical and pharmaceutical ones; however, they are not similar in many respects. A medical prescription is considered to be a precise order for a predetermined specific drug or device which will usually operate, to a high degree of certainty, to relieve specific symptoms of a patient's ailment or to correct his condition of illness. On the other hand, a hearing aid "prescription," surrounded by so many variables and often unforseeable factors, may eventually be totally or partially discarded if the recommended instrument proves not to be optimumly effective to the user. If recommended following proper testing and consideration of the patient's otologic history, the device recommended will likely be the best suited type for the specific hearing loss, but minor variances in degree, range of loss and in the instrument itself, make numerous minute and complex adjustments, unforseen in the "prescription," necessary for a proper fit. These adjustments must be made by the dealer and sometimes extend over a fair amount of time. Accordingly, a hearing aid "prescription" today is not closely analogous to the more precise and usually highly effective medical prescription.

c. Conclusions. A hearing aid "prescription" is not analogous to a pharmaceutical "prescription," although consumers, accepting such a term in the most commonly used sense, may believe that it is. The fitting of a hearing aid is still in part an "art": the dealer takes a recommendation made on the basis of scientific testing and attempts to match up and adjust a hearing appliance to a customer's individual hearing problem. However, references to "prescribing" and "prescriptions" may mislead consumers into believing that a hearing aid can be fitted to precisely fit recommended specifications and that such an instrument can be expected to alleviate his particular handicap, that is, he expects the same, or similarly effective results from the hearing aid prescription that he would expect from a drug prescription. Proposed Section 440.9(h) would totally eliminate the use of "prescriptive" terms; this may be a drastic step to take in view of the fact that equipment may be available soon that will permit recommendations to be made with a great deal of precision.

8. Issue 27.

Do the words and phrases set forth by way of example in § 440.9(j), when used to describe a hearing aid or part thereof, have the capacity or tendency to lead consumers to believe that the hearing aid, or part thereof, so described is hidden or cannot be seen;[58]

Issue 28.

Do the words and phrases set forth by way of example in § 440.9(k) have the capacity or tendency to lead consumers to believe that the hearing aid so described can be worn without any visible cord or wire;[59]

Issue 29.

Do the words and phrases set forth by way of example in § 440.9(l) have the capacity or tendency to lead consumers to believe that the hearing aid so described can be worn without any button or other receiver in the ear;[60]

Issue 31.

What effect does a representation that a hearing aid can operate without batteries have on consumer beliefs or perceptions as to the operation of the particular aid?

a. The evidence. Issues 27, 28, 29, and 31 deal with areas of concern pointed up by the experiences of those hearing-impaired individuals who are seeking to find hearing aids that can be worn inconspicuously, without cords, buttons, or tubing, and that

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58 The expressions referred to are: invisible, hidden, hidden hearing, completely out of sight, conceal your deafness, hear in secret, unnoticed even by your closest friends, no one will know you are hard of hearing, your hearing loss is your secret, no one need know you are wearing a hearing aid, and hidden or out of sight when inserted in the ear canal.

59 The expressions referred to are: no cord, cordless, 100 percent cordless, no unsightly cord dangling from your ear, no wires, and no tell-tale wires.

60 The expressions referred to are: no button, no ear button, and no buttons or receivers in either ear.

require the minimum of maintenance and operational cost. Cosmetics play a major role in the selection of many hearing aids particularly when parents are making purchases for their children.[61]

John H. Payne, owner of John H. Payne and Associates, an Indianapolis, Indiana, hearing aid dealership, believes that, if he wanted to get 300-400 prospective customers into his store, all he would have to do is run an ad announcing that he has an "invisible" hearing aid for sale. He testified that the effectiveness of such a lure is enhanced by the consumer's exercise of extremely poor judgment in his approach to his hearing problem. Tr. 9200. Nonetheless, the history of hearing aid development would seem to indicate that the consumers' hopes for finding a more nearly concealed, cosmetically appealing instrument are not at all unrealistic as it includes therein substantial technological advances toward just such an instrument see Part II of this report. Thus, neither the search nor the hope for concealment of the device is a recent phenomenon.

Today, ads appear proclaiming the advent of aids so inconspicuous as to amount to revolutionary breakthroughs when compared to some of the older instruments:

> Norelco 'invites You to Rediscover the Warm, Wonderful World of Effective, Comfortable, and Inconspicuous Hearing,' ***offers you the security of total concealment with maximum sound amplification and clarity.
>
> R-8-D352-2431.

ASHA notes the following two examples:

> HEAR CLEARLY AGAIN WITH NOTHING IN EITHER EAR,
>
> Wonderful for Nerve Loss***Nothing Behind or In Front of Ear.
>
> ASHA, R-10-1830 referring to R-8-D303.
>
> HEAR once again***CLEARLY***with nothing in either ear.
>
> ASHA, R-10-1836 referring to R-8-D503-3650.

As a result of seeing or hearing such representations, hearing-impaired individuals go to professionals, to clinics, and to

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[61] William H. Plotkin, Note 47, supra at 5987; James M. Anthony, M.D. (otolaryngologist), Dallas, Texas, Tr. 8496; Fern Feder, Note 2, supra at 8523-24.

dealers looking for these "invisible" aids that have "nothing showing." It is consequently quite a disappointment when they learn, on seeing the device, that there will be something visible in the ear, perhaps an earmold or tubing; it is even more of a shock if they are shown a behind-the-ear hearing aid.[62] One can also imagine the disappointment of an individual who responds to advertising for an all-in-the-ear aid, i.e., the closest thing to being an "invisible" device, only to learn they cannot be used except by patients who have a relatively mild loss. Patricia G. Mastricola, audiologist for Otologic Professional Associates of Chicago, has found in her practice that "so-called" invisible bone-conduction aids are appropriate for less than 1% of the patients she sees.[63] She stated that cordless or "invisible" claims are often used to describe behind-the-ear instruments which, although cordless, are not invisible. Tr. 8620-21, 8667.

David Rompala, a clinical audiologist at the Schwab Rehabilitation Hospital mentioned that even the hearing-impaired individuals who have a loss appropriate for the in-the-ear aid's use would not be referred for such an instrument if their loss were more than "minimal"; he defined that term as indicating a condition worse than normal hearing, but not as bad as a mild loss of hearing. Tr. 9132-33, 9096-97.

Ads containing no qualifications were viewed by some of the witnesses as "come-ons." Mr. Rompala specifically mentioned such representations as "Sonar," "now you see it, now you don't," "now hear this: nothing outside the ear," and "Beltone Designs Tiny Hearing Aid," as examples. Tr. 9150. Richard Conlin, the Project Director for the Public Interest Research Group, Lansing, Michigan, testified that in conducting a survey, his group found ads that were "inappropriate" and which they felt were often designed and used to invite consumer inquiries which would result in a salesman's call rather than in the delivery of the promised "goods." For example, a Beltone ad offered a model hearing aid that one might try out in his home without cost or obligation. This aid was described as weighing less than a third of an ounce and as being an all-at-ear-level, one unit instrument with no wire leading from the body to the hearing aid. A response to this ad brought no model hearing aid, but a sales contact and presentation instead. Tr. 7768.

The battery which is the principal power source for almost all hearing aids, is a source of major concern to hearing aid wearers. Needless to say, the required frequent replacement of these items means continual maintenance and expense. Independent

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[62] Mary Burke, Note 14, supra at 6409.

[63] See also Mosley, Note 36, supra at 7740.

witness, Mike Pasiewicz of Antioch, Illinois, testified that he had at one time actually gone into a dealer's shop with questions about different types of aids and components after he had heard or seen a "sonar" device advertised as having no battery or requiring no battery for operation. He explained he was particularly attracted by this representation as he was tired of paying $3.00 for a pack of six batteries, when each battery lasted only an average of 3 days; at 50¢ per battery, this was expensive. He did not find the device he was looking for, however, and in fact was "thrown out" of the store when he asked the dealer too many questions. Tr. 8905-06.

Here is another example of a similar type of advertising collected by ASHA:

> "revolutionary new Ultra-Low Current amplifier," 1300 hours of battery life," "four times as long as conventional aids in the same power class"
>
> ASHA, R-10-1807 referring to R-10-D57, Exh. 100-J(2), (3), and (4) respectively.

Although this representation doesn't claim that the aid operates without batteries, the response it would call forth would probably be only slightly less enthusiastic than Mr. Pasiewicz's reaction to the "sonar" advertisement described above.

ASHA suggests that advertising for battery-less operation gives consumers one or more of the following ideas: that there is no need to check and change batteries; no need to carry spare batteries or to reorder batteries; no need for concern, or at least for less concern, about the hearing aid becoming inoperative during an important communication situation; and no continuing costs for replacement of batteries. R-10-1834. Claims of this type may be exceptionally appealing to the elderly and physically handicapped as well as to those on fixed or lower incomes. R-10-1835.

To prevent the use of advertising of this type, the following rule sections have been proposed:

> 440.9(j) No seller shall represent, through the use of words or expressions such as 'invisible,' 'hidden,' 'hidden hearing,' 'completely out of sight,' 'conceal your deafness,' 'hear in secret,' 'unnoticed even by your closest friends,' 'no one will know you are hard of hearing,' 'your hearing loss is your secret, 'no one need know you are wearing a hearing aid,' 'hidden or out of sight when inserted in the ear canal,' or by any other words or

expressions of similar import, that any hearing aid or part thereof is hidden or cannot be seen, unless such is the fact.

440.9(k) No seller shall represent, through the use of words or expressions such as 'no cord,' 'cordless,' '100 percent cordless,' 'no unsightly cord dangling from your ear,' 'no wires,' 'no tell-tale wires,' or other words or expressions of similar import, that a hearing aid can be worn without any visible cord or wire, unless such representation is true and it is clearly and conspicuously disclosed that a plastic tube (or similar device) runs from the instrument to the ear, if such is the fact.

440.9(l) No seller shall represent, through the use of words or expressions such as 'no button,' 'no ear button,' 'no buttons or receivers in either ear,' or other words or expressions of similar import, that a hearing aid can be worn without any button or other receiver in the ear, unless such representation is true and unless it is clearly and conspicuously disclosed that an ear mold or plastic tip is inserted in the ear, if such is the fact.

440.9(n) No seller shall represent that any hearing aid can operate without batteries, unless the power source for such a hearing aid can be recharged from a household electric outlet.

On the side of rule proponents, ASHA generally approves of the tenor of most of the proposed subsections as far as they go but it contends that several modifications should be effected. These are discussed below.

On the other hand, the Hearing Aid Industry Conference, generally representative of the industry view, attacked the proposed subsections as placing upon the industry substantial and pervasive prohibitions that will make it extremely difficult for it to continue in its traditional role of identifying, seeking out, and helping the hearing-impaired. To the extent that such efforts will be limited or curtailed in the future by the proposed trade regulation rule, many individuals who could benefit from some form of assistance, either medical, surgical, or by amplification, will be denied the help they so desperately need with the end result being their inability to perform as effectively and efficiently as they could if they were using amplification. R-3-3985.

HAIC immediately recognizes the exception contained in Section 440.9(n) (permitting an aid that operates on rechargeable batteries to be advertised as operating without batteries) as an endorsement of a deceptive representation: it argues that unless the power source does not come from a battery at all, whether its battery is rechargeable on household electrical current or not, such a hearing aid does not operate without batteries. R-3-3972. ASHA, too, cites this exception as inappropriate since a rechargeable battery is nonetheless still a "battery," requiring maintenance and care. Furthermore, the wearer must purchase some type of charging element that will renew the electrical capacity of the battery system. By allowing a "no batteries" representation for an instrument of this type, the consumer may still be misled or confused regarding the needs of the power source. ASHA recommends instead that the prohibition of 440.9(n) be applied across the board to all hearing aids except for those that do, in fact, operate without any batteries, e.g.:

> (n) No seller shall represent that any hearing aid can operate without batteries, unless such is the fact. R-10-1835.

ASHA also expresses its concern about claims which express battery life in specific hours and make or imply a comparison with hearing aids of the same power class. Noting that battery claims are also likely to be misleading if the test conditions on which the claims are based are not similar to those a normal hearing aid user would encounter, it proposes that such claims be made subject to the requirements of proposed subsection 440.9 (e)(5), requiring appropriate qualification in the form of a description of the test environment, test procedures, and test parameters. R-10-1807.

Further noting that although some extant advertising does include unqualified claims for wireless, cordless, tubeless devices, such inappropriate and improper representations have become less frequent since the adoption of Trade Practice Rule 7(b), 16 C.F.R. § 214.7(b) which provides:

> It is an unfair trade practice for any industry member--
>
> * * *
>
> (b) to use in advertising the words or expres sions, 'no cord,' 'cordless,' '100% cordless,' 'no unsightly cord dangling from your ear,' 'no wires,' 'no tell-tale wires,' or other words or expressions of similar import, unless such representations are true and unless, in close connection therewith and with equal prominence, a clear and adequate disclosure is made

that a plastic tube (or similar device) runs from the instrument to the ear if such is the fact.

Because it believes that this section has provided adequate consumer protection, ASHA advocates its inclusion in toto in the final trade regulation rule as Section 440.9(k); it further views this precise language as essential for the protection of the consumer from unfair and misleading representations, especially as the miniaturization of hearing aids trend continues. R-10-1830-32.

b. The findings. Because the desire of many consumers for a low-visibility hearing aid and for one requiring the least maintenance and expense is well known, advertisements are frequently found to offer instruments that are "invisible," "cordless," "wireless," "all-in-the-ear," "hidden," and that "operate without batteries." In regard to visibility claims, there is currently no such thing as an absolutely invisible device; some instrumentation is worn in, close to, or leading to the ear. Even the tiny in-the-ear mechanism can be seen in the wearer's ear unless otherwise covered or hidden and, even though it comes closest to being hidden, the fact remains that its use is inappropriate in all but a small percentage of cases.

The behind-the-ear instrument is just that: behind the ear and readily apparent if not otherwise concealed, although concealment is far more possible with this type of aid than with a body instrument. Cordless aids which are usually "ear-level" devices, do not have a cord per se; still there will be visible tubing connecting the microphone with the ear component so that, even though a cord does not dangle, a visible connecting mechanism exists although again the concealment of such an instrument is less difficult than in the case of a body aid.

There are instruments that operate on rechargeable batteries, but recharging equipment for use with household electrical current must be purchased, and battery recharging requires some effort and attention. Other representations regarding extended operating lives of batteries are made for particular hearing aids; and as a general practice, aids for such products do not disclose such material information as test parameters and conditions which would enable the consumer to determine whether the batteries would have similar life spans in normal environments.

c. Conclusions. While hearing-impaired individuals could be misled by the types of advertising covered by the proposed rule, Sections 440.9(j), (k), and (l), whether they are in fact misled, would depend upon the nature of the instrument for which the particular representation is made. Sales representations that make claims which are inappropriate for or inapplicable to the advertised devices are untrue, potentially deceiving, and apparently often intended to be misleading to consumers. The proposed sections clearly proscribe advertising of this type and,

adequately enforced, they should greatly diminish, the problems now extant.

Section 440.9(n), on the other hand, appears to be only partially adequate in that it opens a loophole that would permit a hearing aid operable on rechargeable batteries to be represented as "operating without batteries" or words to that effect. As both ASHA and the industry have pointed out, this would simply incorporate a misrepresentation into the law. It would be unfortunate if consumers were led to believe they could avoid battery maintenance and expense plus the embarrassment of having their hearing devices go "dead" at very inconvenient times by purchasing devices legally represented as operating without batteries, when, in fact, some kind of batteries are required for operation. Although the cost of repeated battery purchases would be somewhat reduced, batteries would have to be purchased at intervals and the user would have to own recharging equipment too, as the batteries would require maintenance, that is, constant recharging, the "going dead" problem would seem not to be diminished.

9. Issue 30.

> Can any hearing aid or feature thereof enable the wearer to eliminate all or most unwanted noises?

a. The evidence. Aside from the telephone (induction) coil (which constitutes an exception under Section 440.9(m)), there is no known hearing aid or feature thereof that will allow wearers to eliminate or screen out all or most unwanted noises while at the same time amplifying the sounds to which they wish to attend, e.g., conversation. The hearing aid microphone receives all sounds approaching from a predetermined angle and amplifies them; for instance, in a crowd or public place where a large sampling of noises may be encountered, there is equal amplification of all sounds entering the microphone and a resultant loss of discrimination. As this matter of "background" noise is a common and significant problem experienced by all hearing aid wearers, a representation that an aid has the alleged ability to eliminate these unwanted noises is playing upon a potent selling point.[64]

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64 ASHA, R-10-1832-33. ASHA cites the occurrence of ads that have emphasized this point:

> This aid has an exclusive new type of microphone called the Linear array dephaser, and this is what it does. It suppresses bothersome background noises and allows you to hear and understand voices more clearly than ever before.

(Continued)

Various witnesses in the proceeding attested to the effectiveness or "drawing power" of such advertisements and representations. Mary Burke, an audiologist for the Hearing Clinic, Northwestern University, noted that people often come to their clinic with advertisements indicating or implying that the advertised product "cuts out all background noises" and allows the wearer to hear what he wants to hear very clearly. Ms. Burke stated that there are, in fact, few if any hearing aids that accomplish this feat; such representations, along with some others, actually belie the nature of the hearing aid which is primarily an amplifier designed to enhance sounds in a specific frequency range. Tr. 6409. James Langford, Associate Professor of Audiology at Northern Illinois University, DeKalb, Illinois, described a recent inquiry that he had received: a lady who had seen an advertisement in the newspaper, mentioning that a hearing aid was available with a capability of cancelling noise and providing better hearing, was trying to obtain such a hearing aid. Tr. 8002.

Part of this particular problem comes not so much from inadequacy in the technology of the hearing instrument itself as from a lack of proper adjustment on the part of the wearer to listening with the aid of the device. The consumer with normal hearing has learned to blot out unwanted background noises but some hearing aid wearers, upon initial attempts to wear an amplification system, are hearing background noises they have not heard for some time. This is particularly true if the hearing loss is fairly severe and if it has developed over a long

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64 (Continued)

> Experienced hearing aid wearers are amazed at the improvement ****
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> ASHA, R-10-1818 referring to R-8-D368-2452.
>
> secures improved speech discrimination as unwanted background noise can be reduced.
>
> ASHA, R-10-1833 referring to R-10-D57, Exh. 100 V.(3).
>
> Annoying background noise is dampened or eliminated (just as it is in normal hearing)
>
> ASHA, R-10-1833 referring to R-10-D57, Exh. 100-BD/1(5).

period of time during which the absence of sound has become a familiar part of the everyday world.[65] The new hearing aid wearer must, therefore, learn to "select" what he wants to hear from among the new sounds amplified during an adjustment period that may take from several days to a substantially longer period of time.[66] Thus, learning to adjust to the amplification of undesirable environmental sounds is necessary, regardless of the efforts which have gone into making his hearing aid.[67] The fact, however, remains, that he is permitted to better understand the desirable sounds, while without the aid, he would have difficulty hearing them.[68]

Section 440.9(m) has been drafted with the intent of eliminating the type of misleading and confusing information cited above:

> (m) No seller shall represent that any hearing aid can eliminate unwanted noise; Provided, however, That it shall not be a violation of § 440.9(m) to represent accurately the ability of a hearing aid with a telephone option to attenuate acoustical background signals, if such is the fact.

ASHA contends that deceiving, misleading, or confusing claims regarding the screening out or eliminating of background noises by an amplification system should be prohibited and consequently it supports the proposed rule section. R-10-1834.

While it does not argue against the proposed rule section, the Hearing Aid Industry Conference notes that, aside from the amplification of undesirable noises, the hearing aid wearer reaps the benefits to be gained by the concurrent amplification of the sounds he wants to hear. R-3-3929.

b. The findings. No hearing aid or any feature thereof (except the telephone option) has the capability of eliminating all or most all unwanted noises. This is impossible given the nature of the instrument, that is, an amplifier system which picks up and magnifies all sounds received from a predetermined direction

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65 Richard M. Carter, M.D. (otolaryngologist), Greenwood, South Carolina, Tr. 3650-51; Mike Pasiewicz, Note 10, supra at 8917; David Rompala, Note 10, supra at 9097-98; HAIC, R-3-647, R-3-3912-13.

66 HAIC, id; Lee Wilson, clinical audiologist, President, Society of Medical Audiology, Tr. 10081.

67 Judith A. Rassi, Note 22, supra at 5732.

68 HAIC, R-3-3929.

without ability to discriminate between "desirable" sounds and background noise. Yet advertising often makes such claims for particular products and its "drawing power" is usually very great since background noise is a problem common to hearing aid wearers everywhere.

c. Conclusions. A hearing aid that would eliminate background noise would also eliminate the sounds the wearer wants to receive; considering this fact, advertising for instruments claimed to have a background noise screening ability appear to be mostly "bait" used to bring in consumer inquiries. The telephone option is considered an exception, but directional microphones are not. Section 440.9(m) should assure that this type of false and misleading information is removed from advertising.

PART VII. ADVERTISING REPRESENTATIONS THAT MUST BE QUALIFIED

A. General. Most consumers seem to lack a general understanding of the problems of hearing impairment or of potential ways of dealing with such problems that will enable them to judge, from the advertising they see and hear, whether a particular device might provide them with enough benefits to warrant a purchase. Some mistake symptoms of various origins as indications of a hearing loss when they are not.[1] For others, the hearing loss suffered does not originate in the auditory mechanism of the ear.[2] Such people obviously are not proper candidates for amplification, but again, they may not or do not realize this fact. Consumers are probably unaware that instances of this nature occur with some frequency unless they have personal knowledge of such an experience. Accordingly, without professional testing and consultation, ads that generally proclaim hearing aid advantages, may be taken at face value by consumers who fail to consider that there is some chance that amplification is not, or cannot be, the proper solution to their problems.

For those who have suffered a genuine hearing loss, other problems stemming from advertised claims may arise. Hearing aid wearers or candidates are naturally interested in obtaining instruments that will help them in noisy and group situations, especially if their work or social lives involve conversations, meetings, public gatherings, and other situations in which a considerable amount of background sound and confusion may be present.[3] Not understanding the nature of an amplification system, they may be led to believe that some devices on the market will benefit them in this way. The truth of claims for such devices is questionable at best.[4]

For the individual who has suffered a bilateral hearing loss and who is interested in improving his communication ability, the binaural hearing aid system may hold the promise of

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1 Donald E. Morgan, Chairman, Los Angeles, California, Audiology Task Force of the Commission on Legislation, California Speech and Hearing Association, Tr. 9553-54.

2 Lloyd Mosley, Supervisor of Speech and Hearing Services, University of Illinois Division of Services for Crippled Children, Tr. 7751-52.

3 James Langford, Associate Professor of Audiology, Northern Illinois University, DeKalb, Illinois, Tr. 8043-44.

4 ASHA, R-10-1833.

great benefit. Advertisements for binaural aids do not indicate, however, that in certain instances such systems are plainly inappropriate. Beyond this threshold consideration point, the question looms of whether binaural systems, across-the-board, provide enough benefits to warrant fitting them to virtually all bilaterally impaired persons, or whether the frequent fittings of such systems that have occurred in the past have been more motivated by the fitter's profitmaking desires than from real concern for the customer.[5]

Taken together, the consumers' general lack of knowledge in this area and the potential for confusion or misrepresentation that may come from very generally stated, unqualified hearing aid advertisements, have given rise to questions of whether negative disclosures that will warn consumers of possible pitfalls should not be mandated. These needs along with their underlying premises are the subject matter dealt with in Issues 32-35 and in Sections 440.10 and 440.11 of the proposed rule.

B. Specific issues.

1. Issue 32.

> Would many of those who think they have a hearing problem (and, therefore, might buy a hearing aid) not be able to receive any significant benefit from the use of any hearing aid?

a. The evidence. Although a number of people who "think" they have hearing problems do have them, the evidence indicates that a relatively substantial number of them do not.[6]

Symptoms that would cause one to believe his hearing might be deteriorating sometimes have their origin elsewhere than in the ear mechanism. Disorders, the symptoms of which may be mistaken for hearing impairment, include mental retardation, mental illness, and autism; damage to the central nervous system in which no loss in hearing sensitivity is exhibited; damage to the sensory or peripheral auditory neural system exhibited by an inability to hear speech clearly regardless of the application or amount of amplification; damage to the sensory auditory mechanism exhibiting an inordinate sensitivity to loud sound; and damage to the sensory or peripheral auditory neural system exhibiting little measurable hearing.

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5 Frank M. Butts, M.Ed., audiologist, Williams Otology Clinic, Richmond, Virginia, Tr. 4165.

6 ASHA, R-10-1837.

Dr. Robert N. Kasten, Ph.D., Department of Logopedics of Wichita State University, Wichita, Kansas, estimates that only some 70% of those who think they have hearing problems and, therefore, can be sold hearing aids can receive any significant benefit from the use of such an instrument. He "guesses" that between 50% and 60% of those seen at the University Clinic who suspect they have a problem but have not been previously screened professionally are in need of amplification. He noted, however, that a clinic serving an affluent, intelligent elderly population, more likely to have been previously screened by an otologist, would probably report a much higher percentage of successful fittings that would render significant benefits to the wearers. In making this assessment, he was speaking from his experience with the Northwestern University clinics of which the Evanston, Illinois, facility reported an approximate 90% figure for successful fittings. R-8-6978-79.

David Barwell, an audiologist and dealer in Maryland, tests at least one person per week who thinks he has a hearing loss but who in reality has normal hearing. Tr. 5169. Some individuals seek help from clinics when they perceive problems such as the experiencing of noises in the head, difficulties with memory and maintenance of equilibrium--none of which are symptoms asociated with hearing loss, although the patient may mistake them as such.[7] Several audiologist witnesses report testing such persons only to determine that such difficulties derive from other sources. Theodore S. Tweed, a clinical audiologist with the University of Wisconsin Department of Communicative Disorders recalled specifically evaluating three patients (two children and one adult) none of whom had an actual hearing loss traceable to organic or disease basis. In one case of this so-called "functional hearing loss," that is where the patient did apparently experience hearing impairment, he could not determine whether the problem was psychosomatic or the result of malingering. In the other two cases, functional loss was also found, but he found no merit to dealer recommendations that hearing aids be fitted to these patients. R-8-7631.[8]

Dr. Austin T. Smith, a Philadelphia, Pennsylvania, otolaryngologist and former instructor at Jefferson Medical College, described a phenomenon termed "grandfather deafness"; this is a normal process in which a person, concentrating on one activity, screens out other stimuli, and is sometimes thereby led to believe that his hearing is deteriorating. Tr. 8181. Dr. August Martinucci of Joliet, Illinois, sees some patients who suspect hearing losses but instead have earwax concentrations or ear infections. Tr. 8394. Other witnesses reported their personal experiences

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7 Donald E. Morgan, Note 1, supra.

8 See also, Lloyd Mosley, Note 2, supra at 7750-51.

involving suspected hearing impairments; frequently they also reported the purchase of a hearing aid from which they received no benefit.[9]

Some individuals seek help for problems that are not "traditional" hearing losses. This group includes those with deteriorating discrimination facility, a majority of whom will not be helped by a hearing aid; this is particularly true when an elderly person is involved.[10]

Patients with aphasic nonorganic difficulties, too, cannot benefit from hearing aids and should not have such instruments fitted.[11]

Although Issue 32, indicates that proposed rule Section 440.10(a) addresses this situation, in fact, it really does not altogether do so. That proposed section directs that:

* * *

> No seller shall prepare***or cause the dissemination of any advertisement:
>
> (a) Which makes any general or specific representation that a hearing aid will or has the capacity to affect hearing capability or hearing quality, unless it is clearly and conspicuously disclosed that many persons with a hearing loss (emphasis added) will not receive any significant benefit from any hearing aid; Provided, however, That nothing herein shall prohibit a truthful representation that hearing aids can help many persons with a hearing loss.

This section, by its own terms, limits its potential effects to that segment of the population that actually has a hearing impairment. Thus, of the group referred to in Issue 32, only those persons with a "functional" hearing loss could be said to

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9 Mary A. Nevells, Weymouth, Massachusetts, appearing for the National Council of Senior Citizens, reported visiting a doctor following an incident in which a door-to-door salesman told her she needed a hearing aid only to learn that she had an ear fungus, Tr. 4427-33; Nettie Murray, Miami, Florida, discovered that her "hearing loss" was due to circulatory problems and fluid in her ears, Tr. 4839.

10 Michael Stahl, Director, Clinical Services, Hearing and Speech Center, Grand Rapids, Michigan, Tr. 5541.

11 James Langford, Note 3, supra at 8008.

at all fall within the category of intended beneficiaries of this rule section.

Nonetheless, ASHA notes that the proposed section does state a fact about which potential hearing aid purchasers should be apprised, (R-10-1838) but suggests that the proposed language be modified to read that "some" persons with a hearing loss will not receive any significant benefit from any hearing aid in order that such a disclosure will tend less to discourage appropriate hearing aid candidates. R-10-1837. Other witnesses did not attempt to discuss proposed Section 440.10(a) in relationship to the issue. The industry concentrated its arguments against the position that "many" of the hearing-impaired cannot benefit from hearing aid use, stating again its contention that the language involved in the proposed negative disclosure is too vague and ambiguous to allow effective compliance. R-3-3505-09, 3517-20, 3617-18, 3869-80.

b. The findings. A fairly substantial number of persons who think they have traditional hearing losses and who seek health care in this belief, are not so impaired. "Guesses" indicate that perhaps only as many as 50-60% of patients seeking help for suspected impairments without previous professional screening, are in need of hearing aid systems. However, where professional screening has preceded the visit, this percentage becomes much greater.

Hearing difficulties can originate in many sources other than the ear or can involve more than a mere loss of ability to hear sound. "Functional" hearing losses may be due to psychosomatic factors, or mental or emotional disturbances. Lack of concentration on the part of the listener, wax in the ears, and ear infections are other culprits that may affect hearing. So, too, discrimination problems and certain aphasic, nonorganic difficulties are separate and distinct from simple losses of hearing. Some individuals even mistake sundry, vague, and confusing symptoms, such as memory difficulty, loss of balance, etc., as symptoms of hearing loss when they are not. In any case, ample evidence exists to indicate that nothing has prevented the fitting of this type of individual who can benefit very little, if any, from a hearing aid system. Such devices which, of course, give them no satisfaction, may be discarded, or must later be discarded when subsequent professional (or additional professional) help is sought and the true origin of the problem pinpointed.

c. Conclusions. Although it is true that many persons who "think" they have hearing impairments would not be able to receive any significant benefits from such a hearing device, it is difficult indeed to see how proposed rule Section 440.10(a) would reach this problem to any great extent as it specifically deals with the hearing-impaired portion of the population. That population segment which only "thinks" it has an impairment

and ends up being fitted with unnecessary hearing devices either through improper or inadequate testing, lack of knowledge or incompetence on the part of the fitter, or because of economic gain that motivates a dealer to make such fittings, would seem to not be very well protected by this section of the proposed rule, or apparently by any other section of the proposed rule. On the other hand, a modification of proposed Section 440.10, in accordance with the ASHA proposal, might very well go a long way toward eliminating at least some of this problem. ASHA's proposal would require sellers to disclose the existence and roles of physicians specializing in ear diseases and of audiologists, that is, the existence of the professionally trained components of the hearing health care system. These professionals at least would be much more likely to screen out ersatz cases of hearing losses than would dealers or their salesmen who are often lacking in anything approaching training in the scientific and medical aspects of hearing. Of course, even such a notification would not keep those persons who choose to ignore it from going directly to a dealer-salesman and willingly accepting his recommendation for a fitting, whether it be warranted or not. Additionally, such a modification can be expected to raise a storm of industry protest; however, industry's already posed arguments that consumers have not been shown to be unaware of either medical ear specialists or audiologists and that the audiologist is an unnecessary component in the system do not necessarily find support in the record evidence.

It is also noted that the IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS of the Food and Drug Administration's Regulations for Hearing Aid Devices, § 801.420(3), 42 Fed. Reg. 9295 (1977), which explains the need for professional evaluation to the hearing aid consumer will also assist in remedying the problem outlined in Issue 32, especially so when taken in conjunction with the buyer's right to cancel provided in Section 440.4 of this proposed Trade Regulation Rule. The FDA regulation is scheduled to become effective on August 15, 1977.

2. Issues 33 and 34.

33. Would many of those who can benefit from the use of a hearing aid still have difficulty understanding conversation in noisy situations?

34. Would many of those who can benefit from the use of a hearing aid still have difficulty understanding conversation in group situations?

a. The evidence. One of the most common complaints coming from hearing aid wearers has to do with hearing in a noisy situation.[12] Many hearing aid users have found that

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12 James Langford, Note 3, supra at 8044.

they cannot wear their instruments in their occupations because of surrounding noise.[13] This occurs because the hearing aid in reality is little more than an amplifier, increasing the loudness of the received stimuli regardless of whether the sound is desired or undesired.[14] The group listening situation dealt with in Issue 34 adds to the background noise problem a second aspect: the hearing aid wearer must additionally determine who, among perhaps a number of people, is speaking.[15] Many hearing-impaired consumers would, of course, like to find an instrument that would improve their hearing in these situations, and, in "response" to this desire, a number of advertisements appear indicating or implying that the subject product will provide such benefits. The following representations are illustrative of this genre of claims:

> "because of what it does to overcome the problem hearing aid wearers find most difficult: HEARING CLEARLY (especially voice) IN NOISY SURROUNDINGS." ASHA, R-10-1833, referring to R-8-D370-2457.
>
> "discrimination in noisy areas and crowds." ASHA, R-10-1833, referring to R-10-D57, Exh. 100-A(6).
>
> "Annoying background noise is dampened or eliminated (just as it is in normal hearing)." ASHA, R-10-1834, referring to R-10-D57, Exh. 100-BD/1(5).

Accordingly, many consumers purchase such aids in what rule proponents characterize as the "mistaken" belief that they will be better able to understand conversations in churches, at sporting events and in other noisy and group situations.[16]

Richard Conlin, Project Director for the Public Interest Research Group, Lansing, Michigan, noted what he considered to be inappropriate advertising which turned up in PIRGIM's survey of the hearing care delivery area: An ad for Sears' directional hearing aid stated, "new type of sound system*** you may find that your ability to understand conversation in crowded settings is dramatically improved." Free cleaning and adjustment of the

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13 Patricia G. Mastricola, audiologist, Otologic Professional Associates, Chicago, Illinois, Tr. 8639.

14 National Hearing Aid Society (NHAS), R-3-3638-40.

15 Id. at R-3-3640-41.

16 ASHA, R-10-1838-39.

wearer's current hearing aid, regardless of brand, was offered by Sears in connection with this particular advertising campaign. Mr. Conlin characterized this as advertising with emphasis on getting the customer into the hands of the supplier by whatever means possible, including advertising a breakthrough which is now dated and somewhat less effective than claimed. Tr. 7770.

Although they generally recognized the overall benefits gained through their amplification systems, some consumer witnesses confirmed that they experience difficulties in noisy and group situations.[17]

Sections 440.10(b) and (c) have been proposed to remedy the problem which exists in this area:

> No seller shall prepare, approve, fund, disseminate or cause the dissemination of any advertisement:
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> * * *
>
> (b) Which makes any representation that a hearing aid will enable a person with a hearing loss to distinguish or understand speech sounds in noisy situations, unless, in addition to the disclosure required by § 440.10(a), it is clearly and conspicuously disclosed that many persons with a hearing loss will not be able to consistently distinguish and understand speech sounds in noisy situations by using any hearing aid.
>
> (c) Which makes any representation that a hearing aid will enable a person with a hearing loss to distinguish or understand speech sounds in group situations, unless, ***, it is clearly and conspicuously disclosed that many persons with a hearing loss will not be able to consistently distinguish and understand speech sounds in group situations by using any hearing aid.

To begin with, it was noted that consistently distinguishing and understanding speech sounds in many noisy situations may

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17 Mike Pasiewicz, Antioch, Illinois, Tr. 8949; Edna Mitchell, Chicago, Illinois, Tr. 9008; and Jack Wortzel, Miami, Florida, who was not totally satisfied with the improvement offered by amplification, Tr. 4857-59, 4861-62, 4870.

be difficult for persons with or without a hearing impairment.[18] The evidence indicates that hearing devices or features thereof, such as the compression instrument and the directional microphone, may help hearing-impaired persons somewhat in noisy situations.[19] This evidence has been disputed by other witnesses, however. For example, William E. Lentz, Associate Professor and Director of the Hearing Clinic, Colorado State University, could not accept any generalization that states that the directional microphone will provide the user with superior listening capability in noisy situations. In fact, he is aware of some studies that have found poorer discrimination ability associated with or allowed by directional aids than by the omnidirectional aids to which they were compared. Tr. 11194, 11188-89. His belief is that the microphone location on the external chassis of the hearing aid would have no relationship whatsoever to the discrimination ability in noise despite some of the claims that have been made for features such as the front-focus microphone implying that better reception of speech is obtained from in front of the user; such claims, in his view, are grossly overstated. Tr. 11196.

Other statements indicate that the problems faced by the wearer are not so much due to the fault of the hearing device under the circumstances as to the inability of the wearer to separate out background noises from conversation received. Lee Wilson, clinical audiologist and President of the Society of Medical Audiology, noted that the user can be taught this ability through various exercises which essentially amount to a retraining process and may take many months for the goal to be accomplished. Tr. 10081. HAIC also holds this view, noting that to solve the problem encountered, the user will have to learn to screen speech from background noise and one voice from perhaps a number of others as, in his previous state of impairment, he may have forgotten how to concentrate in a sound environment. R-3-3929-30.

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18 James H. Johnson, engineer, testifying on behalf of HAIC, Tr. 2268; Richard M. Carter, M.D., Greenwood, South Carolina, Tr. 3650; James Keyes, Executive Vice President, Audiotone Division/Royal Industries, Tr. 10695; National Hearing Aid Society, R-3-3638-40; and Hearing Aid Industry Conference (HAIC), R-3-3930.

19 Dean Harris, Ph.D., Director, Audiology Program, Southern Methodist University, Tr. 10416; Joseph C. Elia, M.D., otolaryngologist, Reno, Nevada, who notes that such devices and features provide favorable signal-to-noise ratios and help users to better distinguish and understand speech sounds in many noisy and group situations, Tr. 7475; and HAIC, R-3-3930-31.

Regarding general use of hearing aids in noisy conditions, ASHA argues that no current wearable device is able to significantly reduce the speech-to-competing-noise ratio and that, therefore, many persons who can benefit from the use of wearable amplification will still have difficulty understanding conversation in such situations--it accordingly believes that consumers have a right to know about this very likely prospect prior to their purchases of hearing aids. R-10-1838. Ads without qualifications would clearly represent to prospective purchasers a benefit that may not be possible of achievement, thus, in ASHA's view, such representations must be prohibited. R-10-1803, 1834-35.[20] The industry counters arguments in favor of the proposed rule section by noting first that, if the user is benefited from his hearing aid, the benefit will continue in noisy or group situations, while if he has difficulty distinguishing speech sounds in such situations, this difficulty will not be unlike that encountered by the normal hearer who may be standing or sitting next to him. The question is accordingly posed as to whether any consumer believes he will be able to consistently distinguish sounds in the presence of background noise.[21] Answering this rhetorical question, NHAS feels that, inasmuch as it is so obvious (emphasis added) that no persons will be able to consistently distinguish and understand speech in the subject situation, there is clearly no possibility for harm to the consumer in failing to make the negative disclosure required by Section 440.10(b) and, in fact, such language constitutes needless surplusage which will likely be more detrimental to the consumer than helpful. R-3-3638-40. It finds Section 440.10(c) vague and ambiguous, hence misleading. Admitting the possibility that a person who hears from only one ear may have more difficulty understanding speech in group situations since to locate and to see the speaker helps in understanding, it comments that the problem is not related to the group presence but only to the ability to locate the direction of the speaker in advance. It would, therefore, be misleading to assert that hearing aid

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20 See also Douglas Noffsinger, clinial audiologist and Director of Audiological Activities, Northwestern University School of Medicine, who feels that claims of this type must be regulated for the benefit of those current users who may be susceptible to them and may react by purchasing newer instruments, Tr. 7639-40; and hearing aid dealer, John H. Payne, owner of John H. Payne and Associates, Indianapolis, Indiana, who objects to ads referring to new developments which are able to make people hear better in noisy places as he feels there is no way of knowing in advance whether the advertised instrument can live up to such a statement--yet he notes that should he want 300-400 inquiring potential customers to rush to his door all he need do is to run such an ad, Tr. 9199-9200.

21 HAIC, R-3-3930-31.

wearers are or would be less able to understand speech in groups than persons with normal hearing as the ability to distinguish speech and to identify the origin thereof is decreased proportionately in this situation for both the hearing-impaired and those with normal hearing. This fact, it contends, demonstrates that there is no justification for the proposed disclosure set out in 440.10(c). R-3-3640-41.

Acknowledging the disagreement existing in regard to this issue, some witnesses indicated that they would be extremely hesitant in mandating that advertising include such negative disclosures as those now proposed in Sections 440.10(b) and (c). Robert Sandlin, clinical audiologist and speech pathologist at the Speech, Hearing, and Neurosensory Center of Children's Hospital and Health Center, San Diego, California, regards the negative disclosure pertaining to the distinguishing of sounds in a noisy environment by a hearing aid wearer misleading since everyone has this type of problem when certain signal-to-noise ratios exist, although it is true that more hearing-impaired individuals will have difficulty than will normally hearing individuals. Tr. 10205. Darrell L. Teter, Ph.D., a speech pathologist and audiologist, similarly feels that it might not be right to make this type of disclosure. Tr. 10246. Dean Harris, Ph.D., Director of SMU's Audiology Program, believes that any suggestion in advertising that the hard of hearing cannot be helped in these situations must be avoided, Tr. 10416, and James Keyes, Executive Vice President, Audiotone Division/ Royal Industries, refers to such statements in advertising as "unrealistic" since they give the impression that hearing aids are not of help in the presence of noise or groups, while completely ignoring the fact that they do help the hard of hearing under such circumstances. Tr. 10695. Dr. Donald Krebs, Director of the Speech, Hearing, and Neurosensory Center, Children's Hospital and Health Center, in San Diego, takes the position that the proposed required disclosures are true statements and that the requirements are not unreasonable; however, he suggests that they might be better written so as not to discourage the trial or use of a hearing aid. Tr. 11841. NHAS, in this vein, sees the disclosures as another item that will discourage the hearing-impaired from seeking the benefits of amplification. R-3-3639-40.

b. The findings. The evidence elicited on these two issues permits them to be answered affirmatively; however, these answers do not seem to touch the heart of the matter in dispute.

The facts are that hearing aid users are constantly on the lookout for instruments that will deliver better hearing in both noisy and group situations; it is a common complaint of wearers that they cannot sometimes or oft-times hear in such circumstances. Claims frequently appear promising them improved hearing, however, such claims cannot be totally true due to the nature of the hearing device itself which simply receives and amplifies sounds

coming into its receiver, regardless of their origin and of whether they are desirable or undesirable to the listener. It is up to the wearer, through a process of adjustment to his instrument, to learn to screen out the unwanted stimuli and to direct his attention to the desired stimuli, much the same as a person with normal hearing must do. It appears that many hearing aid wearers have purchased instruments, however, without the understanding either of the nature of amplification or of the users' role in attending under noisy and group circumstances. Part of this, of course, may be due to lack of counselling by the seller prior to the sale and during the adjustment period. It is nonetheless a truism that no person, whether his hearing is normal or impaired, can consistently distinguish and understand speech sounds in every, or even many, noisy situations or in groups. The group situation poses an additional problem to the listener in that he needs to ascertain the location of the speaker. This appears to pose a difficulty often for the monaural hearing aid wearer, yet such innovations in hearing aids as directional microphones may have somewhat alleviated this problem, although dispute does exist as to how much alleviation, if any, is provided. In summary, if the hearing-impaired person is generally benefited by his hearing aid in the presence of usual and normal environmental or background noises, he will also probably benefit at least to some extent in noisy or group situations.

c. Conclusions. Although hearing aids will not enable their wearers to consistently understand conversation in noisy and group situations, this does not mean that significant benefits are not derived from being able to hear all of the sounds received by the instrument equally well; at least, in some cases, the listener will be able to hear those sounds he wants to hear by learning to screen out unwanted stimuli. Without the hearing aid, on the other hand, he may be able to hear less or neither types of sound. To compel sellers to include in their advertising negative disclosures that would tend to discourage potential hearing aid users by denying that they will be able to benefit from amplification in these situations is unwarranted, or at least unwarranted in the language now included in the proposed rule sections. It is possible that a mere prohibition of the use of such claims in advertising, or otherwise, could very well be a less drastic but equally effective measure as those sections now proposed. However, if one possesses competent and reliable scientific evidence which fully establishes that a significant benefit of the type described or claimed may be received by some users, then he should be permitted to make appropriately qualified representations concerning such matters.

3. Issue 35.

> Would many persons with a hearing loss in both ears fail to receive greater benefits from the use of two hearing aids, one in

each ear, than from the use of one hearing aid?

a. The evidence. The inclusion of this issue and its corresponding proposed rule section was prompted by incidents such as those cited below:

James Langford, Associate Professor of Audiology, Northern Illinois University, DeKalb, Illinois, encountered a young woman who visited the University Clinic, questioning why she was getting little or no benefit from her second hearing aid (of a binaural system). Evaluation revealed that the second aid had been fitted to a dead ear from which no significant hearing improvement was obtainable through amplification. Tr. 8008.

Hearing aid dealer, John Kuptz of Master Plan Service Company in Chicago, Illinois, recalled having a customer who had been improperly fitted by another dealer with binaural aids at a cost of $735. When this system proved unsatisfactory, she visited the Mayo Clinic, received the correct monaural system "prescription" which the witness filled for her, and she is now satisfied with her one hearing aid's performance.

A doctor recommended a hearing aid for the left ear in the case of Gertrude Filwett, a 77-year-old consumer from Itasca, Illinois. She took her "prescription" to a Zenith dealer who ordered the required instrument; however, on the following day, a Beltone representative called at her home, represented herself as an "audiologist" who knew what was best for Ms. Filwett, and persuaded her to cancel the Zenith order in favor of the purchase of a Beltone binaural system. The Beltone seller even indicated to her that doctors don't know anything about "this business." Tr. 6092-95. After having much difficulty with the binaural system, including getting repair services for it, she obtained a single Sears hearing aid for the left ear and she now uses this device about 98% of the time. Tr. 6098. Similarly, Wynette Moneka an audiologist at the Chicago Campus of Northwestern University, reported an instance in which a salesman sold one of her clinic's patients a binaural system after the clinic had specifically told the dealer that such a system was inappropriate--cost of this binaural system, $500. Tr. 6148.

A. Bruce Graham, Ph.D., Chief, Division of Audiology, Speech, and Language Pathology at the Henry Ford Hospital in Detroit, Michigan, noted a case he had seen involving a 73-year-old man, who without medical clearance, was fitted in his home with binaural hearing aid glasses. Upon clinical evaluation, his test scores indicated that the $1,040 binaural system had actually reduced his ability to get along with amplification. He could understand nothing in the left ear--not even sentences--yet that ear had been amplified, providing him with only confusion. Following extensive testing, he was advised against wearing any hearing aid at all. Tr. 7426-28. Although Dr. Graham believes

that many individuals with bilateral hearing losses do benefit from two aids, he also believes that the indiscriminate use of binaural fittings without subsequent scoring of results actually creates many problems for some wearers. Tr. 7428-29. In this connection, he also noted that things sometimes do not even work out as clinically predicted. He cited as an example of this the case of one patient who had been wearing monaural amplification and who subsequently was fitted with a binaural system which greatly improved his hearing. However, a couple of weeks later, the patient found that each time he attempted to use the binaural system, he developed violent headaches within an hour or two; thus, the binaural system had to be discarded. Tr. 7430. But, Dr. Graham characterized himself nonetheless as a "notorious" fitter of binaurals, following extensive testing. Tr. 7438-39.

Helen Kelly, Special Assistant Attorney General for Minnesota, has found that a major type of complaint received in her office involves the selling of two hearing aids to consumers who require only one device or none at all. Tr. 7523. Susan Kline of Minneapolis, Minnesota, representing the Minnesota Public Interest Research Group (MPIRG) confirmed this statement with the findings of the group's own survey. Tr. 7580. Additionally, Ms. Kline reported that a 1973 survey conducted by the MINNEAPOLIS STAR found a particularly revealing case in which a man suffering from an otosclerosis-caused conductive loss for which surgery had been recommended, was offered binaural systems by several hearing aid dealers. Tr. 7579.

Thus, some fairly substantial evidence does exist indicating that patients are sometimes unnecessarily or improperly fitted with binaural amplification systems, whether for purely economic reasons on the part of the dealer or not.[22] That such instances occur, however, does not obscure the fact that a serious dispute exists among very competent professionals regarding the relative merits of binaural systems over monaural systems in cases of bilateral impairment.

Douglas Noffsinger, a certified clinical audiologist and Director of Audiological Activities for Northwestern University's School of Medicine, Evanston, Illinois, finds the clinical research literature on binaural hearing aids clear on one matter only: it is extremely difficult to document the advantage of two hearing aids over one in patients with bilaterial impairment. Tr. 7640.

Dr. Roger Kasten, the President-Elect of the Academy of Rehabilitative Audiology, questions the results of various surveys made in the socialized medicine systems of the Scandinavian

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22 Frank M. Butts, Note 5, supra at 4164-65; David Rompala, audiologist, Schwab Rehabilitation Hospital, Chicago, Illinois, Tr. 9094.

countries. Such survey results indicate that approximately 78% of all their systems' fittings are binaural and that reports from those persons involved in the hearing care delivery systems indicate a more significant reduction of the social hearing handicap in such cases as compared to cases involving monaural fittings.[23] Dr. Kasten believes that the Scandinavian attitude as reflected in the survey findings, is that they have fitted binaural amplification on "this many people" who seem to like it, therefore, they should fit binaural amplification on everyone. Dr. Kasten's group subsequently attempted to replicate the Scandinavian results, but could not. Tr. 716-18. In his 1964 doctoral dissertation, he had reported that individuals were found to perform consistently better with binaural systems than with monaurals, however, he noted that the magnitude of binaural superiority was so small as to have little clinical significance. Tr. 754.

ASHA's position is that many persons with bilateral losses are unable to receive greater benefits from binaural systems than from monaural ones due to greatly differing thresholds which make binaural wearers incapable of achieving adequately balanced gains. In fact, some such wearers actually experience a degradation in speech discrimination with binaurals. R-10-1839.

On the other hand, significant authority exists to indicate that those with bilateral impairments do gain benefits that they would not receive with monaural instruments. The National Hearing Aid Society explains that binaural systems are partially advantageous to certain persons in certain situations and for certain purposes; binaural listeners can better ascertain the direction and distance from which a sound emanates: this is important to the brain in its function of "tuning in" the sounds that the user wants to hear, while "tuning out" sounds from other directions. It is also important to the wearer's being able to distinguish speech from background noise coming from a different distance but from the same direction; a monaural listener would have no such distinguishing capability in a similar situation. The binaural listener also has a lower absolute hearing threshold than does the monaural listener and, as he loses the use of one aid, he customarily benefits from the increased gain from the second hearing aid. He is further able to turn the detrimental "head shadow" effect, which detracts from the monaural system wearer's listening ability, into a positive feature that will assist him in directionally locating sounds, and he enjoys a

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23 See Ernest Zelnick, owner, Professional Hearing Aids Service, Brooklyn, New York, who brought up the subject of the practice in the Scandinavian countries, particularly in Denmark at 387, 406.

greater dynamic frequency range of listening, with less recruitment than does the monaural wearer. Safety aspects are also involved in binaural use, as the binaural wearer is able to discern the direction from which a danger signal is coming, while the monaural wearer may not be able to do so. NHAS contends that most of these advantages can be objectively ascertained through testing or they have been established through clinical experience. R-3-3642-47. The Hearing Aid Industry Conference cites authorities who support this position: Dr. Fay Churchill, Instructor in Audiology and Speech Pathology at Alabama College; James R. Curran, audiologist, "Nineteen Misconceptions About Hearing Aids," writing in Hearing Instruments, November 1975; Dr. Mark Ross, Adjunct Professor of the University of Connecticut; and the American Academy of Ophthalmology and Otolaryngology. R-3-3879-80. A number of witnesses also gave support to the general statement (position) that the bilaterally hearing impaired do receive benefits in many, if not most, cases.[24]

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[24] David Vreeland, Florida hearing aid specialist, Tr. 3837; James Delk, independent hearing aid specialist and consulting audiologist, Audiotone Division of Royal Industries, Phoenix, Arizona, who states that in his experience, binaural amplification is superior in 80% of the cases of such hearing impairment, Tr. 10926; Dean Harris, Note 19, supra at 10416-17; Dr. Donald Krebs, Director, Speech, Hearing, and Neurosensory Center, and certified audiologist, San Diego, California, who believes there are people who cannot benefit from binaural hearing, but wouldn't say there are many, Tr. 11892; James Keyes, Note 18, supra at 10695; Sam Hopmeier, President, W. H. Hopmeier, Inc., a St. Louis, Missouri, dealer, who believes there have been more abuses to the hard of hearing by the underselling of binaurals than from overselling as more people have been "short-changed" by not having been offered the opportunity to experience a binaural fitting than those who have been hurt by ill-advised binaural sales, Tr. 3352-53; Dr. Henry Tobin, National Center for Law and the Deaf, who notes that the use of binaural amplification as a rule makes good sense, but it depends ultimately upon the individual and his true abilities to integrate the information thus received, Tr. 4106; Robert Briskey, Beltone Electronics, Chicago, Illinois, who feels that 85% of hearing-impaired individuals should not be prevented from considering the use of binaurals, citing the results of a survey conducted recently in 700 clinics and hospitals in which 44% of those responding indicated that they positively felt that children should be binaurally fitted, Tr. 7259; Dr. Joseph C. Elia, who noted that binaural listeners feel more balance, hear more clearly, use less volume and depend less upon lip reading, thus supporting his view that both adults and children

(Continued)

Other witnesses indicated that they believe binaurals may render significant benefits, but recommended that such fittings should not be made initially, but only after the patient has adjusted to the first aid.[25] Others simply noted that trial periods for patients' adjustment to binaurals would be necessary before it could be determined whether benefits could be derived in individual cases.[26]

Robert Briskey, an audiologist with Beltone Electronics Corporation, Chicago, Illinois, noted that some years ago, he, too, would have believed that 85% of those with bilateral impairments should be wearing binaural systems; but, now, due to recent developments such as the biphasic hearing aid in which the phase relationship between the two ears is altered, as is the frequency response, his personal feeling is that a significant number of binaural fittings may not have been the best or most complementary systems for individual patients because the binaural instruments are identical; however, this does not mean that binaurals should not have been fitted. Tr. 7257-58.

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24 (Continued)
involved with uncorrectable bilateral hearing losses should be binaurally fitted, Note 19, supra at 7483-85; Dr. John F. Corso, Ph.D., Department of Psychology, State University of New York, Cortland, New York, Tr. 1194-95; Dr. Laura Ann Wilber, Ph.D., Associate Professor of Otorhinolaryngology, Albert Einstein College of Medicine of the Yeshiva University, New York, New York, appearing on behalf of the New York State Speech and Hearing Association, Tr. 1388; James H. Johnson, Note 18, supra at 2269; James M. Anthony, M.D., Dallas, Texas, who indicated that if it were medically possible to fit both ears in the case of bilateral loss, it should be done, and that if the loss were not too severe, the majority of patients could be helped by such systems, regardless of the asymmetry between the two ears, Tr. 8454, 8502, 8468, 8489; and Maurice Miller, Professor of Speech Pathology and Audiology, New York University, who believes that if the geriatric patient is to be given the capacity to localize, he will have to be fitted with binaural systems, but who notes that experimental and clinical evidence has indicated that in certain types of presbycusis hearing loss, the use of two aids has also caused significant deterioration in the quality and intelligibility of the signal, Tr. 4753-54.

25 Michael Stahl, Note 10, supra at 5541; Dr. Laura Ann Wilber, Ph.D., Note 24, supra at 1388.

26 Judith A. Rassi, audiologist, Northwestern University, Evanston, Illinois, Tr. 5733; Thomas W. Norris, Ph.D., Director, Division of Audiology and Speech Pathology, University of Nebraska Medical Center, Omaha, Nebraska, R-10-6497-98.

Section 440.10(d) of the proposed rule was drafted to alleviate whatever problem exists in this area:

> No seller shall prepare***any advertisement:
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> * * *
>
> (d) Which makes any representation that the use of two hearing aids, one in each ear, will be beneficial to persons with a hearing loss in both ears, unless, in addition to the disclosure required by § 440.10(a), it is clearly and conspicuously disclosed that many persons with a hearing loss in both ears will not receive greater benefits from the use of two hearing aids, one in each ear, than from the use of one hearing aid.

In its belief that the issue should be answered affirmatively, ASHA argues that any representation which emphasizes the advantages of binaural hearing is misleading if they do not also indicate that many persons cannot obtain greater benefits from binaural systems than from monaural amplification. R-10-1839. Similarly, Douglas Noffsinger, Director, Audiological Activities, Northwestern University School of Medicine, strongly supports proposed Section 440.10(d) because of his belief that the clinical research literature on binaural hearing aids is too unclear to be said to support their superiority. Tr. 7640.

On the other side, HAIC submits that the required affirmative disclosure is in itself misleading in view of the substantiated greater benefits that can be received from the use of two hearing aids. R-3-3928. NHAS, too, notes that while binaural aids are not to the advantage of all persons under all circumstances, the "Commission's assertion" in Section 440.10(d) that binaurals are of no greater benefit to many persons with bilateral impairment is simply not substantiated by the facts. R-3-3642.

Sam Hopmeier, proprietor of W. H. Hopmeier, St. Louis, Missouri, a hearing aid dealer, feels that FTC regulations should in no way discourage all hard-of-hearing individuals from having the opportunity of experiencing binaural fittings; to do so would be a disservice to the majority of individuals who could perhaps improve their hearing potential. Tr. 3355.[27]

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[27] See also James Keyes, Note 18, supra, who indicates at 10695, that the rule requirement does not realistically reflect the greater benefits that can be received by most people with bilateral loss and would tend to discourage (Continued)

b. The findings. This is one of the most disputed issues in this section; the attempt to obtain an answer to it has but revealed the existence of a wide gap between the opinions of some very competent professionals in the hearing health care delivery field. It seems that the evidence would compel a positive answer to the issue inasmuch as many persons with bilateral hearing losses will not stand to gain substantial benefits from binaural hearing systems. But many will gain if such systems can be properly selected and fitted to their ears. As one witness noted, not everything turns out the way clinicians expect it to and sometimes even those binaural candidates fitted after extensive testing and recommendation by an audiologist find that they either cannot wear the second hearing aid or don't derive enough benefit from it to warrant the additional expense and adjustment.

For those who can successfully wear binaural systems, many benefits can be gained: binaural listeners can ascertain better than monaural wearers the direction and distance from which sound is emanating so that the brain can better tune in desired sounds and tune out unwanted sounds; speech can be better distinguished in many situations from the background noise coming from the same direction but from a different distance; the absolute hearing threshold is lower with binaural use and the wearer is able to turn the ordinarily detrimental "head shadow" effect into the ability to directionally locate sounds; there is a greater dynamic frequency range of listening, and the safety aspect is considerable since the wearer will be better able to perceive the direction from which danger is approaching. Many professional audiologists are so impressed by these benefits that they have become, as one audiologist described himself, "notorious fitters" of binaurals. However, at the same time, there is considerable evidence that some fitters have placed binaurals on customers who cannot and should not use more than one hearing aid, if any at all. The exact causes of these instances have not always been specifically designated, although some witnesses questioned whether economic gain from the sale of such systems was the motivation in cases where the individual who recommends the hearing aid is also the seller. A study of the sales manuals leads one to suspect this is often true. Evidence also indicates

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27 (Continued)

such persons from aiming at the best use of their residual hearing capabilities; Dean Harris, Note 19, supra, believes that the statement required by the proposed rule section is simply not true and that such statements contained in advertising will raise suspicion in the minds of many individuals, thus discouraging them from obtaining the greater benefits that are available with binaurals, Tr. 10416-17; James H. Johnson, Note 18, supra at 2269.

that, although binaural benefits may be great, it may be only through trials and time for adjustment that the degree of benefits for each individual can be ascertained.

c. Conclusions. Patients have been fitted with binaural systems when such were inappropriate or unnecessary. While it is true that many persons with bilateral impairments will fail to receive greater benefits from binaural systems than from monaural ones, the word "many" may be interpreted too negatively. It would seem that many individuals would derive greater benefits if the fitting and wearing of their systems are medically feasible and if the instruments used are appropriate to the hearing loss. A better statement of the situation would indicate that "some" such persons will not derive greater benefits. A significant amount of disagreement in this area involves largely permissible and ethical variations in professional judgment.

Although substantial evidence does support the proposed rule section, it is difficult to see how the compelling of such negative disclosure will provide the best benefit to the consumer.

PART VIII. ADEQUACY OF EXISTING CONSUMER PROTECTION MEASURES

A. Introduction. Evidence throughout the record of this proceeding strongly suggests that for the hearing-impaired, existing consumer protection measures provided by the states, the industry's own guidelines and private sources are wholly inadequate.[1]

Every major study conducted by independent consumer organizations, governmental departments, and senior citizen organizations reveal major deficiencies in presently available consumer protection schemes.[2]

The primary source of consumer protection for the hearing-impaired is found in the regulatory efforts of the states. Statutes enacted in 41 states vary considerably in the form and extent of protection provided.[3] The design, implementation, and effectiveness of some of these statutes will be discussed in this part of the report.

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1 See, e.g., American Speech and Hearing Association (ASHA), R-10-1650A-1690; Staff Study of the State Licensing Laws and Training Requirements for Hearing Aid Dealers, Permanent Subcommittee on Investigations of the Committee on Government Operations, U.S. Senate, 94th Cong., 1st Sess., 1975, R-8-D543-1-14; Paying Through the Ear, A Report on Hearing Care Problems, Public Citizens Retired Professional Action Group, Preliminary Draft, 1973, R-8-D421-IV-2/IV-9, XIV-2, XIV-6, MB-1 - MB-5.

2 Major consumer organization studies used for this section include: Sound Trap, Hearing Aid Sales in Iowa, Iowa Students Public Interest Research Group (ISPIRG), June, 1974, R-8-D233; Hear Ye!, Hear Ye! A Study of Hearing Aid Sales Practices in Queens, New York Public Interest Research Group (NYPIRG), undated, R-8-D232; Hearing Aids and the Hearing Aid Industry in Minnesota, Minnesota Public Interest Research Group (MPIRG), Nov. 13, 1973, R-8-D229; You Know I Can't Hear You When The Cash Register's Running, The Hearing Aid Industry in Michigan, Public Interest Research Group in Michigan (PIRGIM), Dec. 3, 1973, R-8-D231. Government studies used include: Senate Staff Study, Note 1, supra; Final Report to the Secretary on Hearing Aid Health Care, prepared by the Department of Health, Education and Welfare Intra-departmental Task Force on Hearing Aids, July, 1975, R-8-D494. Senior citizen's organizations reports used were: RPAG, Note 1, supra; ASHA, Note 1, supra.

3 ASHA, Note 1, supra, at 1656.

A second source of possible consumer protection exists in the guidelines and ethics codes set up within the hearing aid industry itself. The record contains descriptions of the limited efforts undertaken by the industry to adopt and upgrade consumer protection measures.[4]

Various other agencies and offices are also available to assist consumers who have grievances. These organizations include state agencies such as state governors' consumer protection offices, offices of the state attorneys general, the local Better Business Bureaus, senior citizens' groups, and a variety of consumer-oriented organizations.[5] Unfortunately, lack of funding and enforcement powers seriously limit the capabilities of these sources of protection.

Since the age of consumerism is increasingly upon us and since there appears to be a variety of directions a frustrated consumer may turn for help, it might seem that additional protection measures are unwarranted. This, however, is not the case with the hearing aid consumer. In evaluating consumer protection measures for the hard of hearing, the most important criteria to be judged is the effectiveness of the measures. The evidence in the record of this proceeding reveals that the present protection measures are consistently lacking in necessary effectiveness.

B. State laws.

1. Licensure boards. The hearing aid industry is primarily regulated through state statutes that are now in effect in 41 states.[6] Oregon, in January 1960 ". . . became the first state to require dealer licensure."[7] At the time the Oregon statute was passed the industry strongly opposed any sort of licensing

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4 See, e.g., National Hearing Aid Society, (NHAS), R-3-3537-41; ASHA, Note 1, supra at 1681-87; John Kenwood, hearing aid dealer, Tr. 9285-91; Raymond Rich, NHAS member, Tr. 2982-83.

5 See, e.g., George Shanta, President, Chicago Area Council of Senior Citizen Organizations, Inc., Tr. 8863; RPAG, Note 1, supra at CG-33-47; Annie Laurie Gunter, Director, Consumer Protection Agency, Office of the Governor of Alabama, Tr. 8200; James Jeffries, Assistant Attorney General in Wisconsin, Tr. 5585; Phil Shattuck, Illinois Department of Public Health, Tr. 6767.

6 Judith Munger, Attorney, National Council of Senior Citizens, Tr. 4501.

7 MPIRG, Note 2, supra at 70.

attempts and were successful in opposing legislation in other states until 1967. Since that time however, the industry has become more supportive of this type of state intervention and now all but nine states have some form of regulation.[8]

The state statutes as a whole, provide for a variety of combinations in the makeup of the licensure boards. Generally, the boards consist of a physician member, usually an otolaryngologist, an audiologist member, and several hearing aid dealer members. The boards normally have from three to seven members and on the majority of state boards, hearing aid dealers predominate.[9] The governors of most states with licensure laws, have the authority to appoint board members, usually on the recommendation of industry.[10]

John J. Fennema, a hearing aid dealer licensed in Maryland and a member of the Maryland State Board of Hearing Examiners, said that only those dealers whose views accord with those of the Association are recommended [to the boards] and the same ones appear on the list regularly resulting in a small group having too much power. Tr. 1751. Mr. Fennema is not alone in his uneasiness over board control by dealers. From Wisconsin, Assistant Attorney General, James D. Jeffries writes:

> It is our opinion that although it may be necessary to employ persons in the trade in order to competently test other members of that trade as to basic competency, protection against consumer fraud in a particular industry is best accomplished by an agency which is unassociated with the group being regulated.[11]

Mr. Phil Shattuck of the Illinois Department of Public Health says that his department has been interested in having the hearing aid industry regulated since 1969. The department has,

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8 Id.

9 Donald D. Skaarer, Chairman, Georgia State Board of Hearing Aid Dispensers, R-6-26-27; J. L. Agnes, Chief Investigator, Bureau of Consumer Protection, Trade Division, Wisconsin Department of Agriculture, R-6-193A.

10 John J. Fennema, Maryland hearing aid dealer, Tr. 1751; MPIRG, Note 2, supra at 71.

11 Jeffries, Note 5, supra at R-6-289. See also Senate Staff Report, Note 1, supra at 2; ASHA, Note 1, supra at 1676-77.

however, opposed various bills that have come before the legislature because it felt these bills were not adequate from the standpoint of consumer protection. Mr. Shattuck explained that the Department was against a particular bill that would have set up a licensing board composed mainly of dealers because, "[t]he Department of Health felt it was not in the best interest of the consuming public to have boards dominated by hearing aid dealers . . . ." Tr. 6771.

In it's rebuttal to the Senate Staff Study of the State Licensing Laws and Training Requirements for Hearing Aid Dealers, the National Hearing Aid Society strongly objected to the Senate staff's characterization that boards dominated by hearing aid dealers do not have the best interest of the consumer in mind. NHAS also disagreed with the position that the makeup of the boards had the appearance and the reality of a basic conflict of interest.[12] NHAS cited a decision of a Michigan Court which suggests that state boards should be run by members of the industry being regulated. This court reasoned that those people who are already in the industry have the greatest understanding of its problems.

> Another purpose of the (Michigan) constitutional provision, as recognized by the Court of Appeals, is that, if an examining or licensing board of a 'profession' is to function successfully board members must understand the technical and ethical standards of the regulated 'profession.' This may best be accomplished by requiring the members of examining or licensing boards to be members of the respective 'profession.' Nemer v. Michigan State Board of Registration for Architects, Professional Engineers and Land Surveyors, 20 Mich App 429, 433: 174 NW 2d 293 (1969). R-8-558-10.

NHAS further suggests that the hearing aid industry is rather advanced in that nonmembers of the industry are currently included on most state boards. It said few other professional licensing boards have such members.[13]

There are other problems that most boards face that add to and probably in some cases cause their ineffectiveness. The boards generally have scant funds for their operations, very

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[12] The Response of the National Hearing Aid Society to the Staff Study of the State Licensing Laws and Training Requirements for Hearing Aid Dealers, R-8-D558-10.

[13] Id.

few have adequate support staffs to receive or process complaints, and they meet very infrequently, usually only once or twice a year.[14]

Despite the contention of NHAS, there is ample evidence on the record which suggests that the composition of the state licensing boards may be one of the most serious osbtacles to effective consumer protection at the state level.[15]

2. State requirements for licensure. It was thought that registering and licensing hearing aid dealers in order to establish a legal basis for controlling their operations in the industry would result in better protection for consumers. There are those who believe, however, that the idea has backfired in that the license brings an "aura of quasi-professionalism . . ." which has a ". . . greater capacity to mislead and deceive the consumer than existed prior to such laws."[16] Dr. Tom Mahoney, Director of Speech Pathology-Audiology Section of the Department of Social Services in Utah said that "[m]ost hearing aid laws in states are simply registration acts that put a fraudulent air of professionalism on the hearing aid dispensor[sic]." R-6-10. New York PIRG found that because bills in most states are largely void of consumer protection measures the bills' main results have been to provide professional status to the dealer, even though his background, training, and experience may not warrant it.[17]

Requirements for licensure in the 41 states that currently have such statutes, include provisions for education, experience, examinations, and training periods. The statutes combine these four main ingredients in a variety of ways, some states placing

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[14] Senate Staff Report, Note 1, supra at 2; Munger, Note 6, supra at 4504; Donald Morgan, Chairman of the Audiology Task Force of the Commission of Legislation of the California Speech and Hearing Association, Tr. 9507; Jeffries, Note 5, supra.

[15] See, e.g., Angela Loavenbruck, Ed.D., Audiology-Speech Professor, Teachers College, Columbia University, Tr. 1551; Richard Conlin, Project Director, Public Interest Research Group in Michigan (PIRGIM), Tr. 7857-58; ISPIRG, Note 2, supra at 45; NYPIRG, Note 2, supra at D232-11; Jeffries, Note 5, supra.

[16] ASHA, Note 1, supra at 1650A; see also PIRGIM, Note 1, supra at 30-31; Cyril F. Brickfield, counsel for the National Retired Teachers Association and American Association of Retired Persons, Tr. 1434.

[17] NYPIRG, Note 2, supra at 11.

more emphasis on one area than another. For instance, in regard to education of dealers, California, Indiana, Iowa, Ohio, and Washington require only a high school diploma or a certification of general educational development (G.E.D.).[18]

NHAS in its attempt to establish some educational guidance for its members instituted a 20 lesson home-study course for dealers. The HEW Task Force on Hearing Aids in their final report to the Secretary on Hearing Aid Health Care said:

> Of the estimated 15,000 hearing aid dealers in the United States, only about 2,200 dealers have received certification by their trade association, the National Hearing Aid Society, through a 20-week home study course. This course and final examination do not include any evaluation of the dealer's practical skills in testing and fitting hearing aids nor of the dealer's ability to communicate with and counsel the hearing-impaired.[19]

RPAG reported in its analysis of the course that subjects covered in 1 week by the NHAS course required a full semester of study in university audiology programs.[20] This is an important comparison to consider.

Dealers, on the other hand, cite this course as proof of the educational efforts being made by the industry.[21] Though the course may be a worthwhile attempt to educate dealers, it's success is limited because a dealer is not required to take the course and experts consider it totally inadequate.

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18 ASHA, Note 1, supra at 1658. ASHA included New York in this list, but New York has passed a rather strong licensing bill since ASHA's comment was filed.

19 HEW, Final Report, R-8-494-24; NYPIRG, Note 2, supra at 11; Ira Kolman, Chairman, Department of Speech Pathology-Audiology, Loyola College of Baltimore, Tr. 1883; Dr. Roger Kasten, Witchita State University, Tr. 777-86; Elma Griesel, National Steering Committee of Gray Panthers, Tr. 9475.

20 RPAG, Note 1, supra at 111-22.

21 See, e.g., Kenwood, Note 4, supra at 9287; David Barnow, former HAIC president, Tr. 1627; Rich, Note 4, supra at 2982-83; NHAS, Note 4 supra at 3534; John Kojis, President, Maico Hearing Instrument Company, Tr. 1977-78.

A few of the major manufacturers have set up training for dealers but these sessions consist mainly of business and sales techniques.[22] Wayne Staab, Director of Education for Telex, testified that the Telex dealers' training is not extensive from an academic standpoint; dealers education comes from experience, according to Staab. Tr. 7027. Part III of this report details manufacturers efforts at educating dealers. These efforts are mainly conducted through use of training manuals that emphasize selling techniques.

Since the state codes do not require formal education in the field, how then do the codes provide for potential dealers entry into the state licensure system? The answer is two-fold.

One means of educating dealers used in the hearing aid industry is "grandfathering." Under the grandfathering provisions of the state codes, licenses are automatically given to those who have been involved in selling hearing aids prior to the enactment of the licensure laws.[23] RPAG reports that dealers in 29 states were not required to take the state examination if they had been in business 2 to 3 years before the bills became effective.[24]

ASHA believes that grandfather clauses in the state statutes are "a unique form of perpetuating dealer incompetency."[25] In Michigan, a finding of MPIRG was that most dealers that were in the system were grandfathered in. This is true perhaps of 150 out of 200 now practicing in Michigan.[26] Nebraska gave its' dealers who had been in business before the statute became effective, a "free ride" for 18 months before an examination was required.[27]

The second method whereby a person, who is not formally educated in the trade, may obtain licensure is through the trainee provisions incorporated in most state codes. Those wishing to enter the field may apply for a temporary permit

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22 RPAG, Note 1, supra at XIV-2.

23 Linda Joy, Executive Director, Michigan Consumer Council, R-6-220; ASHA, Note 1, supra at 1660.

24 RPAG, Note 1, supra at III-23.

25 ASHA, Note 1, supra at 1659.

26 Conlin, Note 15, supra at 7759-60.

27 Lawrence Murphy, Nebraska Hearing Aid Association, Tr. 7979.

under the conditions that a licensed dealer sponsor them.[28] The statutes have various ways of handling this sort of entry but generally the trainee is issued a permit to dispense and fit aids under the supervision of a licensed dealer for a period ranging from 6 to 18 months. At the end of that period, the trainee must then pass the state exam in order to obtain a permanent license.[29] The trainee provisions of state codes have been criticized for two major reasons. First, the person who is still in training, is allowed to sell and fit aids, possibly without adequate knowledge of the hearing-impaired; and, secondly, the temporary permit may be renewed upon failure of the state exam for as many as three times, thereby allowing a person who is not capable of passing the exam to continue in the business.[30]

ASHA believes that temporary licensure substantially defeats any other possible protection offered by dealer licensure statutes. ASHA conducted a study of the various states licensure laws and found that of the 23 boards that responded to their questionnaire ". . . approximately 80 percent of temporary permit holders who actually tested hearing and fitted and dispensed hearing aids during the permit periods never had to meet full statutory licensure standards."[31] ASHA feels that with this type of licensure loophole, it is not possible for the consumer to be adequately protected by state laws.[32]

The fourth major element provided for in the state codes is the examination given to those desiring a license. The statutes in most states give the responsibility of administering the licensing exam to the state board. Usually the exam is offered

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28 See, e.g., Maine 43 Stat. 1658-J, R-6-40; Rules and Regulations of Virginia Board of Hearing Aid Dealers and Fitters, R-6-156; Dr. Henry Creech, Vice Chairman of the Board of Examiners, State of Virginia, Tr. 5224; Murphy, Note 27, supra at 7979-83.

29 Missouri HB 396 & 257, § 16, R-6-67; Maine Statute, Note 28, supra; Virginia Board Rules, Note 28, supra; James Wallace, Chairman, Tennessee Board for Hearing Aid Dispensers, Tr. 3470.

30 Mark Stewart, Investigator, Camden County, New Jersey, Office of Consumer Affairs, R-6-176; Creech, Note 28, supra at 5224; Leslie Dalton, New Mexico Speech & Hearing Association, Tr. 8723; Morgan, Note 14, supra at 9507.

31 ASHA, Note 1, supra at 1666-67.

32 Id.

twice a year, but this is flexible and is generally left to the discretion of the board. After payment of the required fees, the applicants for licensure in most states must take a two-part exam, one part written and the second practical.[33] The record contains evidence supporting both the reliability of these exams and the near worthlessness of them. Some witnesses believe that state exams are very thorough, testing the applicant's ability in all areas necessary for competent dispensing.[34] Others, such as the Unit Manager of Oregon's Registration Office, believes "[T]he examination is intentionally a low fence type of exam . . . ." Tr. 11785.

If one hypothetically assumes that the exams in every state do sufficently evaluate the proficiency of the applicant, the codes still contain the self-defeating mechanism of allowing those who do not pass the test to continue to work in the field for an additional six months to a year and a half through renewal of the temporary permit.[35] Thus existing state requirements for licensure can only be considered an initial step in providing adequate protection for the hearing aid consumer. The licensure provisions of most codes provide a very mild form of protection in that the educational requirements are very lax, the grandfathering provisions allow for licensure without requiring examination, the exams themselves may not adequately test the competency of the individual, and the renewal of temporary permits provides a state sanctioned loophole for those who cannot perform the required skills necessary to obtain permanent licenses.[36]

The HEW Task Force Report, the Senate Staff study, ASHA, MPIRG, RPAG, and many individuals who wrote to the Commission and who testified during the proceedings believe that most of

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33 RPAG, Note 1, supra. Tables at end of report show that 22 states require such exams for licensure. See also Morgan, Note 14, supra at 9506; Donald Mettler, otolaryngologist, Tr. 11371-72.

34 Wallace, Note 29, supra at 3459; Herbert Richenberg, Director, Henry C. Barkhorn Memorial Hearing and Speech Center, Tr. 3511.

35 See reference cited in notes 29 and 30 supra.

36 See, e.g., Kenneth Johnson, Executive Secretary, ASHA, Tr. 4265; Maurice A. Byrne, Jr., Assistant Director of Law and Legal Counsel for the Department of Consumer Affairs for the Mayor of Louisville, Tr. 1007; David Bartels, N.C. Speech, Hearing and Language Association, Tr. 6327-31; Arthur Fleming, Commissioner, Administration on Aging, HEW, Tr. 619; Loavenbruck, Note 15, supra at 1551; Janet Levy, Director, California Department of Aging, Tr. 11668.

the state licensing requirements do not do a good job of providing sufficiently high standards of protection for the hearing aid consumer.[37]

3. Consumer complaints. In addition to licensing and examining potential dealers, the state licensing boards are charged with receiving and handling complaints made by consumers. Like the other functions of the boards, their performance in resolving these complaints has been the subject of some criticism.[38]

The Senate staff in their report to the Government Operations Committee made an analysis of the complaint handling procedures of the boards of the 39 states who had licensure laws at the time the study was undertaken. In 20 of the 39 states studied, it was found that compliants are taken over the phone.[39] Citizens in these states are more fortunate in regard to the ease with which complaints may be made than are consumers in the other 19 states. In those states, consumers must make complaints in writing and in four of these, the complaint will be considered only if a special form is used.[40]

Most state boards believe that resolution of the complaint can be satisfactorily negotiated through an informal system. This is usually done by a board member having a talk with the dealer who has allegedly provoked the complaint. ASHA believes that this system is a failure, because of the possibility that self-interest will result in ineffectual action.[41] Of course, in some cases when the complaints are not adequately resolved

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37 See references cited in Note 36, supra; see also M. S. Shimanoff, Director, Orange County Office of Consumer Affairs, R-6-112; William H. Behrends, Jr., 1 Lt, USAF, Chief of Audiology, Sheppard AFB, R-6-146; Judith Brown, Deputy Attorney General, Pennsylvania, R-6-212; Jeffries, Note 11, supra; Taketsugu Takei, Director, California Department of Consumer Affairs, R-6-316; David L. Schmitt, Special Investigator, Pennsylvania Bureau of Consumer Protection, R-6-445.

38 See, e.g., Conlin, Note 15, supra at 7858; Patricia Mastricola, Audiologist, Tr. 8661; Bryne, Note 36, supra at 1011-12; Fennema, Note 10, supra at 1751.

39 Senate Staff Study, Note 1, supra at 10.

40 Id.

41 ASHA, Note 1, supra at 1676-77. See also Griesel, Note 19, supra at 9403; Leonard Finkel, Counsel for Legal Research and Services for the Elderly, Tr. 4445-46.

through this informal system, the boards have used formal hearings to arrive at a settlement.[42]

The lack of a full-time, active staff limits the ability of the boards to properly investigate complaints and the boards' infrequent meetings further diminish the possibility of effective action. The Senate Staff concluded that those states that had an aggressive, full-time board, an adequate budget, and that met frequently, were more likely to receive complaints than those that did not have such characteristics.[43] This suggests that the reason some boards are able to say they have not received many complaints may be because of the inactivity of the boards, and that consumers are unaware that complaints against hearing aid sellers should be made to the board. Part of the problem is that the existence of the boards has not been well publicized.

RPAG made a telephone survey of several states with licensure laws in order to determine how easily a consumer would be able to lodge a complaint. It reported that the results disclosed that, "It is extremely difficult for a consumer to find out how or where to make a complaint."[44] RPAG found that it takes several calls to find someone knowledgeable enough to give correct information on where the complaint should be made, and that often a board member, usually a dealer is the one to whom the complaint is supposed to be directed. It was also found that most board members who were contacted could not give any specific information on just how one should go about making the complaint.[45]

RPAG concluded that, "Going through such lengthy and complicated procedures to find help would be hard enough for an elderly or unsophisticated consumer; to have to call a hearing aid dealer to voice a complaint against another dealer would be even more inhibiting."[46]

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42 Rich, Note 4, supra at 2983; Kenwood, Note 4, supra at 9288-89.

43 Senate Staff Study, Note 1, supra at 10.

44 RPAG, Note 1, supra at IV-10 - IV-11. See also Fennema, Note 10, supra at 1751; Michael Stahl, Director of Clinical Services, Hearing and Speech Center, Grand Rapids, Michigan, Tr. 5537-38; Helen Kelly, Special Assistant Attorney General in Minnesota, Tr. 7564.

45 RPAG, id.

46 RPAG, id; See also Munger, Note 6, supra at 4504; Emma Gunterman, Legislative Advocate for the Senior Program of the California Rural Legal Assistance, Tr. 9651; Kelly, Note 44, supra at 7531, 7537, 7538; Irene Bowen, Student Director, National Center for Law and the Deaf, Tr. 1942-43.

Mike Pasiewicz of Antioch, Illinois, an independent witness at the Commission's hearings, reported that he had a problem with noise in his aids but has never gone to the Illinois Hearing Aid Dealers Association because he did not know of its existence. Tr. 8951. Mary Ruth Whitman, an audiologist with the Illinois Department of Public Health testified that some of her patients had complained about their dealers but that she did not refer them to the dealers association, even though she knew of its existence. She said she has no confidence that anything would be done about the complaint since the dealers complained about were members of the Association's board of directors. Tr. 8707-08.

The Minnesota PIRG study reports that the reason state boards receive so few complaints is that the boards are not visible to the consumer, nor are they active in regulating dealers who are complained against. ISPIRG found that in Iowa quite a bit of confusion surrounds the filing of a hearing aid complaint. A member of the ISPIRG staff attempted to lodge an alleged complaint with the local Chamber of Commerce. The staff member was told that the two agencies available to receive complaints in that state were the Consumer Complaint Division of the Attorney General's Office and the small claims courts. The hearing aid board was not mentioned as a possibility.[47]

Even though these two sources exist for Iowa citizens, few realize that they have the option to use them. This was illustrated by the response a member of the study group received when voicing an alleged complaint to a member of the local Chamber of Commerce. The Chamber member suggested calling the Better Business Bureau although the suggestion included a comment that Better Business Bureau only handles state matters. There was, however, no mention of the Attorney General's Office or the small claims court as possible dumping places for the complaint.[48] ASHA said that in cases where there has been deception or abuse the consumers only recourse is in the courts; often an impossible avenue for the old, infirmed, poor, uninformed, and hearing-impaired.[49]

The National Hearing Aid Society submitted a lengthy rebuttal to the testimony of certain witnesses who told the Commission that complaints about the industry are widespread.[50] NHAS maintains

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47 ISPIRG, Note 2, supra at 46.

48 Id.

49 ASHA, Note 1, supra at 1668.

50 NHAS rebuttal submission, R-13-D146, Part 3.

that the ratio of complaints to sales of aids in 1975 was an "incredibly low" 0.2%.[51]

It is important to realize, however, that there is strong evidence in the record countering this position. The evidence takes various forms, but each is important in explaining this apparent low level of complaints. Consistently witnesses other than those sponsored by the industry testified that consumers are reluctant to complain;[52] that those who are not inhibited about complaining often don't know where to lodge the grievance;[53] that state boards and consumer protection agencies often settle disputes informally thus complaints are voiced but not necessarily recorded;[54] and that complaints are seldom carried through to the litigation stage.[55]

4. Penalties. Revocation and suspension of dealers licenses are the two principle penalties provided for in the state codes.[56] A few states such as Wisconsin and Vermont

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51 Id. at 16.

52 See, e.g., Gunterman, Note 46, supra at 10791; Rafael Penelver, attorney on behalf of the National Council of Senior Citizens, Tr. 4910-14; Georg Cooper, consumer, Tr. 9651; Maurice Miller, Professor of Speech Pathology and Audiology, New York University, Tr. 4752-53; Fennema, Note 10, supra at 1751.

53 Griesel, Note 19, supra at 9375; ISPIRG, Note 2, supra at 47; Bryne, Note 36, supra at 1011-12; MPIRG, Note 2, supra at 74.

54 PIRGIM, Note 2, supra at 35; MPIRG, Note 2, supra at 74; Senate Staff Study, Note 1, supra at 10.

55 A good explanation was provided by William Brown, Attorney General of Ohio, R-6-303, who stated that: "The number of complaints which this office has on file should not be regarded as indicative of the incidents of complaints against the hearing aid industry in general, because the Office of the Attorney General functions primarily as a law enforcement, rather than a complaint-handling agency. Therefore, generally speaking, the only compliants of which we have record are those which are serious enough to have been referred to this Office for enforcement action." See also John Brennon, consumer, Tr. 247; Gunterman, Note 46, supra at 9651.

56 See, e.g., Nevada Statute and Rules and Regulations, R-6-50; Missouri HB 396 & 257, § 21, R-6-69; Ralph Hoover, Chairman, West Virginia Board of Hearing Aid Dealers, R-6-184; Estelle Siker, M.D., Director, Community Health Division, Connecticut, R-6-202; New York 5341A SB 784, R-6-236; Skaarer, Note 9, supra at R-6-27.

include a $500 fine as one of the authorized penalties.[57] Grounds for suspension or revocation generally include fraud, unethical conduct, and negligence.[58]

Although the penalties as enumerated in the codes seem harsh, the extent to which they are imposed is very limited. Judith Munger testified that of the 2,383 complaints reported to the Government Operations Committee only 43 resulted in suspensions or revocations.[59] The Chairman of Georgia's State Board of Hearing Aid Dealers reported to the Commission that there was only one suspension and one revocation of license in his state in 1974.[60]

The Senate Staff Study tally of revocations and suspensions during the period from 1970-1974 shows that half of all revocations and suspensions were for nonrenewal of license. During the same period, "only seven civil prosecutions by law enforcement authorities were brought against dealers, and these occurred in four states." The staff also found that in seven states, there were sixteen criminal prosecutions, ten resulting in fines or imprisonment.[61]

It is obvious that although the codes call for severe penalties, these cannot be considered to be serious deterrents since the penalties are so rarely used.

C. Other state consumer protection measures. Other avenues that consumers may explore in attempting to resolve complaints are those offered by miscellaneous state consumer protection agencies. Although these offices do their best to serve consumers, they are generally understaffed, under publicized, and lacking in any real enforcement capabilities.[62] The Director of the Alabama Governor's Consumer Protection Agency, Annie Laurie Gunter, testified that her office acts as a clearing-house for consumer complaints but does not have any enforcement powers. Tr. 8232-33. A hearing aid user in Maryland, John Brennan, testified that he was able to satisfactorily resolve a dispute in that

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57 Vermont Public Act 95, § 4586, R-6-246; Agnes, Note 9, supra at R-6-194.

58 Maine 463 Stat. 1658-N, R-6-41.

59 Munger, Note 6, supra at 4504-05.

60 Skaarer, Note 9, supra.

61 Senate Staff Study, Note 1, supra at 11.

62 See, e.g., Kelly, Note 44, supra at 7556-56; Gunter, Note 5, supra at 8232.

State's Office of Consumer Affairs. Mr. Brennan felt that he was an unusual consumer in that most people do not know of the existence of this complaint channel. Tr. 247. Ms. Patricia Powers, an instructor at the Utah State University, compiled a list of complaints received by various state agencies in Utah totaling 300 complaints within 1 year. She said for this same time period the State Attorney General's office had received only 25 complaints. When questioned by counsel about this discrepancy, Ms. Powers suggested that people do not know the proper complaint channels so that unless a professional intervenes to help the consumer, the complaint is not properly registered. Tr. 9906-07.

The offices of the state attorneys general have not proven to be an effective answer in dealing with hearing aid complaints. These offices work under the same low staff, case overload conditions encountered by the other state consumer protection offices.[63]

The state attorney general offices do have enforcement powers available, however, the top priorities of these offices have not generally included the investigation or litigation of hearing aid complaints.[64]

The record indicates that state attorney general offices generally have two positions in regard to hearing aid complaints; both of these have resulted in an inactive pursuit of code violations. The record contains evidence that some of these offices feel there must be a large volume of complaints filed before the office will accord them a high priority.[65] Representatives of other state attorney general offices testified that their offices cannot serve as depositories for complaints. Their workload is such that they can only afford to become involved when it appears that litigation is justified.[66]

Thus the various state offices designed to afford consumers the protection they need have had very limited success. The conditions of understaffing, heavy caseloads, lack of enforcement powers, poor visibility, and the necessity of prioritizing are all major problems obstructing the effectiveness of these agencies insofar as the abused hard-of-hearing consumer is concerned.

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63 See, e.g., Griesel, Note 19, supra at 9419; Kelly, Note 44, supra at 7556-56.

64 Griesel, Note 19, supra at 9419-20.

65 ISPIRG, Note 2, supra at 48.

66 Brown, note 55, supra.

D. Industry consumer protection measures. The principle industry document for consumer protection is referred to by the National Hearing Aid Society as the Code of Ethics.[67] Certification of dealers and salesmen by this dealers' organization provides another level of control of hearing aid dealers.

NHAS states that it's main objective in certification has been to improve the competency and reliability of it's dealer members.[68] The procedures necessary for certification are prescribed by the National Hearing Aid Society in its Code of Ethics. John Kenwood, a society member and hearing aid dealer in Illinois, described the process by which a dealer becomes certified.[69]

1. Certification procedures. Mr. Kenwood testified that the first step to certification for most dealers is completion of the NHAS 20-week study course. Upon completion of the course work, the applicant is examined on the material. Next, the applicant must submit the names of three persons knowledgeable in the hearing aid field, including one otolaryngologist, who are willing to assure the society that the applicant is sufficiently proficient in selecting and fitting aids. In addition to these names, the applicant must provide three character references and supply the society with a financial report. After the references are checked, the applicant must then pledge to abide by the Society's Code of Ethics. Tr. 9287-88.

2. Disciplinary actions. Disciplinary action against violators of certifications standards is also described by Mr. Kenwood. The Society's disciplinary authority is vested in the National Grievance Committee. If a member is found by the Grievance Committee to be in violation of the code, the Committee has several alternate actions available for dealing with the violator. These include:

1. File its opinion of the complaint with the Executive Secretary to be held for future reference.

2. Reprimand the member found guilty and file the complaint for future reference with the Executive Secretary.

3. Fine the member a sum not to exceed $200.

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67 Code of Ethics of the Hearing Aid Industry, R-6-51.

68 NHAS, Note 4, supra at R-3-3534.

69 Kenwood, Note 4, supra at 9287-88. See also Rich, Note 4, supra at 2982-83.

4. Suspend the member for a period not to exceed one year from the privileges of the Society and also fine the member.

5. Expel the member from membership. Tr. 9289.

Mr. Kenwood contends that it is rarely necessary for the Committee to employ any of these alternatives, because dealers value their membership in the Society; and, therefore, voluntarily correct any violation. Tr. 9289.

ASHA, however, feels very strongly that within the industry there are many violations of the Code and that these violations are never punished. ASHA gives the example of clause (d) of the Code which says a dealer must clearly identify his place of business as a commercial operation, and not as a professional or governmental entity. Examples of violations of this provision are rampant including such names as "Medicare Hearing Aid Service" and "Professional Center." ASHA offers these examples as "indisputable evidence that existing voluntary private consumer protection plans fall far short of providing genuine benefit to consumers."[70]

The Code does provide for a Grievance Committee but the process begins with a review of the complaint by the Society's Executive Secretary. This secretary has the power to reject any complaint so that it is possible that the Grievance Committee never has an opporutnity to review the alleged violation. ASHA believes that this is the reason why the society can boast that complaints are few and far between.[71]

The Senate Staff Study found that both NHAS and the manufacturers rely on state licensing agencies to police the dealer.[72] This report has already revealed the ineffectiveness of these bodies. ASHA believes that the industry codes "have surpassed state licensure and registration in their ineffectiveness" in providing consumers' protection.[73]

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70 ASHA, Note 1, supra at 1682. See also Dorothy Shannon, Chief of Speech and Hearing Section of Sinai Hospital, Tr. 1861; Angela Loavenbruck, Note 15, supra at 1546-47; John Payne, Chairman, Hearing Aid Advisory Committee to the Indiana State Board of Health, Tr. 9261.

71 ASHA, id. at 1684.

72 Senate Staff Study, Note 1, supra at 9.

73 ASHA, Note 1, supra at 1681.

3. The four-point consumer protection plan. On the recommendations made in a survey conducted for the industry by Payne and Payne, a consulting firm in Austin, Texas, NHAS on May 7, 1975, developed a four-point consumer protection plan.[74] This plan's four major components call for: (1) prior medical clearance, (2) expanded educational opportunities, (3) trial rental purchase option, and (4) improvement of complaint procedures.[75]

The industry believes that these voluntary measures to upgrade dealer practices along with the industry support of the state licensing laws, act as proof that the industry is capable of providing needed services and protection to the consumer, thus making the proposed trade regulation rule unnecessary.[76]

ASHA believes that these guidelines, not to be confused with the code, will never be stringently imposed on the dealer members. It is ASHA's belief that the plan was actually devised to "get (the industry) off the hook" in light of the actions that were developing at the federal level.[77]

The prior medical clearance provided for in the industry guidelines was said to contain the inherent weakness of allowing the consumer to sign a waiver and that this waiver seriously restricts the usefulness of the requirement.[78]

Educational opportunities for dealers were expanded in the guidelines from the existing 20-week home study course, by the development of the Hearing Instruments Institute. The purpose of the institute is to "upgrade the educational level of present hearing aid specialists and to provide entry level training."[79] Courses will be offered on a college level and a 2-year Associate of Applied Science degree will be available upon completion.[80]

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74 NHAS, Note 4, supra at 3537.

75 Id.; See also The Hearing Aid Journal, November, 1975, R-8-D633-39.

76 Luke Fortner, President, NHAS, Tr. 2840-48, 2864.

77 ASHA, Note 1, supra at 1686.

78 RPAG, Note 1, supra. Table lists 17 states that require a medical exam but that allow a waiver. See also 21 C.F.R. 801.421(a)(1) and (2); 42 Feg. Reg. 9296.

79 NHAS, Note 4, supra at 3539.

80 Id. at 3540.

Members of the Society must also offer purchasers a trial rental-purchase option. However, each member is allowed, under the guidelines, to establish his own terms for this option including limitations and fees.[81]

Efforts by the industry through the establishment of these guidelines will hopefully raise the level of protection available to the hearing aid consumer. Nevertheless, these guides have serious shortcomings and loopholes. Also they only exist on paper and have not been incorporated officially as part of the Code of Ethics. Even if they eventually are brought to the status of the code, the membership in the Society represents only a relatively small percentage of those people actually selling and fitting aids.[82] Thus, whatever improvements are made by the Society in regulating its members will be applicable only to that narrow percentage of dealers that belong to the Society.

In handling consumer complaints the industry intends to improve it's record by working with the local Better Business Bureaus and local authorities in providing third party arbitrations.[83] RPAG was told that a "hot line" has been set up by the industry to receive complaints and provide consumers with information on a toll free line.[84]

If these industry guidelines are enforced and if all dealers were members of NHAS and subject to its directives, and if there existed sufficient policing powers within the industry for violations of the code then perhaps additional consumer protection measures on a federal level would not be necessary. These hypotheticals, however, are not present realities.

E. Private consumer protection measures. The remaining potential source of consumer protection are the Better Business Bureaus, senior citizens organizations, and consumer-oriented groups.

The Better Business Bureaus function as intermediaries between sellers and buyers of a variety of products.[85] They can be helpful as a source for advice about local services, products, or merchants. Although they may have the capacity

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81 Id.

82 HEW Final Report, Note 2, supra at 24.

83 NHAS, Note 4, supra at 3541.

84 RPAG, Note 1, supra at XIV-3; see also Curt Clinkscales, National Director, National Alliance of Senior Citizens, Tr. 10621.

85 ASHA, Note 1, supra at 1687.

to bring pressure upon an unethical businessman by advising interested consumers to stay away from a particular enterprise, this capability cannot be considered adequate or very effective.

Arthur Lynch, a representative of the American Association of Retired Persons (AARP), testified that consumers wrote to his organization as a last resort after unsuccessful attempts to solve the problem through a Better Business Bureau. Tr. 1451.

Annie Lauri Gunter, Director of the Consumer Protection Agency for the Office of Alabama's Governor, said that the Better Business Bureaus operate in Alabama, but that in her view their complaint handling mechanisms are inadequate. Tr. 8217-18.

Senior citizens organizations and consumer groups are becoming increasingly active in monitoring legislation, receiving complaints, and advising and directing consumers.[86] These functions serve a useful purpose in increasing the awareness of consumers, giving consumer direction, and helping in the negotiation of disputes. All of these activities are beneficial, but none of these groups has the requisite authority to force industry to comply with sound consumer protection measures. Existing private measures cannot be considered even minimally adequate in providing the hearing aid consumer with protection.

F. Cancellation provisions. Two types of state laws afford the purchaser of a hearing aid with the right to cancel the sale. The first of these are the well-known cooling-off laws which afford a buyer the right to cancel a sale within 3 business days if the contract was made in the home or outside the seller's place of business. This type of law does not provide a hearing aid purchaser with sufficient protection because very few hearing aids are delivered within the 3-day period. Thus the buyer has no opportunity to ascertain if the aid will assist him.[87]

The second type of state law affording cancellation rights are those which are specifically applicable to hearing aid sales, regardless of where those sales may have been made. These are discussed in Section H of this Part infra.

G. Requirements for medical clearance. There was considerable testimony or evidence to the effect that prospective purchasers

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86 See, e.g., reports by ASHA, Note 1, supra; RPAG, Note 1, supra; Shanta, Note 5, supra, at 8860-63; Gunterman, Note 46, supra at 9650; Griesel, Note 19, supra at 9399-9420.

87 See, e.g., Shattuck, Note 5, supra at 6768-69. The provisions of these laws vary from state to state. However, the Commission's trade regulation rule concerning a cooling-off period for door-to-door sale would seem to require all such contracts to conform to its provisions 16 C.F.R. Part 429 and Note 2.

of hearing aids should be required to undergo a medical examination by a physician.[88] Indeed some state laws required such an examination[89] and some of these laws were criticized for permitting certain categories of patients to waive the requirement.[90] However, as noted in Part II, of this report, FDA has issued regulations which will prohibit the sale of a hearing aid unless the prospective user presents a signed written statement from a licensed physician that the patient has been medically evaluated and may be considered a candidate for a hearing aid. Persons over 18 may waive this requirement.[91]

B. Effect on state laws. This proceeding was initiated and the hearings concluded prior to the Commission directive regarding increased participation by state and local officials in rulemaking proceedings. As a consequence the specific effect of the

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88 See, e.g., David Resnick, Ph.D., National Council of Senior Citizens, Tr. 5385; Dr. Henry Hecker, Audiologist, Tr. 5263; Brickfield, Note 16, supra at 1436; Dr. Henry W. McCurdy, Executive Director of the American Council of Otolaryngologists, Tr. 3695-96; Stephen Epstein, National Council of Senior Citizens, Tr. 4564; Paul Ginsberg, Assistant Professor of Economics and Community Medicine, Michigan State University, Tr. 4641-42; Laura Ann Wilber, Associate Professor of Otorhinolaryngology, Albert Einstein College of Medicine, Yeshiva University, Tr. 1352; Barbara Troup, Clinical Audiologist, Tr. 941-42; Robert Oberhand, Otolaryngologist, Tr. 3041-42; Johnson, Note 36, supra at 4261; Dr. Robert J. Ruben, Professor and Chairman, Department of Othorhinolaryngology, Albert Einstein College of Medicine, Tr. 3978; Dr. David McPherson, Director, New Haven Hearing and Speech Center, Tr. 5113-5115.

89 RPAG, Note 1, supra. The table at end of report lists 12 states requiring medical exams of minors (New York was not included at the time this report was made.) See also Lee Wilson, Clinical Audiologist, President of the Society of Medical Audiologists, Tr. 10037; Helen Kelly, Note 44, supra at 7522-23.

90 See, e.g., Ronald Scheurer, Vice President of Audibel Wholesale, Tr. 11470; Creech, Note 28, supra at 5220; Cooper, Note 52, supra at 10777.

91 See 21 C.F.R. 801.421(a)(1) and (2); 42 Fed. Reg. 9296 to be come effective Aug. 15, 1977.

proposed rule on state and local laws was seldomly addressed.[92] Another factor which tended to minimize objections from state and local officials to the proposed rule was the inclusion in 440.14(d) and (e) of the proposed rule of a detailed statement regarding the extent to which the rule would be interpreted to preempt or supersede state laws or local ordinances. This statement indicates that the rule will be interpreted to preempt state and local actions only to the extent that they may be inconsistent with the rule provisions. The statement then provides that inconsistent state laws which do not furnish a buyer with equal or greater rights than the rule are superseded. It is next provided that though the state laws accord the buyer equal rights and are therefore not superseded, the language, form and manner used to notify the buyer of these rights must be identical to that prescribed in the rule. The statement further provides that state and local authorities may enforce those provisions of state laws or local ordinances to the extent that they have not been superseded by the rule. Finally the statement provides that the rule shall not supersede state or local laws or regulations which more strictly limit the terminology by which hearing aid sellers may legally refer to themselves.

Because Section 440.14(a) exempts sellers who comply with the proposed rule from compliance with the Commission's cooling-off rule,[93] state and local government laws or regulations which mandate some type of cooling-off provision which may be applicable to hearing aid sales are not affected by the rule. In other words, in its present form, the rule would not affect the cooling-off laws of the states.

Several states have recently enacted legislation that provides a purchaser of a hearing aid with the right to cancel the sale and to receive a refund of a portion of the purchase price. In 1976 Kentucky, for example, adopted a measure which would require sellers to include in sales contracts a provision authorizing the buyer to cancel the sale prior to midnight of the 30th day after actual receipt of the hearing aid.[94] In most respects, the Kentucky law tracks fairly closely the provisions of the proposed rule pertaining to the buyer's right to cancel,

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92 Written comments from state and local officials are in Section 6 of the record and amount to slightly more than 450 pages. The majority of these reflect support for the rule. Approximately 14 state and local officials testified at the hearings. They too generally expressed support for the proposed rule.

93 16 C.F.R. 429.

94 Byrne, Note 36, supra at R-10-3061-64.

including the amount of the cancellation charges, using Alternative 1 Section 440.4(g)(1)(i) and (ii).[95] The Kentucky legislation also contains the exceptions found in Section 440.4(i) of the proposed rule.[96] However, the form of notice differs from that prescribed in the proposed rule.[97]

Maine provides a trial period under conditions somewhat different from that included in the proposed rule.[98] In that state, the seller must contact the buyer not less than 20 or more than 35 days after the sale for the purpose of making any adjustment in the fitting or repairs or service without charge. If the buyer at that time expresses his written satisfaction with the aid, the seller may collect any balance due and the sale is final. If not, the buyer may cancel. Thus the buyer may cancel the sale at any time ranging from 20 to 35 days depending upon the date of the seller's contact with him. Upon cancellation, the seller may retain 10% of the purchase price plus the reasonable price of any earmolds.[99] Detailed instructions regarding the form and content of the notice are included in the legislation.[100]

In his comments on the proposed rule, Michael A. Feldman, Assistant Attorney General, Consumer Fraud Division, State of Maine, did not address the preemption question. However, he expresses the view that the notice provision of Section 440.4 was far too complex to be understood by many of the hard of hearing. R-6-31. The proposed rule, if adopted in its present form, would undoubtedly require changes in the regulatory practices of the State of Maine.

In 1975, New York adopted legislation which requires dealers to offer buyers a 30-day money back quarantee. If the consumer returns the aid, the seller may keep a service charge not in excess of 5% of the cost of the hearing aid and accessories.[101]

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95 Byrne, Note 36, supra at Exhibit 57, R-10-3268-71.

96 Id.

97 Id. at R-10-3269.

98 A copy of the bill is included in the record. R-6-35.

99 Id.

100 Id. at R-6-36-37.

101 A copy of this legislation is included in the record. R-6-232-40. The money back quarantee provision is in § 785, paragraph 4. R-6-237.

Presumably the rule would not have too much effect on New York although the form of the notice used in that state might present a problem.

A somewhat similar situation exists with respect to the State of Vermont which enacted legislation in 1975 that requires the seller to refund the full purchase price of the aid, except for the cost of the earmolds and services that must be itemized separately.[102] Again the form of the notice does not conform to that contained in the proposed rule.[103]

By this time, other states may have enacted legislation which accords the buyers of hearing aids the right to cancel the sales and to obtain a refund of all or a portion of the purchase price. It would appear at this point, based on the review of the legislation in the mentioned four states, that all or a portion of any such laws would be superseded by the rule and that substantial changes in the forms of notices used to inform buyers of their rights would be required.

A number of hearing aid dealers who are not audiologists refer to or represent themselves as "hearing aid audiologists," and this is permissible under the laws of some states,[104] although the use by dealers of any term containing the word "audiologist" has been prohibited at least in 23 states.[105] Therefore the definition of the term "audiologist" in Section 440.2(h) of the proposed rule coupled with the provisions of Section 440.8(c) would prohibit the use of the term "hearing aid audiologist" in those states where it is presently permitted. The record does not disclose any material objection to this effect of the rule by state law enforcement officials.

The final provision of the proposed rule which seems most likely to have an effect on state and local laws or regulations is found in Section 440.7 which requires that a seller obtain the prior written consent of a potential buyer prior to visiting the buyer's home or place of business for the purpose of inducing a sale.

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102 18 V.S.A. § 4583, R-6-246.

103 Vermont Health Regulations, Part III, Chapter 3, Section 2. R-6-248-50.

104 See, e.g., Brown, Note 55, supra at R-6-292.

105 ASHA, R-10-1673. See also ASHA rebuttal submission, R-13-D147, Part II, p. 6; James Langford, Associate Professor of Audiology, Northern Illinois University, Tr. 8006-07.

There were several objections to this provision. One was that such detailed regulation was a matter best left to the states.[106] Another was that the requirement that the consent comes from the hearing-impaired person rather than from members of his family or acquaintances was too restrictive. This view was expressed by Jack G. Nelson, Director, Division of Professional Licensing, State of Washington, who said that the rules of his Division permitted direct contact after a bona fide referral. R-6-381.

Some state officials expressed the view that it would work a hardship on the hearing-impaired in rural areas who would otherwise not have access to a hearing aid specialist or other provider of hearing aids.[107]

State officials generally recognized that the prior consent provision accorded consumers protection against high pressure sales tactics in the home and for that reason recommended its adoption. None indicated that it would interfere with the attainment of any important state policy goals.[108] However, some said the prior consent provision was unnecessary if the 3-day cooling-off rule was made applicable to in-home sales of hearing aids or if the other provisions of the proposed rule were enforced.[109]

By way of summary, it can be said that the prior consent provision will provide additional protection to consumers for the majority of the states do not prohibit in-home sales of hearing aids or even regulate the practice specifically. With respect to those states which regulate or otherwise restrict

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106 See, e.g., Robert T. Timmerman, Chairman, Ohio Hearing Aid Dealers and Fitters Licensing Board, R-6-331; Skaarer, Note 9, supra at R-6-24.

107 Harlan S. Cato, Jr., President, North Carolina Hearing Aid Dealers and Fitters Board, R-6-410; Missouri State Senator John C. Ryan, R-6-431; William G. Morris, Chairman, Nevada State Board of Hearing Aid Specialists, R-6-48; Gunter, Note 5, supra at 8202.

108 James V. Guffey, Secretary, North Dakota Department of Commerce and Consumer Affairs, R-6-29; Gunterman, Note 46, supra at 9721-22; John E. Quinn, Superintendent, Department of Business Regulation, Bureau of Consumer Protection, State of Maine, R-6-75-76. Shimanoff, Note 37, supra at R-6-116; Brown, Note 55, supra at R-6-297-98.

109 See J. L. Agnes, Note 9, supra at R-6-195; Brown, Note 37, supra at R-6-209-10; John W. Delaney, Acting Secretary of Consumer Affairs, Commonwealth of Massachusetts, R-6-215; Jefferies, Note 5, supra at 5626, 5592.

outside sales, the proposed rule would, of course, supersede those provisions which do not accord the buyer equal or greater rights.[110]

I. Summary of findings and conclusions.

1. Findings. Forty-one states have incorporated licensing requirements for hearing aid dealers into their state codes. The licensing statues generally include stipulations for gaining licensure, recommendations of penalties for violators and sometimes procedures for filing complaints. The implementation of the provisions of the state codes are charged to the state boards. Board membership consist primarily of hearing aid dealers who generally receive their appointment from the state governor.

In general, the states' requirements for obtaining a hearing aid dealer's license are very similar. Most state codes require that the potential dealer have a high school diploma or its equivalent; that he be of good moral character; that he maintain ethical business practices; that he take and pass the state exam; and that he pay the required fee.

The codes offer some protection to consumers in that minimum requirements must be attained before a person may operate permanently as a hearing aid dealer.

There are provisions in the codes that give consumers the option of appealing to the state boards for reconciliation of disputes involving the hearing aid or hearing aid dealer. Although this avenue is available, few consumers know of its existence; some procedures for filing a complaint tend to inhibit the consumer and the effective resolution of complaints taken to the boards are somewhat limited.

State consumer protection offices and offices of the state attorneys general have to deal with a wide range of consumer complaints. Testimony indicated that violations of state laws by hearing aid dealers must, therefore, become excessive before they can be given a spot at the top of these agencies' priority lists.

Penalties for violation of the state codes by a licensed dealer are very similar in all states and include suspension or revocation of the violator's license. The penalty is harsh but its use has been very restricted.

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110 E.g., New York simply forbids a dealer from canvassing from house to house or by phone for the purpose of selling a hearing aid without prior request from a prospective customer. Elinor Guggenheimer, Commissioner, Department of Consumer Affairs, City of New York, R-6-229; see paragraph 2, § 785 of S. 5314, R-6-237.

Industry's attempts to provide the consumer with protection have been only marginally successful. The certification of dealers by the National Hearing Aid Society provides for very limited screening of potential dispensers. NHAS has set up a 10-week home study course for its members and has recently begun a program of courses to be offered at the university level. The home-study course does not sufficiently cover material essential for the proper fitting of hearing aids.

Certification of dealers by the dealers' organization only accounts for a small percentage of those people actually selling and fitting hearing aids. Any protection certification may afford the consumer is therefore limited to that relatively small percentage of dealers who are certified members of the society.

The NHAS Code of Ethics enumerates the penalties that could be imposed upon members who violate the code but the penalties are weak and like the state penalties for violators, they are seldom enforced.

The industry is attempting to improve it's record in regard to consumer protection by the institution of a four-point consumer protection plan. This plan calls for an upgrading of dealers' education, improved complaint handling procedures, prior medical clearance before sale of an aid and a lax trial-rental option for dealers. This plan has not yet been fully implemented by the industry.

Private measures to provide consumers with adequate protection are very limited. Due to monetary restrictions, lack of enforcement powers and the multiplicity of problems that must be handled, private sources can necessarily provide only a minimal amount of protection.

In its present form, the proposed rule would have minimal effects on the laws and regulations of the states and local jurisdictions. A few of the states have adopted, in a variety of forms, provisions requiring the sellers of a hearing aid to accord the buyer the right to cancel the sale, and to receive a refund of a portion of the purchase price. The proposed rule would require changes in the forms of notice given the buyer respecting the right to cancel in these jurisdictions, and probably would require changes in the computation of the amount a seller might retain if the sale was cancelled by the buyer.

The proposed rule would not affect any valid cooling-off laws of the states or local jurisdictions which accord the buyer a right to cancel an outside sale within 3 or more business days without penalty or fee.

The prior consent provision of the proposed rule in Section 440.7 will operate to reduce outside sales. As discussed in other parts of this report, (see, e.g., Parts III and IX) this will serve to inconvenience those consumers who might desire to shop for hearing aids in their homes. On the other hand, the provision will serve to protect other consumers from the abusive practices which have characterized sales of that type.

2. Conclusions. State codes have been unsuccessful in providing consumers with adequate consumer protection measures. The requirements for licensure in most states are far too lenient to be effective. Control of the state boards by dealers is a major problem in successfully implementing the limited protection measures of the state codes and in effectively handling consumer complaints.

Industry attempts to provide consumer protection have been limited and have more successfully served to protect the dealer members. Private sources are restricted by lack of funding and abundance of workload and can therefore only be considered minimally successful in providing adequate consumer protection. In short, existing consumer protection measures are inadequate to protect purchasers of hearing aids.

Based on analysis of the material contained in the record respecting the effect of the proposed rule on existing state and local actions or regulatory schemes respecting the sale of hearing aids, it must be concluded that adoption of the proposed rule would not interfere with the attainment of any important policy goals of those jurisdictions. It would, and perhaps unnecessarily, require changes in the notices designed to inform buyers of the right to cancel the purchase of a hearing aid provided by state laws.

PART IX. ECONOMIC EFFECT OF THE RULE

A. General discussion. In this part of the report, the potential economic effects of the proposed rule, taking into particular account the effects on small business and consumers, will be assessed. This is the subject matter of Issue 4.[1]

The proposed rule would have an obvious and pervasive economic effect on the hearing aid industry at both the manufacturer and retail levels. It will also have an economic effect on consumers generally and the hard of hearing specifically. Some of these effects will be beneficial while others will be detrimental to a greater degree to some parties than to others.

Typically hearing aids are sold directly by the manufacturer to dealers, clinics, and other dispensers who in turn sell them directly to the consumer.[2] The number of brands which a dealer carries may be limited to those made by only one or two manufacturers or by several manufacturers.[3] Hearing aid manufacturers generally do not engage in the retail sale of hearing aids to the consuming public.[4]

A large number of small manufacturers fabricate a fairly broad range of hearing aid models which are generally sold in small lots. David Barnow, a former officer of Beltone, testified that there are presently about 60 competing hearing aid brands. Tr. 1627. In 1975, approximately 600,000 aids were sold by the manufacturers for an estimated total price of $60 million dollars.[5] Based on information obtained from a small hearing aid manufacturer, Consumers Union estimated that the total manufacturing cost for the average hearing aid was about $75 in 1971.[6]

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1 40 Fed. Reg. 59748.

2 HAIC, R-3-3860.

3 Paul M. Shuford, Counsel, Virginia Hearing Aid Dealers Association, testified that contrary to the former practices more dealers are carrying a number of different lines, Tr. 663.

4 HAIC, R-3-3860.

5 Id. at R-3-3860-61. According to allegations in recent complaints issued by the Commission against hearing aid manufacturers based on 1970 figures, the top four companies accounted for 50% of the dollar value of shipments; the top eight for 70% and the top 20 for over 90% of industry shipments. See, e.g., Paragraph Six of the Complaint in Radioear Corporation, C-2419, R-13-342.

6 Hearing Aids, (Consumers Union Reprint, 1971), R-8-D228-6.

The charges of manufacturers for refurbishing aids which have been used during a trial rental period and returned to the seller vary, as do the charges for replacing such aids with a new aid. John Fennema, a Maryland dealer, reported that most of the manufacturers with whom he traded were willing to accept the returned aids and most of them did not charge him anything for refurbishing. Tr. 1749. Otto Butz, another dealer, agreed that most manufacturers make no charges for returns but that some other manufacturers charge varying amounts up to $45. Tr. 6622, 6638, 6644, 6651. In one of its submissions Dahlberg, a manufacturer, reported that a dealer could receive a new replacement aid for $25 or have the used aid reconditioned and returned without charge. R-8-1974-75. Zenith also makes no charge for reconditioning but charges 15% of the original price for a replacement aid. R-8-1947.

Distribution channels for hearing aids have increased over the years with the opening of retail outlets in chain stores such as Sears and Montgomery Ward, and with the entrance of audiologists into the practice of fitting and distributing hearing aids. It is now estimated that there are over 6,000 retail dealer outlets in the United States. Over 3,600 of these dealers are members of the NHAS,[7] and presumably they accord prospective purchasers the right to enter into a trial rental arrangement before purchasing a hearing aid.[8]

Data submitted by NHAS in its written comment show that the typical hearing aid dealer is a male, approximately 50 years old, who earns about $16,350 and who has been in business for about 13.5 years. He owns his own business employing 2.5 persons, in a downtown location of a city having over 100,000 population. R-3-3695.

According to other information provided in the NHAS comment, the average wholesale price of a hearing aid, plus postage and handling charges, accounts for 37% of the retail sales price. Business expenses including warranty service and general overhead, account for 37.7%, hospital and home calls 6%, and profit 16.25%. R-3-3697. However, in his testimony, Luke Fortner, President of the National Hearing Aid Society, said that the distribution of the selling price is as follows: one-third for hardware, one-third for overhead, and one-third for personnel with the average dealer realizing less than 6% profit, and in some cases, less than 1% profit. Tr. 2863.

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[7] See NHAS, R-3-3521.

[8] Id. at R-3-3540.

Other evidence in the record confirms the fact that the average price of a hearing aid to a dealer is about $100 while the same aid is sold to the consumer for about $350.[9] The average dealer sells approximately 100 hearing aids per year; however, a high-volume dealer generally sells over 500 units annually while the typical small dealership sells only 85.[10]

Some audiologists dispense hearing aids thereby making it unnecessary for a consumer to visit a hearing aid dealer. The dispensing audiologist sells the hearing aid at cost and makes separate charges for his examination, testing, and counseling under the heading of "professional fees." Assuming that a satisfactory aid is obtained, the ultimate costs to the consumer are not much different regardless of the route he takes to obtain his hearing aid.[11] For example, Jane Madell, Director of Audiology at the New York League for the Hard of Hearing, testified that professional service ordinarily totalled about $100, plus a $98 dispensing fee plus an assumed cost of $180 for the hearing aid for a total of $378. If the least expensive aid were used, the costs would be decreased to $278. Tr. 5895-96.

Of course, if a dealer restricts his sales to those who are referred from audiological clinics or from otologists, it would be possible for him to sell hearing aids to consumers for much lower prices and yet realize a profit. For example, John Kuptz, the owner of Master Plan Service of Chicago, reported reductions of 30% to 50% in his prices. Tr. 5642, and noted that other big Chicago dealers were competitively meeting his prices with sales to this type of referral patient. Tr. 5652. Audiologists confirmed reports that dealers do not charge the full or suggested

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[9] John Kojis, President, Maico Hearing Instrument Company, Tr. 1967; W.F.S. Hopmeier, a hearing aid dealer said that some aids sell for as little as $200 with others listing at $435, with the bulk of the individual sales falling in the $375 to $425 category, HX-51, p. 4. Myron M. Samole, Executive Vice President, Fidelity Electronics, Ltd., testified that the wholesale price of hearing aids ranged from $60 to $195, Tr. 6676.

[10] See Hearing Aids and the Hearing Aid Industry in Minnesota, MPIRG Report, November 1972, R-8-D229-15-16; John Fennema, Maryland Hearing Aid Service, Tr. 1744.

[11] See, e.g., Thomas W. Norris, Director, Division of Audiology and Speech Pathology at University of Nebraska Medical Center, Tr. 6865.

retail price to consumers who are referred to them with a recommendation for the purchase of a hearing aid.[12]

Based on the foregoing brief overview of the structure and general business practices of the industry, it is possible to identify those provisions of the proposed rule which may be expected to have an economic impact on dealers, manufacturers, and upon consumers as well.

The proposed rule contains a number of provisions which impose constraints on the advertising practices of hearing aid sellers. These include prohibited representations concerning the hearing aid sellers themselves (Section 440.8); prohibited representations concerning hearing aids (Section 440.9); and a list of advertising representations that must be qualified or accompanied by disclosures (Sections 440.10, 440.11 and 440.7). Since many of these representations may be made directly by means other than advertising, as that term is defined in Section 440.3(g) of the proposed rule, the mentioned provisions also serve to constrain or restrict the selling techniques of many hearing aid sellers.

Section 440.4 requires the seller to accord the buyer the right to cancel the sale. Section 440.5 imposes certain requirements on leases and rentals for periods of 30 days or less. The specific subject of selling techniques is addressed in Section 440.7. The most important provision of this section is in paragraph (b) wherein a seller is prohibited from visiting the home or place of business of a prospective buyer without having obtained the prior written consent of the buyer. This consent must include a notification that the seller may attempt to sell a hearing aid during the course of such a visit.

All of the foregoing rule provisions have been considered in some detail in the preceding parts of this report as they fall within the purview of one or more of the designated issues. Therefore, in this part of the report an effort will be made to restrict the discussion, findings, and conclusions to the probable economic effect of those provisions. It should be added that the compliance provision of the proposed rule (Sections 440.12 and 440.13) that require a seller to take measures designed to insure that its employees comply with the rule and impose recordkeeping requirements will undoubtedly result in some increased costs for sellers and that these costs will be passed on to consumers. The record does not contain sufficient detail to enable one to predict the magnitude of those costs. It does not appear that

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12 See, e.g., Dr. John R. Franks, Assistant Professor of Audiology, Arizona State University, who said referrals from his clinic are routinely given a 15% discount, Tr. 9812; Dr. David M. Resnick, R-10-515.

these provisions are unreasonable or that these costs will be significant in the light of the recordkeeping requirements for retail business generally. The relatively small number of sales of hearing aids by the average dealer is also a significant factor in minimizing these costs.

The general economic effect of the advertising and selling constraints upon manufacturers, hearing aid dealers, and consumers are discussed in that order in the sections which follow.

E. Economic effect on manufacturers. Members of the Hearing Aid Industry Conference summarized their predictions of the economic effect of the rule as follows:

> . . . [T]he economic impact of the rule would be higher costs, higher prices, increased concentration in the manufacture of hearing aids and a marked decrease in the ability of the industry to invest in necessary research and development, community services and to continue to efficiently serve the hearing impaired at the lowest possible cost.[13]

Basically the thrust of the HAIC prediction is that the rule will result in decreased sales of hearing aids thereby resulting in the consequences outlined in the summation quoted above.

In specifically addressing the requirements for affirmative advertising disclosures, HAIC said that statements containing the required information will discourage the hearing impaired from seeking help, not only because the advertising will not in itself be persuasive but also because the requirements will result in manufacturers' curtailing their advertising. R-3-3983. In particularly discussing the effect of the Section 440.10 advertising disclosure which requires the statement (in conjunction with claims) that "many persons with a hearing loss will not receive any significant benefit from any hearing aid," Ansel Keliman, President, Telex Communications, Inc., noted that when his company incorporated a similar disclosure in their advertising in compliance with a 1971 FTC consent order,[14] the efficacy of their advertising fell so dramatically that the company discontinued all consumer advertising during the following 12 to 18 months. Tr. 6912.

Again addressing the rule's effect on advertising, one expert said the disclosure requirements would result in increased advertising costs. While in most cases advertising reduces the cost

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[13] HAIC, R-3-3989.

[14] The Telex Corporation, 79 FTC 61, 66 (1971).

of the product due to increased sales, the rule would reverse this process. Specifically, the size of advertisements would have to be increased to provide room for the disclaimers resulting in higher costs, and these increased costs would be passed on to the consumer through higher prices for hearing aids, if the firm intends to stay in business. She went on to say that the impact would be particularly important in the hearing aid industry where it is already more costly to reach the hearing-impaired consumer--a very select audience. Advertisements containing such disclosures would tend to discourage this frequently hesitant consumer even more from seeking assistance. If this turns out to be the case, she will recommend to her advertising clients that, if they are required to spend their advertising dollars in telling potential customers that their products won't help them, then they should skip advertising altogether.[15]

John Kojis, President of Maico Hearing Instrument Company, said that the responsibility placed on manufacturers for "co-op advertising" which might violate rule provisions would be impossible to live with and would result in the industry's halting this form of advertising. Tr. 1985.

In short the manufacturers say that restrictions on advertising will result in reduced advertising, less effective advertising, and fewer sales of hearing aids.[16]

HAIC was also disturbed about the effect of the provision that would require prior written consent for house calls to be made by dealers. R-3-3983. It said that such a provision will discourage such calls by dealers and will deter many from making them in the future. R-3-3984. One industry representative estimated that this provision alone would result in a reduction of 90% in home sales.[17]

The biggest concern of the manufacturers with respect to the economic impact of the proposed rule is the potential effect of the buyer's right to cancel. HAIC pointed out in its written

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15 Ruth Lesko, President, Lesko, Inc., an agency used by Radioear Corporation, Tr. 7197-98. This testimony was supported by that of Richard Fechheimer, Senior Vice President, Grey-North Advertising, Inc., an agency used by Beltone, Tr. 6968, 6970, 7010; See also James H. Johnson on behalf of HAIC, Tr. 2298.

16 HAIC R-3-3983. Lesko, Note 15, supra at 7202-04.

17 Myron M. Samole, Note 9, supra at 6660, 6716. Others shared the view that the provision would sharply decrease home sales. See, e.g., John Kojis, Note 9 supra at 1981-82; see generally Section 3 of the record.

comment that only a slight decrease in sales could have a measurable impact on the unit cost of production, and it predicts that the negative impact of the buyer's right to cancel on consumers' minds will have this result. R-3-3981, 3986. The right to cancel will also result in increased numbers of returns of hearing aids which have been tried out but not purchased by consumers. These "returned" aids will have to be tested by the manufacturer in order to ascertain if they are in proper working order and any troubles found will have to be corrected necessitating in some instances replacement of internal parts or external cases. Then the returned aids must be suitably marked and placed in the distribution channels a second time. HAIC estimates that these refurbishing activities will more than double the initial cost of producing the aid, and on top of this the reconditioned aid will then have to be sold at a reduced price, providing less revenue than would be obtained from the sale of a much less costly new aid. R-3-3986-87.

HAIC goes on to express the fear that the predicted decline in sales accompanied by increased costs will particularly weaken the position of small or marginal manufacturers making it impossible for them to remain in business; the end result of their disappearance then will be an increased concentration of the industry in the hands of fewer business concerns. R-3-3987-88.

Robert Baesemann, an economist,[18] testified in support of the HAIC position. He predicted that the ultimate costs of the right to cancel would be assumed primarily by manufacturers due to their larger sizes, as opposed to the size of retail dealers. Thus the manufacturers may be expected to "buy" back the returned aids from dealers at a compensatory price that will operate to eventually increase the overall cost of all aids to the dealers in the process. Tr. 7318-21.

Dr. Baesemann said that, if there is a viable market for used aids, the cost of such returns to the manufacturer would be equal to the cost of production, plus the cost of refurbishing the return, plus the distribution costs of both these operations. The net cost then would be the gross cost less the price the used aid brings on the market. However, if the aid could not be sold, as he predicts will be the case, the manufacturer will simply dispose of it without attempting to recondition it or to sell it a second time. In that event the cost of the return to the manufacturer will be the wholesale cost of the aid. R-10-5148. As this is what is likely to occur and, as the charges paid by the consumer for the privilege of returning the aid will not pay

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18 Ph.D., Assistant Professor of Economics, Graduate School of Management, Northwestern University, Tr. 7316-7422. Dr. Baesemann's prepared statement is included in the record as Document 104D in § 10 at pp. 5146-56.

the full cost of the return, the balance of such cost will be treated as a "selling cost," which will increase with volume and be ultimately distributed over the entire user population. R-10-5149.

Dr. Baesemann predicted that the foregoing process will operate to raise increased barriers to entry into the industry as existing dealers and manufacturers will necessarily establish closer ties in order to minimize the costs of returns; at the same time, dealers will tend to reduce the number of lines they carry in order to also reduce the number of return arrangements they must maintain to satisfy the individual requirements of different manufacturers. Thus a new or smaller manufacturer will find it difficult to place his products with dealers. R-10-5150-51.

A second consequence of the rule's operation he said, would be the creation of additional uncertainties in the industry resulting from the existence of and potential use by customers of the right to cancel. These uncertainties will cause all firms to reduce output in order to lessen their exposure to such additional risks--the more aids they sell the greater the return risk to them. This output reduction will serve to diminish the supply of hearing aids and increase costs accordingly. R-10-5150. As small firms will presumably be more negatively impacted by such risks than the larger firms will be, they will thus tend to decrease their sales and attendant production to a greater degree than will the large firms--this too will serve to produce increased market concentration and a rise in prices. R-10-5152.

A somewhat different view of the probable economic effects of the buyer's right to cancel was offered by Dennis Murphy, Ph.D., an FTC Staff Economist, in a written rebuttal statement. R-13-2060-73. Dr. Murphy agreed that the cancellation privilege may increase producer costs and ultimately prices also, but this requires one to assume that the dealers will not be able to sell the used (returned, refurbished) aids, that the demand for hearing aids will not increase in the future, and that manufacturers and dealers will not alter their marketing practices. Dr. Murphy did not agree with the pessimistic predictions. R-13-2062. Neither did he think that smaller firms would decrease production in order to protect themselves from random revenue losses. He said that small firms could expect larger returns during certain periods, but that these would be countered by periods during which returns would be relatively low. He does not believe that economic theory is developed to the point that would permit the confident prediction of small firms' reaction to the rule's operation in the manner suggested by Dr. Baesemann. He would expect instead that the manufacturers who do not now offer return privileges would be compelled to do so but that, at the same time, they would increase their efforts to insure that hearing aids were sold only to those persons most likely to benefit from amplification under normal and actual conditions of use. Such efforts might well include the tempering of their currently-used promotional claims in an

attempt to prevent consumers from forming unwarranted expectations and an increase in the supervision of the sales practices of their dealers. R-13-2064.

Dr. Murphy also did not agree with Dr. Baesemann's assumption that the used hearing aid market would be saturated by the increased supply of returned aids. He accepted the industry's assumption that the average age of hearing aids at the time of trade-in is 3.2 years[19], but he said it would be unlikely that a consumer would value such an aid as highly as a modern reconditioned aid which had been used for only 30 days or less. He pointed to other evidence in the record which indicated that only a slight effort has been made to develop a used hearing aid market.[20] R-13-206.

To counter Dr. Baesemann's predictions regarding the return privilege's potential effect on new or small manufacturers, Dr. Murphy pointed to the example set by Starkey Laboratories which though a relatively new entrant into the manufacturing sector of the industry according to Dr. Baesemann, now has 2,000 dealers. Tr. 7317. Starkey has been able to garner a 2% market share for itself and, for several years now has offered a 60-day trial period, with satisfaction guaranteed, at no cost to the customer. R-13-2065, 2074. Ralph Campagna, President, RCI, Inc., noted that custom earmold, all-in-the-ear hearing aids are offered on a 30-day trial basis by most manufacturers. Tr. 2658.

Dr. Murphy also disputed the practical significance of the costs and procedural difficulties a dealer might have in returning an aid to the manufacturer at the conclusion of an unsuccessful trial period. These would be unlikely to be serious obstacles, he said, as manufacturers would minimize dealers' problems while

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19 Statistics set forth in the National Hearing Aid Journal show that the average hearing aid user trades for a newer model at intervals of 3.4 years, R-10-6434.

20 John Fennema, a Maryland dealer suggested that a market for used aids could be developed by offering them at a discount of about $50, Tr. 1749; The Minnesota Hearing Aid Society reported that 27% of the consumers surveyed reported a willingness to buy a reconditioned hearing aid, R-8-1310; See also letter from Joseph B. Chaiklin, Professor of Audiology, University of Minnesota, R-8-3647.

Dr. William Lentz, in a rebuttal submission said that the contention that there was not a market for used hearing aids was without foundation. He said the many requests to dealers for used aids for persons who could not afford new ones exceeded the supply, R-13-1972.

it must be remembered that we are talking about the return of perhaps 4 or 5 aids a month. R-13-2067. It might be added that none of the dealers who testified at the hearings complained of any procedural difficulties they have had in returning hearing aids to manufacturers.

Perhaps the best rebuttal to the claims that the proposed rule will result in fewer sales and will have dire economic effects on manufacturers lies in the fact that there are vast numbers of the hard of hearing who are capable of wearing hearing aids and of receiving significant benefits from them but do not as yet have them.[21] In other words, there is a potential demand for hearing aids that far exceeds the numbers presently being manufactured and sold. While fair and nondeceptive advertising might make it somewhat more difficult to reach this group of persons than would be true if the type of misleading and deceptive advertising described and depicted in this record were used,[22] the potential market is there and should be developed. A second rebuttal point is provided by the evidence in the record which indicates that the offering of a trial rental period--the equivalent in most respects to the buyer's right to cancel--has previously resulted in increased sales and is considered a successful marketing technique by those who have used it.[23]

More realistic advertising should have the effect of making it more likely that consumers will accept the limited benefits which amplification can provide. Certainly, if the purchased hearing aid does not provide the benefits claimed in the advertising, the consumer will not be satisfied with the device and will be more inclined to return it.[24] Using statistics provided by HAIC, those consumers who are examined by audiologists prior to fitting and purchase, or whose dealers provide them with trial rental periods may be expected to have a return rate of only 4.5% (median rate for all returns estimated by 26 witnesses).[25] If the

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21 See, e.g., David Barnow, a former Beltone official and former president of HAIC, who said that fully 75% of the hard of hearing are in hiding, Tr. 1631.

22 See, e.g., Leonard W. Finkel, Legal Research & Services for the Elderly, Tr. 4445-46; see also Part III of this report.

23 John J. Fennema, Note 10, supra at 1747.

24 See, e.g., Mary Burke, audiologist, Tr. 6409, 6414.

25 See HAIC rebuttal submission, affidavit of Eleanor Goddard May, Associate Professor of Business Administration, Colgate Darden Graduate School of Business Administration, University of Virginia, R-13-2227.

rule results in more careful and appropriate fittings and a cessation of the unfair and deceptive sales and advertising practices documented in the record, it would not be unreasonable to expect that this type of median would be experienced by most manufacturers with respect to cancellations. Such a rate of return is not large enough to impose an economic hardship on manufacturers of hearing aids.

C. Economic effect on dealers. The provisions of the proposed rule which seem most likely to have an economic impact on hearing aid dealers are the same as those identified in the preceding section as having an economic impact on manufacturers. Like the latter group, retailers see the proposed rule's effects as including reductions in sales, increasing costs, and eventually higher charges for hearing aids.[26] Particular concern was expressed over the provisions which would require prior written consent for visits to the potential customer's home and which would provide the buyer's right to cancel.[27]

The various advertising restrictions that would be imposed by the rule are objectionable to the dealers because of their anticipated limitations upon advertising in general and upon comparative advertising in particular. These limitations, they say, will restrict competition and reduce the ability of dealers to provide consumers with the information required to make an intelligent purchasing selection from among the many hearing aids available on the market. They add that the rule provisions will actually provide an economic disincentive to technological development.[28]

The prior written consent provision for home-sales visits is objectionable to dealers as they believe it will discourage the activities of those hearing aid specialists who are willing to provide "in-home" services. These services are said to be of particular benefit to the elderly and to those who do not have ready access to transportation.[29] Some hearing aid dealers report that they make only a few house calls, and these are always made in response to invitations, primarily to assist the sick or shut-ins.[30]

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26 NHAS, R-3-3688-89.

27 Id. at R-3-3585-90 and R-3-3688-94.

28 Id. at R-3-3621-29.

29 Paul Burris, Manager, Professional Services, Dahlberg Electronics, Tr. 2499.

30 See, e.g., Otto Butz, Tr. 6623, 6630; Fennema, Note 10, supra at 1753; John H. Payne, Tr. 9227.

In discussing the activities of one of his employees who operates in rural Illinois and who makes home calls, W.F.S. Hopmeier said that all such calls were arranged by prior telephone contact and invitation. He reported that the requirement of prior written consent would impose an unnecessary encumbrance upon home-sales operations and would impede the rendering of services to the hard of hearing in rural settings. Tr. 3340-41. Mr. Hopmeier noted that the gross 1975 sales of the individual whose operation he described was only $25,000 while the employee's earnings amounted to only $6,417 before taxes. HX-51, p. 6.

Another dealer, DuWayne Tremmel, said that he announced prospective visits to homes by means of letters stating that he would be in the prospective customer's vicinity on a certain date and expected to stop by the home at a stated time to discuss the individual's hearing needs. He did not consider such calls to be unannounced (Tr. 8355) but he felt that requiring advanced written consent to make such visits would pose problems for both consumers and dealers. Tr. 8359. He noted that the provision would result in fewer calls in a given locality thus increasing the cost of calls that are made, and probably also making it necessary for a reduction in his staff. Tr. 8359.

Serious concern about the effect of the prior consent provision was voiced also by Neil H. Offen, Senior Vice President and Legal Counsel, Direct Selling Association. After stating that his Association included no members of the hearing aid industry and that the dollar amounts of in-home hearing aid sales were insignificant, (Tr. 1480), Mr. Offen said that the practical problems involved in actually obtaining written consent would result in considerable expenditures of time and resources, (Tr. 1515), and reduce the number of sales contacts and demonstrations outside fixed business locations. The result would be reduced sales and less competition. Tr. 1483.

It is appropriate to note that the recent FDA hearing aid regulation prohibits dispensers from selling hearing aids unless the prospective users present statements from licensed physicians indicating that their hearing losses have been medically evaluated and that they are candidates for amplification.[31] Although this requirement may be waived by patients who are 18 years of age or older,[32] it can be expected to have a considerable effect upon unannounced and surprise sales presentations of hearing aids in the home. Presumably the dealer would first have to arrange for the patient to receive a medical evaluation before he could finalize the sale. Together the advance consent provision of the proposed rule and the FDA regulation can be reasonably expected to

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31 21 C.F.R. 801.421(a)(1), 42 Fed. Reg. 9296.

32 Id. at 801.421(a)(2).

produce a considerable decrease in the numbers of in-home sales of hearing aids.

A significant reduction in the sales of hearing aids outside the seller's place of business would have a serious impact on those manufacturers and their associated dealers who currently make a large number of such sales. For example, evidence in the record indicates that out of Beltone's 1972 sales, 64% were "outside" sales; in 1973, the figure was 61.6%; and in 1974, it was 60%.[33] Another company informed its dealers that 75% of their sales would be made outside their places of business.[34]

Like the manufacturers, the dealers see the provision of a buyer's right to cancel as having the most serious impact upon them. NHAS said in its comments that the overall effect of the right to cancel would be to raise the price of hearing aids and related services, impair the quality of the delivery system, and promote economic concentration in the retail sales market R-3-3694.

The reduction in sales will result in part from the psychological problems experienced by the characteristics of the hard of hearing. The availability of an absolute right to cancel will foster indecision, will encourage those who could benefit from hearing aids to forego rehabilitation efforts, and will cause them "to flee from all help" that could be provided by amplification and lapse back into the "false comfort" of their disability. R-3-3687-88. To guard against the expenses entailed in frequent cancellations which may occur, the seller will have to raise prices in order to provide a cushion or protective buffer for himself since the proposed cancellation charges will not adequately compensate him for the increased costs or lost profits. R-3-3688-89.

The dealers do not believe that they will be able to sell a significant number of used hearing aids and that, as a consequence, many of the returned devices will remain unsold. Even those dealers who may be able to sell returned aids must expect that the profit from such sales will be less than from sales of new aids. R-3-3689-90.

NHAS points out that dealers' selling and overhead expenses vary with the volume of their respective businesses. Based on one survey, the Michigan State Auditor found that, for dealers who sell less than 125 aids, these expenses amount to $80 per unit. For dealers selling 125-300 aids, such expenses amounted to $119.15 per unit.

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[33] See Staff rebuttal submission, R-13-2034.

[34] See Staff rebuttal submission, R-13-1145-46.

The range of gross profits varied from $139.35 to $277.96.[35] Because of such differences, some dealers will be forced to raise their prices.

The dealers who are inadequately compensated by the cancellation charges provided in the rule section and who cannot, for competitive reasons pass their increased costs on to their customers, will be forced out of business. This, it is said, will result in increased economic concentration in the marketplace and in reduced price competition. R-3-3691.

At present many dealers include the costs of counseling and other services in the price of the hearing aid. It is predicted that the proposed rule will force some of these dealers to state these charges separately and this, too, will result in higher costs. The right to cancel will also encourage dealers, in a cost saving measure, to reduce the risk of loss involved with patients who show some adjustment difficulties by limiting the time they spend with such individuals. They may also attempt to avoid making sales to those who seem to present a greater than average risk. R-3-3691-92.

NHAS thought that the emphasis on the right to cancel also would tend to penalize reputable dealers who render competent counseling services to their customers while tending to reward those dealers who seek final sales at one-time meetings. The right to cancel would also cause increased emphasis to be placed on high volumes of one-time product sales and less emphasis upon counseling and repeat business from satisfied consumers. R-3-3693.

The foregoing predictions of NHAS were sharply challenged by other participants in the proceeding. In a written submission on behalf of the National Council of Senior Citizens, David M. Resnick, pointed out that dealers often charge the same markup when the purchaser buys one or two aids when it seems obvious that two aids would not require twice as much counseling or instructions as one would. He suspects that the real reason dealers currently lump all of the costs into the price of the hearing aid is to conceal the fact that the counseling and after-sale services do not amount to much. R-10-510. Indeed, it is clear from many of the consumer complaints in section four of the written record that too often such after-sales services are a fiction.

Paul B. Ginsburg, an economist, also did not agree with the NHAS predictions. He thought that the dealers who will be hurt by the right to cancel are those who do not offer trial return privileges at the present time and who will lose the profits they once gained through their exclusive franchises, buyer ignorance and the like. Tr. 4630-31. He said that dealers will still be permitted to profit under the proposed rule on the sale of

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35 NHAS, R-3-3690, n.160.

batteries and earmolds. Therefore, the only loss to them would be costs which appear not to be covered by the cancellation charge. These would include some labor, the inventory carrying charge of about 1% per month, and the cost discount allowed when the used aid is sold. Professor Ginsburg said that it should be remembered that in many cases the manufacturer is willing to pay the cost of refurbishing the aid so the dealer will be left only to recoup the discount, and, the rental fee would seem sufficient to cover this. In his area, the discount on the sale of a used aid amounted to about $25. Tr. 4630-32.

The American Speech and Hearing Association also questioned the costs which dealers typically cited in justification of a 200-400% markup. R-10-1692. It said that free service calls and free hearing tests are a myth and that Section 440.7(d) of the rule would prohibit the future use of such spurious representations. Specifically, it noted that many dealers offer discounts of about $50 to buyers referred by physicians or audiologists. This suggests that dealers are charging about $50 for the "free" hearing tests and home visits. R-10-1693. ASHA also said that the actual economic effect of the rule, taking into account these and other circumstances, would be minimal, and that claims that the rule would put the dealer out of business cannot be sustained. R-10-1696.

Industry representatives also predicted that the right to cancel would encourage dealers to carry only one line of hearing aids in order to minimize problems associated with returns--the multi-line dealer would incur greater costs than would a single line dealer.[36]

The likelihood that the buyer's right to cancel would result in decreased sales was disputed by those who contended it would actually result in increased sales. For example, Dr. Earl R. Harford testified that after his clinic adopted a trial policy, more aids were sold as the clinic personnel became more liberal in recommending that persons try hearing aids.[37]

Despite the industry contentions to the contrary, the buyer's right to cancel provision in the proposed rule differs little from the trial rental period already offered by so many dealers, either on their own initiative or because of pressure upon them from audiologists and otologists who refer patients to them for

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36 See, e.g., Robert Briskey, Beltone Electronics Corporation, Tr. 7331-32.

37 Professor of Audiology and Director, Division of Hearing and Speech Sciences, Vanderbilt University Medical School, Tr. 150.

fittings. As these dealers did not report that the trial rental period has had an adverse economic effect upon them, and as some have actually experienced increases in their sales, the record does not support the conclusion that the buyer's right to cancel would have an adverse effect on hearing aid dealers generally.[38] However, in the case of the dealer who uses high-pressure tactics, who does not properly fit his customers, or who fits his customers with aids they do not need, there seems to be little doubt that the buyer's right to cancel will operate to his economic prejudice.

The belief that the cancellation right will encourage high-pressure selling, reduce counseling efforts, and cause dealers to reject doubtful candidates is suspect. In fact, it would seem much more likely that a dealer would exercise greater care in fitting a customer, would seek to become more effective in giving the necessary instructions and counseling on use techniques in order to preserve his sales, and would thereby encourage the buyer not to exercise his right to cancel. It should be noted that Section 440.6 of the rule would permit the dealer to extend the trial if he wishes to do so.

D. Economic effect on consumers. To the extent that the proposed rule will cause a cessation of the deceptive and unfair practices now used by certain industry members to sell unnecessary or inappropriate hearing aids to consumers, it will provide consumers with significant economic benefits. In the absence of detailed statistics which would permit one to assess the number of sales attributable to such practices, it is impossible to quantify a dollar estimate of the savings that will be afforded. Nevertheless, the record in this proceeding shows that a significant number of such abuses occur, and that a significant number of consumers are sold hearing aids from which they do not derive any significant benefit.[39] It follows that the rule will have a substantial and favorable economic effect on those consumers.

Two provisions of the proposed rule seem to have the greatest potential for favorable economic impact on consumers generally. These require prior consent for calls to be made in the

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38 John J. Fennema Note 10, supra at 1747; John Kuptz, Tr. 5642; Otto Butz, Note 30, supra at 6621.

39 See, e.g., J. Schein, and M. Delk, The Deaf Population of the United States. Silver Spring, Maryland: National Association of the Deaf in Cooperation with the Deafness Research and Training Center, New York University, 1974, Table VII.5, p. 121 (ASHA, R-10-D-57-Exh. No. 9).

home or outside the seller's place of business and the provision of a buyer's right to cancel hearing aid sales. They will be discussed in that order.

In theory at least, the consumer receives an economic benefit when a seller visits his home and fits a hearing aid there since it makes it unnecessary for him to undertake a trip or trips to the seller's place of business. The economic benefit lies in the savings in time and transportation costs for the consumer, and indeed it may even be impractical or impossible for a consumer to make such a trip at all.[40] Therefore, if the proposed rule provision makes it impracticable for sellers to make such visits, certain consumers will be deprived of this economic benefit. This is unlikely to occur, however, since many sellers apparently do not solicit business which requires outside calls, but will pay such visits to a home or hospital only upon request.[41]

The foregoing economic benefit must be also balanced against the detriments of many of the in-home sales of hearing aids which are characterized by high-pressure tactics, and which often result in the consumer's purchase of an unnecessary or improper hearing aid.[42] To the extent that the rule provision would inhibit or prevent sales of this nature, the consumer who might otherwise be victimized by this sort of transaction will benefit. In short, the consumer who wants a dealer to visit his home can issue an invitation to that dealer to do so, and probably it will be accepted. The consumer who does not want a dealer to visit his home and does not want to be subjected to the sales tactics that are frequently incident to such visits, can simply refuse to sign the prior consent without being subjected to the embarrassment of turning the dealer away at the door.

Thus the buyer's right to cancel provision has perhaps the greatest potential of providing consumers with a significant economic benefit. The fact that this benefit may be realized only at a price, i.e., some slight additional cost for hearing aids and services relating to the selection and fitting of such devices, is not a sufficient reason to forego this important benefit.

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40 DuWayne Tremmel, a hearing aid dealer, Tr. 8320; NHAS, R-3-3585-87; Paul Burris, Manager, Professional Services, Dahlberg Electronics, Tr. 2499.

41 DuWayne Tremmel, id.; John H. Payne, Note 30, supra at 9227; John J. Fennema, Note 10, supra at 1788.

42 See generally Part III of this report. See also ASHA, R-10-1631-34.

The purchase of a hearing aid involves a substantial financial commitment on the consumer's part. The approximate average hearing aid cost of $350 is the equivalent of more than 1.4 times the monthly income of one-half of those over-65 persons who live alone or with nonrelatives.[43] Unfortunately, the purchaser of a hearing aid does not fully realize the difficulty of determining, prior to the purchase, whether or not the aid will provide him with the benefits he expects. He is, in effect, gambling a relatively large sum of money in the hope that the device will actually improve his ability to hear.[44]

The amounts of consumer expenditures for hearing aids, using the 600,000 production figures provided by HAIC[45] and the average cost of $350,[46] exceeds $210,000,000. Again, using the estimated 4.5% return median provided by an HAIC witness,[47] the consumer losses, assuming no right of return privilege is afforded, would amount to $9,450,000 per annum. It must be recalled, too, that the median figure of these returns is based on returns by those customers who presumably had been subjected to fairly comprehensive audiological examinations prior to their purchases of hearing aids. In addition, it must be kept in mind that many of these purchasers did have the right to return their aids and receive refunds therefore under the trial rental plans offered by some dealers; however, these figures do not include the unknown numbers of consumers who purchased their aids from dealers who offered no right of return or from dealers who sold them aids they did not need or from which they received no significant benefits. Taken together and in the light of these considerations, it is reasonable to assume that consumers have spent many millions of dollars for hearing aids that did them no good and for which they could not get purchase price refunds. The buyer's right to cancel would thus afforded a great number of consumers with the opportunity of restricting this kind of loss, incident to the purchase of a useless hearing aid, to the amount of the cancellation charges authorized by the rule, or, approximately $60 per hearing aid. Assuming the 4.5% return rate is appropriate, the savings to consumers would be $9,450,000 minus $27,000 (representing the cost to consumers of the returned aids) or $9,423,000. These savings

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43 Paul B. Ginsburg, on behalf of National Council of Senior Citizens, R-10-429-30.

44 Id.

45 See Notes 4 and 5 supra.

46 See Note 9, supra.

47 See Eleanor Goddard May, Note 25, supra at R-13-D93-5.

are so great that they overwhelmingly outweigh the possible losses to consumers resulting from increases in the price of hearing aids and accompanying services.

It is indeed probable that the right to cancel will have even a more far reaching economic impact than can precisely be predicted at this time. It may cause a substantial change in the current system of hearing aid delivery. The right to cancel will lessen any incentive a dealer may have to sell unnecessary hearing aids or to be careless in the fitting of aids, for he may expect to have them returned if he errs in these respects. Thus if the dealer exercises greater care in the dispensing of aids, the overall return rate may fall below the currently suggested median of 4.5%. There are many consumers who can benefit from the use of a hearing aid and many of these will present no unusual adjustment problems provided they are fitted with appropriate instruments in the proper ear. It is the group which would seem to offer the greatest opportunity for the dealer to reduce his return rate through proper fitting.

There is also the possibility that the right to cancel will encourage dealers to refer more of their potential customers to physicians or audiologists for prefitting examinations and evaluations, or to even refuse to fit persons who have not previously undergone these procedures. This, too, should have a considerable impact on the return rate and provide a corresponding economic benefit to consumers as it would serve to screen out those who simply cannot, for one reason or another, receive a significant benefit from a hearing aid.

E. Summary of findings and conclusions.

1. Findings. The evidence in the record shows that the proposed rule will have important economic effects on the hearing aid delivery system. These effects will be felt by hearing aid manufacturers, dealers, audiologists, physicians, and consumers. As might be expected, such effects will be considered to be favorable in some respects and objectionable in others, depending upon the views of recipients of those effects.

In 1975 approximately 600,000 hearing aids were sold to dealers at an average unit cost of approximately $100; these in turn were sold to consumers at an average unit price of $350. Most manufacturers have made provisions for the return of aids used in the trial rental programs which are now offered by many dealers, and will either replace such aids with new devices at a relatively nominal charge or will recondition the returned aids for the dealer at no additional charge.

The average hearing aid dealer sells about 100 aids per year, with higher volume outlets selling around 500 units or more. Dealers who restrict their sales to customers who have been previously examined by physicians or audiologists and have

been found to be suitable hearing aid candidates, can and do charge less for hearing aids with the expectation of making a profit, than can dealers who engage in their own testing and evaluating procedures. In fact, the majority of dealers will offer a discount from the suggested retail price to consumers who are referred to them by audiologists.

The compliance provisions of the proposed rule will impose some recordkeeping and other requirements on sellers of hearing aids. These do not appear to be significant, nor do the administrative costs entailed in returning hearing aids to manufacturers for replacement or reconditioning appear to be so great as to justify separate or detailed consideration.

The various constraints on advertising contained in the proposed rule, i.e., prohibitions on certain representations and affirmative disclosure requirements, will serve to increase advertising costs to some extent and in some cases may discourage advertising generally. In assessing these potential results, it is pointed out that the provisions of the rule, if promulgated, will affect all advertisers equally, except to the extent that an advertiser may have frequently and habitually engaged in the type of advertising that will be prohibited or curtailed by the rule provisions. In these circumstances it can be expected that, unlike a cease-and-desist order addressed to only one advertiser, the rule will place all advertisers on an equal footing and thus prevent several of them from receiving a benefit by way of the constraints placed on a competitor. Therefore, the economic impact will be equally distributed among all advertisers and the effect of these provisions on costs will be less than would otherwise be expected. In other words, those who wish to advertise will devise ways to do so in an effective manner in spite of and in compliance with the provisions of the rule.

Section 440.7(b) of the proposed rule requiring that sellers obtain the prior written consent of a potential buyer for a visit to the buyer's home or place of business will serve to reduce the numbers of outside sales of hearing aids. The economic benefits of outside sales to consumers that presumably will not take place because of this provision must be balanced against the economic disadvantages incurred by those consumers who have been sold unnecessary hearing aids or who have been improperly fitted with hearing aids in the course of such visits. When this balance is struck, it would seem from the evidence in the record that the curtailment of unannounced and uninvited solicitations outside sellers' places of business is more than justified. However, this provision will result in a decrease in such sales, and thus will operate to the prejudice of manufacturers and dealers whose overall transactions include a substantial percentage of these sales.

The buyer's right to cancel provision has the greatest potential of providing economic benefits to consumers as it will permit

those who have purchased hearing aids which do not significantly improve their hearing to recoup a substantial amount of the purchase price. It is probable that the major costs associated with the reconditioning or replacement of returned hearing aids will be borne by the manufacturers with the expectation that they will ultimately be passed along to the dealers and to consumers. The amount of these costs cannot be accurately predicted although increased efforts to sell reconditioned aids to those who cannot afford to purchase new ones could and should result in an increased market for used aids that will diminish such costs.

The costs to dealers resulting from the buyer's right to cancel will serve to make them more cautious in seeing to it that unnecessary hearing aids are not sold and in exercising greater care in the fitting of the appropriate aid to the individual consumer. This may result in increased participation in the hearing health care delivery process by audiologists and physicians. This should also result in screening out those who cannot benefit from a hearing aid and in enhancing the prospect that those who can profit from the use of a hearing aid will be correctly fitted with an appropriate aid.

The right to cancel will have the most unfavorable economic impact on those dealers who have made it a practice to attempt to sell one or more hearing aids to all of the hard of hearing they contact without regard to the needs of the individual and without regard to the likelihood of successful results.

2. Conclusions. The proposed rule will not have an unfavorable economic effect on manufacturers generally. It should not make it more difficult for a manufacturer to enter the market or to compete successfully with other manufacturers. It will, on the other hand, have an unfavorable economic impact upon those manufacturers and dealers who have concentrated their efforts upon outside sales. It seems that the number of such sales will decrease thus making it necessary for these manufacturers and dealers to redirect their efforts toward increased "inside" sales.

For the conscientious dealer who makes a genuine, honest, and forthright effort to identify customers who will benefit from the amplification provided by a hearing aid and who will develop the capabilities and skills necessary for proper selection and fitting of hearing aids, the rule should not have an unfavorable impact, regardless of the size of his dealership or the volume of his hearing aid sales. For the dealer who has expended his principal efforts in outside sales, who has sold unnecessary or inappropriate hearing aids, or who has improperly fitted the hearing aids he has sold, the rule will have serious economic effects and, if he is to survive in the marketplace, drastic changes will have to be made in his methods of doing business.

The economic effect of the proposed rule on consumers will be generally favorable. It is probable that the prices consumers pay for hearing aids, examinations, and other services associated with the fitting of devices will be increased to some undeterminable but slight extent. However, any such increases will be more than offset by the benefits that will be received by those who formerly would have purchased hearing aids from which they derived no significant benefits and who will, by virtue of the rule, be in a position in the future to recoup a large part of the purchase price. Because the rule drastically reduces the cost to a consumer if he tries an aid for the first time, or if he tries another aid, many who were previously reluctant to risk a large financial loss will now be willing to try a hearing aid for the first time, or to try a second or newer aid. Certainly, this will stimulate sales. Secondly, all consumers will be economically benefited by the more careful examination and fitting techniques that dealers will be forced to adopt in an effort to reduce the number of sale cancellations.

Finally, the rules of the game of "hide-and-seek" in this industry will be changed to some extent. If a hearing-impaired person prefers to stay in hiding, that is <u>his</u> <u>right</u>. If he does, this will decrease sales to some extent. But hucksters have no constitutional right to seek and ferret out reluctant consumers with deception and trickery under the misguided impression (or excuse) that this is the <u>only</u> <u>way</u> to "help" the obstinate and socially withdrawn potential consumer. Manufacturers, dealers, and their salesmen will have to rely on a more honest and forthright form of advertising to inform consumers of the potential benefits of their products. Free trials, or trials with slight risk of loss, will bring many potential consumers "out of hiding." Therefore, with an improved approach by industry to "seeking out" and "educating" consumers, the rule should stimulate sales in the long term and should not result in any significant reduction in sales of hearing aids to those who can derive significant benefits from them.

G. Martin Shepherd
Presiding Officer

August 1, 1977

APPENDIX I

INITIAL NOTICE

federal register

TUESDAY, JUNE 24, 1975
WASHINGTON, D.C.
Volume 40 ■ Number 122

PART II

FEDERAL TRADE COMMISSION

■

HEARING AID INDUSTRY

Proposed Trade Regulation Rules

FEDERAL TRADE COMMISSION

[16 CFR 440]

HEARING AID INDUSTRY

Proposed Trade Regulation Rule; Notice of Proceeding

Notice is hereby given that the Federal Trade Commission, pursuant to the Federal Trade Commission Act, as amended, 15 U.S.C. 41, et seq., the provisions of Part 1, Subpart B of the Commission's procedures and rules of practice, 16 CFR 1.7, et seq., and section 553 of Subchapter II, Chapter 5, Title 5 of the U.S. Code (Administrative Procedure) has initiated a proceeding for the promulgation of a Trade Regulation Rule for the Hearing Aid Industry.

In accordance with the above notice the Commission proposes the following Trade Regulation Rule and to amend Subchapter D, Trade Regulation Rules, Chapter I of 16 CFR by adding a new Part 440:

PART 440—PROPOSED TRADE REGULATION RULE FOR THE HEARING AID INDUSTRY

Sec.

AUTHORITY: 38 Stat. 717, as amended (15 U.S.C. 41, et seq.)

§ 440.1 Preamble.

In connection with the advertising, promotion, offering for sale, sale, marketing, or distribution of hearing aids in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, it is an unfair and deceptive act or practice and an unfair method of competition within the meanings of sections 5 and 12 of that act for any seller to fail to comply with the following provisions of this Part.

§ 440.2 Definitions.

For the purposes of this Part the following definitions shall apply:

(a) *"Hearing aid."* Any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for impaired hearing.

(b) *"Sale"* or *"purchase."* A sale or purchase, or lease or rental for a period of more than 30 calendar days, of a hearing aid to a member of the consuming public.

(c) *"Seller."* Any person, partnership, corporation, or association engaged in the sale, lease or rental of hearing aids, or any employee, agent, salesperson and/or representative of same, whether made to a "buyer" or to another "seller."

(d) *"Buyer."* Any person, partnership, corporation, or association assuming a financial obligation in connection with a "sale," either for its personal use or for the use of a person on whose behalf the financial obligation is assumed.

(e) *"Purchase price."* The total price paid or to be paid for a hearing aid, including all interest charges, taxes, and charges for services rendered in connection with a sale; *Provided however*, That "purchase price" shall not include the pro rata portion of any charges for services:

(1) When such charges are separately stated in the contract for sale; and

(2) When the "buyer" has been given the option of not purchasing such services; and

(3) When such services have been rendered prior to the date of the buyer's exercise of his right to cancel under § 440.4.

(f) *"Represent" or "representation."* Any direct or indirect statement, suggestion or implication, including but not limited to one which is made orally, in writing, pictorially, or by any other audio or visual means, or by any combination thereof, whether made in an advertisement or otherwise.

(g) *"Advertisement" or "advertising."* Any written or verbal statement, illustration, or depiction, other than a label or in the labeling, which is designed to effect the sale of any hearing aid, or to create interest in the purchase of any hearing aid, whether the same appears in a newspaper, magazine, leaflet, circular, mailer, book insert, catalog, sales promotional material other literature, billboard, public transit card, point-of-purchase material, or in a radio or television broadcast or in any other media. "Advertisement" or "advertising" does not include:

(1) Signs which only identify the name of a seller and are located at the seller's place of business; or

(2) A listing in a telephone directory which gives only the seller's name, address and telephone number, and the brand(s) of hearing aids offered for sale; or

(3) Representations directed solely to physicians or audiologists.

(h) *"Audiologist"*. A person who:

(1) Possesses the Certificate of Clinical Competence in audiology granted by the American Speech and Hearing Association (ASHA); or

(2) Meets the educational and experience requirements for ASHA certification in audiology and has successfully completed the examination required for ASHA certification in audiology; or

(3) Meets the requirements of any applicable State law which defines the term "audiologist".

(i) *"Clearly and conspicuously disclose" or "clear and conspicuous disclosure."* Disclosing in a manner which (or a disclosure which):

(1) Can easily be understood (in the case of television and print advertising, also easily seen and read) by the casual observer, listener, or reader among members of the public; and

(2) Occurs each time the representation which creates the requirement for the disclosure is made, and in immediate conjunction with such representation, except that the disclosure required by § 440.8(a) need be made only once, in immediate conjunction with the major theme of an advertisement and at the outset of any other communication; and

(3) Is made in the same language, e.g., Spanish, as that principally used in communicating with the person(s) to whom the disclosure is addressed; and

(4) In any television advertisement, is made in the manner and form prescribed by § 440.3(a); and

(5) In any radio advertisement, is made in the manner and form prescribed by § 440.3(b); and

(6) In any print advertisement, is made in the manner and form prescribed by § 440.3(c).

(j) *"Used hearing aid."* A hearing aid which has been worn for any period of time by a buyer or potential buyer; *Provided however*, That a hearing aid shall not be considered "used" merely because it has been worn by a buyer or potential buyer as part of a bona fide evaluation conducted to determine whether to select that particular hearing aid for that buyer, if such evaluation has been conducted in the presence of the seller or a hearing health professional selected by the seller to assist the buyer in making such a determination.

(k) *"Telephone option."* An option available on hearing aids which enables the wearer to hear the electrical signal on the telephone line rather than the acoustic signal produced by the telephone.

§ 440.3 Form and manner of making required disclosures in television, radio and print advertisements.

(a) *Disclosures in television advertisements.* (1) Except for a disclosure required by § 440.8(a), any disclosure shall be made clearly and conspicuously and at least as clearly and conspicuously as any representation which creates a requirement for such disclosure.

(2) Except for a disclosure required by § 440.8(a) or § 440.10(a) (which shall be made simultaneously in the audio and video portions of the advertisement), any disclosure shall be made in the same portion (audio or video) of the advertisement in which the representation which creates the requirement for the disclosure is made.

(3) The video portion of any disclosure shall contain letters of sufficient size so that it can be easily seen and read on all television sets, regardless of the picture tube size.

(4) The video portion of any disclosure shall contain letters of a color and shade that readily contrast with the back-

ground, and the background shall consist of only one color or shade.

(3) No other sounds, including music, shall occur during the audio portion of any disclosure.

(4) The video portion of any disclosure shall appear on the screen for a sufficient duration to enable it to be completely read by the viewer.

(b) *Disclosures in radio advertisements.* Except in connection with § 440.8 (a), any disclosure in any radio advertisement shall be made clearly and conspicuously, and at least as clearly and conspicuously as the representation which creates the requirement for such disclosure. No other sounds, including music, shall occur during the disclosure.

(c) *Disclosures in print advertisements.* Except in connection with § 440.8 (a), any disclosure in any print advertisement shall be made clearly and conspicuously and at least as clearly and conspicuously as the representation which creates the requirement for such disclosure.

[See § 440.2(i).]

§ 440.4 Buyer's right to cancel.

(a) A seller shall include in every receipt or contract pertaining to a sale, in immediate proximity to the space reserved for the signature of the buyer, or on the first page if there is no space reserved for the signature of the buyer, a clear and conspicuous disclosure of the following specific statement in all capital letters of no less than twelve point bold face type of uniform font and in an easily readable style:

THE BUYER HAS THE RIGHT TO CANCEL THIS PURCHASE OR RENTAL FOR ANY REASON AT ANY TIME PRIOR TO MIDNIGHT OF THE 30TH CALENDAR DAY AFTER RECEIPT OF THE HEARING AID(S). SEE THE ATTACHED "NOTICE OF BUYER'S RIGHT TO CANCEL" FOR AN EXPLANATION OF THIS RIGHT.

(b) A seller shall furnish each buyer, at the time such buyer assumes any financial obligation with respect to the purchase, a completed form in duplicate, captioned "Notice of Buyer's Right to Cancel," which shall contain in no less than ten point type (twelve point bold face type for words in the "Notice of Buyer's Right to Cancel" which appear below entirely in capital letters) of uniform font and in an easily readable style, a clear and conspicuous disclosure of the following specific statements in the following format. A copy of such completed form shall be retained by the seller in accordance with § 440.13(a)(2).

NOTICE OF BUYER'S RIGHT TO CANCEL

This notice is for the buyer and each person who has assumed a financial obligation on the buyer's behalf: YOU HAVE THE RIGHT TO CANCEL THIS PURCHASE OR RENTAL. Here is information on:

Your right to cancel,
How to cancel,
What happens if you cancel, and
Other things you should know.

YOUR RIGHT TO CANCEL.

Any time before the end of _____
_____
(30 calendar days from the date you received the hearing aid(s))

you can cancel this purchase or rental for any reason and get most of your money refunded. If you purchased or rented two or more hearing aids in this transaction, you can cancel your purchase or rental of any or all of them. Upon cancellation, the seller can keep the following *cancellation charges:*

$_____ (for 30 days rental, for each cancelled hearing aid)
$_____ (for each custom ear mold made for the cancelled hearing aid(s))
$_____ (for batteries)

No other cancellation charges, penalties or fees are legal. However, the seller *can* keep the charges for any lease or rental period which ran prior to this transaction.

If, before the end of _____
_____
_____
(30 calendar days from the date you received the hearing aid(s))

the seller substitutes any other hearing aid(s) for the one(s) you originally purchased or rented, then the seller is required to provide you with a new "Notice of Buyer's Right to Cancel" and an additional 30 day period in which you can cancel the purchase or rental of the substitute hearing aid(s). The seller is not entitled to keep any of the cancellation charges listed above when such a substitution is made, but you will have to pay the additional cost involved if a more expensive hearing aid is being substituted. If you cancel the purchase or rental of the substitute hearing aid(s), the seller can keep only the cancellation charges listed above.

HOW TO CANCEL.

To cancel this purchase or rental, your cancellation must be actually delivered to the seller or postmarked no later than the end of

_____
_____
(30 calendar days from the date you received the hearing aid(s))

You may cancel by giving the seller any form of *written* notice of your cancellation, so long as you make it clear to the seller that you are *cancelling* and, if you received the hearing aid at your home, whether you want the seller to pick it up there. If you wish, you may use the "Cancellation Notice" form provided at the end of this notice. Keep a copy of your cancellation notice for your records.

WHAT HAPPENS IF YOU CANCEL.

The *seller's responsibilities* if you cancel are as follows: Within 15 calendar days after the date of your written cancellation notice he must:

(1) Actually return to you anything you traded in on the cancelled hearing aid(s) (including your old hearing aid(s)); and

(2) Cancel all financial obligations you assumed, as part of the purchase or rental, to cover the purchase or rental of the cancelled hearing aid(s); and

(3) Cancel all security interests (such as a mortgage) which were created in your property, as part of the purchase or rental, to cover the purchase or rental of the cancelled hearing aid(s); and

(4) Refund all payments you made toward the purchase or rental price of the cancelled hearing aid(s), less the cancellation charges listed in this notice and the charges for any lease or rental period which ran prior to this transaction.

Your responsibilities if you cancel are as follows:

(1) If you picked up the hearing aid at the seller's place of business, then you must return it there, either by actually delivering it or by having it postmarked (you must pay the postage) no later than 7 calendar days from the date of your written notice of cancellation; or

(2) If the hearing aid was delivered to your home, then you have a choice of what to do:

(i) You may return the hearing aid to the seller's place of business, either by actually delivering it or by having it postmarked (you must pay the postage) no later than 7 calendar days from the date of your written cancellation notice, or

(ii) If you notified the seller that you will make the hearing aid available at your home, you must do so. Then, if the seller does not pick it up within 20 calendar days from the date of your notice, you may keep it.

OTHER THINGS YOU SHOULD KNOW:

The seller is entitled to receive a cancelled hearing aid back in substantially as good condition as it was when you received it. However, the seller cannot refuse to accept a cancelled hearing aid because it shows signs of normal wear and tear such as scratches on the casing. Nor can the seller refuse to accept a cancelled hearing aid because of its defects, unless those defects were caused by your mistreatment of it.

To protect yourself at the time you cancel, you should do the following: If you deliver a cancelled hearing aid to the seller's place of business or the seller picks it up at your home, you should obtain a receipt from him. If you mail a cancelled hearing aid to the seller, the hearing aid should be sent "certified mail, return receipt requested."

If you cancel but do not fulfill your responsibilities, the seller will be entitled to sue you for the fair market value of the cancelled hearing aid(s) and the services you have in fact received.

If the seller refuses to honor a valid exercise of your right to cancel this purchase, or does not fulfill his other responsibilities, you have a right to sue him to make him fulfill all his responsibilities. In addition to giving you a right to sue the seller, such a refusal or failure would be a violation of a Federal Trade Commission Rule. Such violations should be reported promptly to the Federal Trade Commission, Washington, D.C. 20580.

The granting of this right to cancel does not deprive you of any of the other rights given to buyers under the law. Nor does it limit any rights you have concerning warranties made by the seller or provided by law.

CANCELLATION NOTICE

_____
(Date of cancellation)

To: _____
(Seller)
_____
_____
(Seller's address)

I hereby cancel my purchase or rental of the hearing aid(s) which I received on _____
_____
(Date you received the hearing aid(s))

(*If* two or more hearing aids were purchased or rented at the same time, the buyer *must* check the appropriate box so that the seller will know how much of the purchase or rental is being cancelled)

I am cancelling the purchase or rental of:

- ☐ both hearing aids
- ☐ the hearing aid for my left ear
- ☐ the hearing aid for my right ear
- ☐ other (explain)

you received the cancelled hearing aid at your home *and* you want the seller to pick it (them) up there, then check this box ☐)

(Buyer's signature)

(Buyer's address)

(If you do not use this form you may still give written notice to the seller by any other means, as long as you make it clear to the seller that you are *cancelling* and, if you received the hearing aid at your home and you cannot or do not want to return it to the seller's place of business, that the seller should pick up the hearing aid *at your home*.)

(c) Before furnishing copies of the "Notice of Buyer's Right to Cancel" to the buyer, a seller shall complete both copies of each such notice by entering:

(1) The date which is "30 calendar days from the date on which the buyer received the hearing aid(s)", in each of the three blanks provided for it. If the seller does not or cannot know the exact date on which the buyer's receipt of the hearing aid(s) will take place, then the appropriate blanks shall be completed so as to reasonably insure that the 30 calendar day period does not begin to run before receipt by the buyer has actually taken place; and

(2) The cancellation charges allowed under § 440.4(g)(1); and

(3) The seller's full name and address on the "Cancellation Notice" form; and

(4) The date the buyer received the hearing aid(s) (in the "Cancellation Notice" form). If the seller does not or cannot know the exact date on which the buyer's receipt of the hearing aid(s) will take place, then the date of receipt by the buyer shall be estimated so as to reasonably insure that it does not precede the actual receipt of the hearing aid(s).

(d) A seller shall not include in any contract or receipt any confession of judgment or any waiver of any of the rights to which the buyer is entitled under this Part, including but not limited to the buyer's right to cancel the sale in accordance with the provisions of § 440.4.

(e) At the time the buyer purchases a hearing aid, a seller shall inform him orally of the existence of the buyer's right to cancel.

(f) A seller shall not misrepresent in any manner the buyer's right to cancel; nor shall the seller make any representation or perform any act or practice which in any way negates, contradicts, detracts from or is inconsistent with a full understanding or a proper exercise of such right to cancel.

(g) A seller shall honor any valid notice of cancellation by a buyer and within 15 calendar days after the date of such notice:

(1) Refund all payments made toward the purchase price of the cancelled hearing aid(s), less any lease or rental charges applied as payments toward the purchase price of the cancelled hearing aid(s) and only those "cancellation charges" which are properly set forth in the "Notice of Buyer's Right to Cancel" as required by § 440.4(c) and are within the following limits:

(i) [Following are two mutually exclusive formulas for the "cancellation charge" for 30 days rental]

(A) *Alternative 1.* The cancellation charge for 30 days rental for each cancelled hearing aid shall not exceed the total of $15 plus 5 percent of the purchase price (excluding any "cancellation charges" for any custom ear mold or batteries).

(B) *Alternative 2.* The cancellation charge for 30 days rental shall not exceed the sum of $30 per cancelled hearing aid or 10 percent of the purchase price (excluding any "cancellation charges" for any custom ear mold or batteries), whichever is the lesser. This $30 maximum shall be adjusted annually after the effective date of this part to account for the annual percentage adjustment in the United States City Average All Items Consumer Price Index (1967=100) published by the Bureau of Labor Statistics of the United States Department of Labor. The computation of this annual adjustment shall be as follows: The Index for the month in which this part becomes effective shall be the Base Index. The Index for that same month in subsequent years shall be divided by this Base Index and the result of that division shall be multiplied by the sum of $30 to arrive at the maximum which shall obtain until the publication of the Index in the next subsequent year.

(ii) The cancellation charge for any custom ear mold and a 30 day supply of batteries shall not exceed twice the actual cost of such ear mold and or batteries to the seller or the seller's regular selling price for such ear mold and or batteries, whichever is the lesser. In computing the actual cost, all rebates, discounts, and any other similar allowances provided to the seller must be considered; and

(2) Return any goods or property traded in on the cancelled hearing aid(s), in substantially as good condition as when they were received by the seller; and

(3) Take all action necessary or appropriate to terminate:

(i) All financial obligations assumed by the buyer as part of this transaction to cover the purchase of the cancelled hearing aid(s); and

(ii) All security interests created in connection with this transaction to cover the purchase of the cancelled hearing aid(s).

(h) If, within 30 calendar days from the buyer's receipt of a purchased hearing aid, a seller substitutes another hearing aid for the originally purchased one, the seller shall treat such a substitution as a "sale" of a hearing aid for the purposes of § 440.4 by providing each buyer with a new "Notice of Buyer's Right to Cancel" and an additional 30 calendar day period in which to cancel. The cancellation charges set forth in the subsequent "Notice of Buyer's Right to Cancel" shall remain the same as those indicated in the original "Notice of Buyer's Right to Cancel."

(i) The provisions of paragraphs (a) through (h) of this section shall not apply to a sale:

(1) Made pursuant to a written recommendation of a specific hearing aid, by serial number or by model, made by a physician or an audiologist who receives no direct or indirect financial compensation from the seller for such recommendation or for services rendered in connection with such recommendation; *Provided, however*, That § 440.4(i)(1) shall not be construed to prevent any physician or audiologist from requesting or requiring as a condition of his referral to a seller that a patient be offered a trial period prior to a purchase; or

(2) Made to replace a damaged or worn out hearing aid when the replacement hearing aid which is sold is identical to such damaged or worn out hearing aid.

§ 440.5 Leases or rentals.

When leasing or renting a hearing aid for a period of up to 30 calendar days, a seller shall:

(a) Limit any lease or rental charges for any trial period(s) of up to 30 calendar days to only the total dollar amount of cancellation charges permitted to be retained by the seller under § 440.4(g)(1); and

(b) Clearly and conspicuously disclose such lease or rental charges orally to the potential buyer before any financial obligation relating to the lease or rental is assumed by the potential buyer; and

(c) Furnish each potential buyer, at the time any financial obligation relating to the lease or rental is assumed by the potential buyer, a form or contract which clearly and conspicuously discloses, in no less than ten point type of uniform font and in an easily readable style:

(1) The complete name and address of the lessor or renter; and

(2) The dates on which the trial period begins and ends; and

(3) All lease or rental charges.

§ 440.6 Seller may grant greater rights.

The seller may accord a buyer greater or more extensive rights than those to which the buyer is entitled under the provisions of this Part. In such instances, a seller may make suitable amendments in all appropriate documents to reflect the granting of such rights.

§ 440.7 Selling techniques.

(a) No seller shall utilize any device to demonstrate the performance which a consumer can expect from a hearing aid, when the performance of such a device differs in any material respect from that of said hearing aid.

(b) No seller shall visit the home or place of business of a potential buyer for the purpose of inducing a sale without having obtained, prior to any such visit, the express written consent of such potential buyer to such a visit. Such consent shall clearly and conspicuously state that such potential buyer is aware that the seller may attempt to sell a hearing aid during such a visit.

(c) If a hearing aid has been used, loaned, rented, leased, reconditioned, re-

furnished, repaired or rebuilt, that fact shall be clearly and conspicuously disclosed:

(1) In the oral sales presentation, before the buyer assumes any financial obligation with respect to the purchase; and

(2) In any advertisement relating to such hearing aid; and

(3) On the container in which such hearing aid is packaged; and

(4) On a tag which is physically attached to such hearing aid.

(f) No seller shall represent that a person can or may be able to participate in a hearing aid testing or evaluation program if the primary and/or ultimate purpose of such program is to sell hearing aids to persons who participate unless such purpose is clearly and conspicuously disclosed.

(g) No seller shall prepare, approve, fund, disseminate or cause the dissemination of any advertisement which, because of its form and/or content, cannot be easily understood as being designed to effect the sale of hearing aids, or to create interest in the purchase of hearing aids, by the audience to whom such advertisement is directed.

§ 440.8 Prohibited representations concerning hearing aid sellers.

(a) No seller shall make any representation to members of the consuming public without clearly and conspicuously disclosing that it is a seller of hearing aids. The disclosure requirement of § 440.8(a) will be satisfied by a clear and conspicuous statement of the name of the seller's business, if that name includes the words "hearing aid center" or other words which clearly identify that the establishment is a seller of hearing aids.

(b) No seller shall represent that it is a governmental or other public service establishment or nonprofit medical, educational or research institution unless such is the fact. Such a representation is made by the use of names such as "hearing center" (but not "hearing aid center"), "hearing institute," "hearing aid institute," "hearing bureau," "hearing aid bureau," "hearing clinic," "hearing aid clinic," "speech and hearing center," "speech and hearing aid center," and "senior citizen surveys."

(c) No seller shall represent that it or any of its employees, agents, salespersons and/or representatives is a physician or an audiologist, unless such is the fact. One example of a violation of § 440.8(c) is the use of the term "audiologist" to describe one who is not an audiologist as defined in § 440.2(h); and

(d) No seller shall represent that the service or advice of a physician or an audiologist will be used or made available in the selection, adjustment, maintenance or repair of a hearing aid, unless such is the fact.

(e) No seller shall represent that it or any of its employees, agents, salespersons and/or representatives is a "counselor" or a "consultant."

§ 440.9 Prohibited representations concerning hearing aids.

(a) No seller shall represent that any hearing aid will restore or help restore normal or natural hearing or will enable or help enable wearers to hear sounds normally or naturally.

(b) No seller shall represent that any hearing aid will in any way reverse, halt, or retard, or in any way help to reverse, halt or retard the progression of hearing loss, including but not limited to the use of expressions such as "Act now before it's too late," "Delay may be harmful," or "I caught your hearing loss just in time." Section 440.9(b) does not prohibit, however, a clearly stated and adequately qualified representation as to the difficulties which a consumer may encounted in adjusting to a hearing aid if he gets out of practice in using his hearing.

(c) No seller shall represent that a hearing aid model or feature is new for a period greater than one year from the date on which it was first marketed in the United States.

(d) A seller shall maintain an adequate system for insuring that all advertising it prepares, approves, funds or disseminates is in compliance with § 440.9(c).

(e) No seller shall represent that any hearing aid brand or model possesses any general or specific feature or characteristic or embodies any concept or principle (hereinafter referred to as a "characteristic") unless:

(1) Each such characteristic is clearly and conspicuously disclosed; and

(2) Each such disclosed characteristic provides some significant benefit(s) to the wearer of a hearing aid; and

(3) There is a clear and conspicuous disclosure of each such specific benefit; and

(4) There is a clear and conspicuous disclosure of the specific condition(s) under which or the category or categories of hearing aid wearers by which each such disclosed benefit will be received; and

(5) At the time of making any such representation the seller possesses and relies upon competent and reliable scientific or medical evidence which fully establishes that each benefit is significant and will be received by a significant number of buyers under the condition(s) disclosed; *Provided, however,* That if a seller who is not a manufacturer determines prior to making a representation that the representation is contained in materials which he has received from the manufacturer, such seller shall not be liable for failure to possess and rely upon such evidence if such seller can establish that he neither knew nor had reason to know, nor upon reasonable inquiry could have known:

(i) That the manufacturer did not possess such evidence; or

(ii) That the representation could not be substantiated by such evidence; or

(iii) That the representation was false; and

(6) If the represented characteristic(s) is (are) compared generally or specifically to the comparable characteristic(s) possessed by any other hearing aid brand(s) and/or model(s), including but not limited to any representation of newness (other than a representation that a hearing aid is not "used" as described in § 440.2(j)):

(i) There is a clear and conspicuous disclosure of the hearing aids with which such comparison is made; i.e., so that the comparison is not in the form of a dangling comparison; and

(ii) There is a clear and conspicuous disclosure of each particular characteristic with respect to which such comparison is being made; and

(iii) Each such compared characteristic provides a significantly greater benefit than the benefit provided by the comparable characteristic in the disclosed hearing aid brand(s) and/or model(s) with respect to which the advertised hearing aid(s) is (are) being compared; and

(iv) At the time of making any such representation the seller possesses and relies upon competent and reliable scientific or medical evidence which fully establishes that each compared characteristic provides a significantly greater benefit than the benefit provided by the comparable hearing aid brand(s) and/or model(s); *Provided, however,* That if a seller who is not a manufacturer determines prior to making a representation that the representation is contained in materials which he has received from the manufacturer, such seller shall not be liable for failure to possess and rely upon such evidence if such seller can establish that he neither knew nor had reason to know, nor upon reasonable inquiry could have known:

(A) That the manufacturer did not possess such evidence; or

(B) That the representation could not be substantiated by such evidence; or

(C) That the representation was false.

(f) For purposes of § 440.9(e)(6), a general or unqualified representation that a hearing aid is unique, revolutionary or special will be deemed to be a comparison to all other hearing aid brands and models; *Provided, however,* That a representation that a hearing aid is revolutionary or special will not be deemed to be a comparison to all other hearing aid brands and models if it is clearly and conspicuously disclosed that the comparison being made is to less than all other hearing aid brands and models.

(g) No seller shall represent that a hearing aid model is smaller than other hearing aid models unless, in addition to making all disclosures prescribed by § 440.9(e):

(1) The quality and range of sounds produced by representative samples of such hearing aid model are at least of

substantially the same quality and range of the sounds produced by representative samples of each of the different brand(s) and/or model(s) of hearing aids with which it is being compared, and at the time of making any such representation the seller possesses and relies upon competent and reliable scientific or medical evidence which fully establishes the relative quality and range of sounds produced by such hearing aids; *Provided, however,* That if a seller who is not a manufacturer determines prior to making a representation that the representation is contained in materials which he has received from the manufacturer, such seller shall not be liable for failure to possess and rely upon such evidence if such seller can establish that he neither knew nor had reason to know, nor upon reasonable inquiry could have known:

(i) That the manufacturer did not possess such evidence; or

(ii) That the representation could not be substantiated by such evidence; or

(iii) That the representation was false; or

(2) It is clearly and conspicuously disclosed that such hearing aid does not produce sounds which are at least of substantially the same quality and range as the sounds produced by the hearing aid brand(s) and/or model(s) with which it is being compared.

(h) No seller shall use the words "prescribe" or "prescription" or any other word(s) or expression(s) of similar import.

(i) No seller shall represent that a hearing aid which routes the signal from one ear to the other ear enables the wearer to hear out of the ear from which the signal is being routed.

(j) No seller shall represent, through the use of words or expressions such as "invisible," "hidden," "hidden hearing," "completely out of sight," "conceal your deafness, "hear in secret," "unnoticed even by your closest friends," "no one will know you are hard of hearing," "your hearing loss is your secret," "no one need know you are wearing a hearing aid," "hidden or out of sight when inserted in the ear canal," or by any other words or expressions of similar import, that any hearing aid or part thereof is hidden or cannot be seen, unless such is the fact.

(k) No seller shall represent, through the use of words or expressions such as "no cord," "cordless," "100 percent cordless," "no unsightly cord dangling from your ear," "no wires," "no tell-tale wires," or other words or expressions of similar import, that a hearing aid can be worn without any visible cord or wire, unless such representation is true and it is clearly and conspicuously disclosed that a plastic tube (or similar device) runs from the instrument to the ear, if such is the fact.

(l) No seller shall represent, through the use of words or expressions such as "no button," "no ear button," "no buttons or receivers in either ear," or other words or expressions of similar import, that a hearing aid can be worn without any button or other receiver in the ear, unless such representation is true and unless it is clearly and conspicuously disclosed that an ear mold or plastic tip is inserted in the ear, if such is the fact.

(m) No seller shall represent that any hearing aid can eliminate unwanted noise; *Provided, however,* That it shall not be a violation of § 440.9(m) to represent accurately the ability of a hearing aid with a telephone option to attenuate acoustical background signals, if such is the fact.

(n) No seller shall represent that any hearing aid can operate without batteries, unless the power source for such a hearing aid can be recharged from a household electric outlet.

§ 440.10 Advertising representations that must be qualified.

No seller shall prepare, approve, fund, disseminate or cause the dissemination of any advertisement:

(a) Which makes any general or specific representation that a hearing aid will or has the capacity to affect hearing capability or hearing quality, unless it is clearly and conspicuously disclosed that many persons with a hearing loss will not receive any significant benefit from any hearing aid; *Provided, however,* That nothing herein shall prohibit a truthful representation that hearing aids can help many persons with a hearing loss.

(b) Which makes any representation that a hearing aid will enable a person with a hearing loss to distinguish or understand speech sounds in noisy situations, unless, in addition to the disclosure required by § 440.10(a), it is clearly and conspicuously disclosed that many persons with a hearing loss will not be able to consistently distinguish and understand speech sounds in noisy situations by using any hearing aid.

(c) Which makes any representation that a hearing aid will enable a person with a hearing loss to distinguish or understand speech sounds in group situations unless, in addition to the disclosure required by § 440.10(a), it is clearly and conspicuously disclosed that many persons with a hearing loss will not be able to consistently distinguish and understand speech sounds in group situations by using any hearing aid.

(d) Which makes any representation that the use of two hearing aids, one in each ear, will be beneficial to persons with a hearing loss in both ears, unless, in addition to the disclosure required by § 440.10(a), it is clearly and conspicuously disclosed that many persons with a hearing loss in both ears will not receive greater benefits from the use of two hearing aids, one in each ear, than from the use of one hearing aid.

§ 440.11 Required disclosures concerning telephone options.

(a) No seller shall prepare, approve, fund or disseminate any advertisement which represents that a hearing aid has a telephone option, unless it is clearly and conspicuously disclosed that the telephone option will not work on all telephones.

(b) Before a buyer assumes any financial obligation with respect to a hearing aid which has a telephone option, a seller shall clearly and conspicuously disclose the limitations of the telephone option orally to the buyer. Such disclosure shall include the following information:

(1) A statement that the telephone option will not work on all telephones; and

(2) A statement which indicates whether or not the telephone option will work on the telephones in the seller's trade area. If the telephone option will work on some, but not all, of the telephones in the seller's trade area, a statement indicating the types of telephones on which it will work shall be included in this disclosure; and

(3) A statement which indicates whether or not the approximate percentage of telephones in the seller's trade area on which the telephone option will work is increasing, decreasing, or remaining about the same.

§ 440.12 Necessary steps to insure compliance with this Part.

Every seller shall take such steps as are necessary to reasonably insure full compliance with the provisions of this Part by its employees, agents, salespersons, and/or representatives. At a minimum, such steps shall include:

(a) Furnishing each employee, agent, salesperson and/or representative with a copy of the Rule in this Part, either at the time of its promulgation or at the time their employment is commenced; and

(b) Obtaining from each employee, agent, salesperson and/or representative a signed and dated receipt for the copy of the Rule in this Part provided in accordance with § 440.12(a); such receipt to state that the recipient is aware that the seller is required to and will take appropriate disciplinary action for violations of this Part, which shall, in the event of willful violations or repeated violations, consist of the imposition of a fine, suspension, or dismissal of the employee, agent, salesperson and/or representative involved; and

(c) Establish and maintain a disciplinary system which will include, in the event of willful violations or repeated violations, the imposition of a fine, suspension, or dismissal of the employee, agent, salesperson and/or representative involved.

§ 440.13 Record maintenance and retention.

A seller shall maintain accurate and adequate records which may be inspected by Commission staff members upon reasonable notice and which pertain to the activities listed below. Such records shall be retained for a period of no less than three years. In the case of records covered by § 440.13(d), the three year period shall commence each time a representation supported by such records is made.

(a) All hearing aid sales. Documents which must be maintained and retained include but are not limited to:

(1) Copies of all contracts of sale; and

(2) Copies of all "Notices of Buyer's

Right to Cancel" provided to buyers in accordance with § 440.4(b); and

(3) Copies of all cancellation notices of any kind received from buyers exercising the right to cancel; and

(b) All hearing aid leases or rentals. Documents which shall be maintained and retained include but are not limited to copies of all contracts or forms provided in accordance with § 440.5; and

(c) All home sales visits. The prior express written approval required for each home sales visit by § 440.7(b) shall be maintained and retained; and

(d) Substantiation of representations. Documents which must be maintained and retained include but are not limited to all evidence required by §§ 440.9 (e) through (g); and

(e) All steps taken in accordance with the requirements of § 440.12.

§ 440.14 Effect on prior Federal Trade Commission actions and on State laws and ordinances of State political subdivisions.

(a) Sellers in compliance with this Part are exempt from the provisions of the Federal Trade Commission Trade Regulation Rule Concerning a Cooling-Off Period for Door-to-Door Sales, 16 CFR Part 429.

(b) This Part shall not be construed to supersede the Trade Practice Rules for the Hearing Aid Industry, promulgated July 20, 1965, by the Federal Trade Commission (16 CFR Part 214) except in the following instances:

(1) section 440.7(c) of this Part supersedes Rule 14 (a) and (b) (§ 214.14 (a) and (b)).

(2) section 440.8(b) of this Part supersedes Rule 10(a) (§ 214.10(a)).

(3) section 440.8(d) of this Part supersedes Rule 6(a) (§ 214.6(a)).

(4) section 440.9(h) of this Part supersedes Rule 6(c) (§ 214.6(c)).

(5) section 440.9(j) of this Part supersedes Rule 7(a) (§ 214.7(a)).

(6) section 440.9(k) of this Part supersedes Rule 7(b) (§ 214.7(b)).

(7) seection 440.9(l) of this Part supersedes Rule 7(c) (§ 214.7(c)).

(c) This Part shall not be construed to supersede any of the provisions of any outstanding Federal Trade Commission Cease and Desist Orders. The method for resolving any inconsistencies between this Part and such Cease and Desist Orders shall be by a petition to amend the provisions of such Orders.

(d) By taking action in this area, the Federal Trade Commission does not intend to preempt action in the same area, which is not inconsistent with this Part, by any State, municipal, or other local government. This Part does not annul or diminish any rights or remedies provided to consumers by any State law, municipal ordinance, or other local regulation, insofar as those rights or remedies are equal to or greater than those provided by this Part. In addition, this Part does not supersede those provisions of any State law, municipal ordinance, or other local regulation which impose obligations or liabilities upon sellers, when sellers subject to this Part are not in compliance therewith. This Part does supersede those provisions of any State law, municipal ordinance, or other local regulation which are inconsistent with this Part to the extent that those provisions do not provide a buyer with rights which are equal to or greater than those rights granted a buyer by this Part. This Part also supersedes those provisions of any State law, municipal ordinance, or other local regulation requiring that a buyer be notified of a right which is the same as a right provided by this Part but requiring that a buyer be given notice of this right in a language, form, or manner which is different in any way from that required by this Part. In those instances where any State law, municipal ordinance, or other local regulation contains provisions, some but not all of which are partially or completely superseded by this Part, the provisions or portions of those provisions which have not been superseded retain their full force and effect.

(e) This Part is not intended to supersede any State law, municipal ordinance, or other local regulation which more strictly limits the terminology by which hearing aid sellers may legally refer to themselves.

Statement of Reason for the Proposed Rule

It is the Commission's purpose, in issuing this statement, to set forth its reason for proposing this Trade Regulation Rule with sufficient particularity to allow informed comment. For the purpose of assisting persons interested in commenting on the Proposed Rule, as well as the Commission's deliberations on the Proposed Rule, the Commission invites interested persons to direct their attention to the list of questions that follow this Statement in the section under the heading of "Invitation to Comment on the Proposed Rule." It should be emphasized that this listing of questions is solely intended to focus discussion on areas of importance to the Commission's decision and is not to be construed as a limitation upon the scope, form, or content of permissible comment by interested parties. Nor should these questions be interpreted as designating disputed issues of specific fact. Such designations shall be made by the Commission or its duly authorized presiding official pursuant to the Commission's procedures and rules of practice.

The Commission has reason to believe that many consumers buy hearing aids from which they do not receive any significant benefit or any significant additional benefit if they are current hearing aid users buying a second hearing aid or a "better" hearing aid. The commission has reason to believe that there are several, sometimes interrelated, reasons for this. With perhaps two exceptions,[1] the Commission has reason to believe that prospective hearing aid buyers will not be able to determine whether they will in fact obtain a significant benefit (or a significant additional benefit) from the selected hearing aid without being able to wear that aid in a representative variety of actual use situations. The Commission also has reason to believe that many prospective hearing aid buyers will not be able to determine the relative importance to them of the advantages and limitations of a hearing aid, or the nature of the experience of wearing a hearing aid, without the opportunity of wearing an aid in a representative variety of actual use situations. But it appears that many prospective hearing aid buyers are not given the opportunity to wear the selected hearing aid in a representative variety of actual use situations prior to the purchase of the selected aid. In addition, the Commission has reason to believe that hearing aid consumers are often particularly subject to and the victim of a wide variety of selling abuses. Thus the inherent nature of hearing loss and hearing aids, and the selling abuses to which many hearing aid buyers are subjected, appear to result in many consumers purchasing hearing aids from which they receive no significant benefit (or significant additional benefit).

The "buyer's right to cancel" set forth primarily in § 440.4 of the Proposed Rule, is designed to protect consumers from this result.

The Commission has reason to believe that many hearing aid buyers make their puchases in their homes or places of business at the conclusion of a sales visit that they were not expecting. There are various ways in which "leads" to potential buyers are obtained. The Commission is aware of the argument that such "lead" solicitation activities are necessary because many of those who need help will not initiate the necessary contacts on their own. Unfairness to consumers may easily result from sales presentations of which consumers have had no warning and for which they are frequently unprepared. In the past, the Commission has dealt with this matter by requiring advertisements designed to solicit "leads" to disclose that a salesperson may call on those who respond for the purpose of selling a hearing aid.[2] In an effort to protect consumers and at the same time permit industry members to seek out and work with those who

[1] When a professional expert who is financially independent of any seller (either a physician or an audiologist) performs services which, in the expert's professional opinion, are adequate to determine which patients will in fact obtain a significant benefit (or significant additional benefit) from a specific hearing aid, and when a damaged or worn out hearing aid is being replaced by an identical hearing aid.

[2] Mather Hearing Aid Distributors, 78 F.T.C. 709, 742 (1971) and Mountain States Hearing Service, Inc., 77 F.T.C. 640, 646 (1970).

may need help but will not initiate the unnecessary contacts, the Commission proposes to utilize the remedy set forth in § 440.7(b) (express written consent prior to sales visits to the home or place of business of a potential buyer) instead of the "salesman may call" remedy utilized in the past.

In addition to providing for a "buyer's right to cancel" and requiring that express written consent be obtained prior to any sales visit to the home or place of business of the potential buyer, the Proposed Rule contains various rule provisions of a more traditional nature. These provisions proscribe various practices and prescribe various disclosures, in order to insure that consumers have accurate and adequate information and in order to eliminate deception in the hearing aid industry.

The Commission has determined that it has reason to believe the above statements on the basis of information compiled by the Commission's staff during an extensive investigation of the hearing aid industry. In the course of this investigation the Commission's staff has received documentary evidence of these practices from and has conducted interviews with consumer representatives of various organizations, consumer interest groups, members and representatives from the hearing aid industry, physicians specializing in diseases of the ear, audiologists, representatives of organizations of hearing health professionals, and officials and staff members of Federal, State and local government agencies. The Commission has not adopted any findings or conclusions of the Commission's staff. All findings in this proceeding shall be based solely on matter in the rulemaking record.

Furthermore, the Commission has for some years undertaken extensive adjudicative efforts in the hearing aid industry. The Commission, having reason to believe that adjudication is inadequate to deal with the consumer protection problems which the Commission has reason to believe exist in the hearing aid industry, undertakes this proposed rulemaking proceeding for the purposes of carrying out the provisions of section 5 of the Federal Trade Commission Act by defining with specificity certain acts or practices which it has reason to believe are unfair or deceptive.

Invitation To Propose Issues of Specific Fact for Consideration in Public Hearings

All interested persons are hereby given notice of opportunity to propose any disputed issues of specific fact, in contrast to legislative fact, which are material and necessary to resolve. The Commission, or its duly authorized presiding official, shall, after reviewing submissions hereunder, identify any such issues in a Notice which will be published in the Federal Register. Such issues shall be considered in accordance with section 18(c) of the Federal Trade Commission Act as amended by Public Law 93-637, and rules promulgated thereunder. Proposals shall be accepted until not later than August 25, 1975, by the Special Assistant Director for Rulemaking, Federal Trade Commission, Washington, D.C. 20580. A proposal should be identified as a "Proposal Identifying Issues of Specific Fact—The Hearing Aid Industry," and when feasible and not burdensome, submitted in five (5) copies. The times and places of public hearings will be set forth in a later Notice which will be published in the Federal Register.

Invitation to Comment on the Proposed Rule

All interested persons are hereby notified that they may also submit to the Special Assistant Director for Rulemaking, Federal Trade Commission, Washington, D.C. 20580, data, views or arguments on any issue of fact, law or policy which may have some bearing upon the proposed rule. Written comments, other than proposals identifying issues of specific fact, will be accepted until ten (10) days before commencement of public hearings, but at least until August 25, 1975. To assure prompt consideration of a comment, it should be identified as a "Hearing Aid Industry Comment," and, when feasible and not burdensome, submitted in five (5) copies.

The data, views, arguments and comments received concerning the Proposed Rule and any issues related thereto, together with the transcript of hearings, will be available for examination during regular business hours in the Commission's Division of Legal and Public Records, Room 130, Federal Trade Commission, Washington, D.C. All such data, views, arguments and comments will be considered by the Commission before final action is taken in this matter.

Comments are invited with respect to any aspect of this proposed rulemaking. Whenever possible, comments should be directed at and should refer to specific sections of the Proposed Rule or to issues related thereto. The Commission invites comment particularly with respect to the following:

(a) Do many consumers buy hearing aids from which they receive no significant benefit (or no significant additional benefit if they are current hearing aid users buying a second hearing aid or a "better" hearing aid)? Are you personally aware of any such situations? If so, please describe them in detail.

(b) Is it necessary for a prospective hearing aid buyer to wear the selected hearing aid in a representative variety of actual use situations before it can be determined whether a significant benefit (or a significant additional benefit) will in fact be received?

(c) Can a prospective hearing aid buyer determine the relative importance *to him* of the advantages and limitations of a hearing aid without wearing the selected hearing aid in a representative variety of actual use situations?

(d) Can a prospective hearing aid buyer determine the nature of the experience of wearing a hearing aid without wearing the selected hearing aid in a representative variety of actual use situations?

(e) Are many hearing aid buyers the victims of selling abuses? What selling abuses? Are you personally aware of any hearing aid selling abuses? Will the "buyer's right to cancel" provided by § 440.4 of the Proposed Rule protect consumers from selling abuses? How? Is there any other consumer protection remedy that will protect consumers from selling abuses as well as the "buyer's right to cancel"?

(f) Should the Proposed Rule exempt sellers from the requirements of § 440.4 when a hearing aid is sold pursuant to a written recommendation of a specific hearing aid, by serial number or by model, made by a physician or an audiologist who is financially independent from the seller, as it does in § 440.4 (i)(1)?

(g) Should the Proposed Rule exempt sellers from the requirements of § 440.4 when a hearing aid is sold to replace a damaged or worn out hearing aid when the hearing aid being sold is identical to the hearing aid it is replacing, as it does in § 440.4(i)(2)?

(h) Is it reasonable to expect that physicians and audiologists who recommend the purchase of specific hearing aids, by serial number or by model, will look out for the best interests of their patients and protect them from sales abuses, as long as such physicians and audiologists are financially independent from the sellers to whom they refer their patients?

(i) Do the hearing aid seller licensure laws which have been enacted in various States adequately protect consumers from sales abuses, so that the protection provided by the Proposed Rule is not really needed?

(j) Is the "Notice of Buyer's Right to Cancel" required by § 440.4(b) clear and adequate?

(k) Is 30 calendar days from receipt an appropriate period of time in which to expect the buyer to decide whether to cancel?

(l) Is it necessary for § 440.4(g)(1) of the Proposed Rule to set maximum limits on the "cancellation charges" that the seller will be permitted to retain upon cancellation?

(m) Are the "cancellation charges" permitted by § 440.4(g)(1) too high for consumers?

(n) Are the "cancellation charges" permitted by § 440.4(g)(1) high enough to effectively discourage buyers from canceling unless they receive no significant benefit from the selected hearing aid? (Or no significant additional benefit over their old hearing aid if a second hearing aid or a "better" hearing aid is being purchased?) Are they high enough to insure that the buyer will make a good faith effort to adjust to and benefit from the selected hearing aid?

(o) Are the "cancellation charges" permitted by § 440.4(g)(1) too low for sellers?

(p) Should § 440.4(g)(1)(i) be changed to permit only one 30 day rental "cancellation charge" based on the purchase price of only one hearing aid, even

if two hearing aids (one for each ear) are being cancelled, in order to discourage the sale of two hearing aids (one for each ear) when only one (or even none) is appropriate?

(q) Should § 440.4(g)(1)(i) utilize either Alternative 1 or Alternative 2 as the formula for computing the maximum permissible 30 day rental "cancellation charge"? Or should § 440.4(g)(1)(i) utilize a different formula? For example, should the formula be 10 percent of the purchase price (excluding any "cancellation charges" for any custom ear mold or batteries)? Or should it be $30, adjusted annually in accordance with the Consumer Price Index?

(r) What are the uses of hearing aids returned by buyers who exercise their right to cancel?

(s) Should § 440.4(g)(1) be amended to permit the seller to retain a "cancellation charge" in the amount of his actual out-of-pocket cost of having wiring embedded in the frames of eyeglasses for the purpose of conducting a signal between the temples in CROS, BICROS and similar types of hearing aids? What safeguards would be needed to discourage the unnecessary sale of such wiring in eyeglass frames?

(t) Should the "buyer's right to cancel" provided by § 440.4 of the Proposed Rule supersede the FTC's Door-to-Door Sales Rule, in effect since June 7, 1974, which provides buyers with the right to cancel a door-to-door sale of a hearing aid (or any other product) selling for $25.00 or more any time up to midnight of the third business day after the sale and receive a refund of all of the purchase price?

(u) Should the definition of "used hearing aid" in § 440.2(j) be amended to allow hearing aids returned by buyers exercising their rights to cancel under this Part to be resold as new if they are reconditioned by the manufacturer and provided with a "new hearing aid" guarantee? What safeguards would be needed to insure honest compliance with the limits of such an exception in the usual meaning of "used"?

(v) Is the limit on any lease or rental charges for a trial period of no greater than 30 days (provided by § 440.5) necessary in order to protect consumers who might otherwise pay more for a 30-day rental of a hearing aid than they would have forfeited as "cancellation charges" if they had purchased instead of rented?

(w) Is § 440.7(b)'s requirement that prior express written consent be obtained prior to sales visits to the home or place of business of a potential buyer necessary in order to protect consumers? Does § 440.7(b) remove the need for any "lead solicitation" to disclose that those who respond may be visited by a salesperson for the purpose of selling a hearing aid?

(x) Is it necessary in order to protect consumers for sellers to be required to disclose that they are sellers whenever they make any representations to the public?

(y) §§ 440.8(b), 440.8(c), and 440.8(e) limit or prohibit the use of certain terms by sellers. Are these limitations and prohibitions appropriate? Are there other terms whose use by sellers should be limited or prohibited?

(z) In order to protect consumers should § 440.10(a) require all hearing advertisements making performance claims to disclose that many persons with a hearing loss (i.e., potential hearing aid buyers) will not receive any significant benefit from any hearing aid? Should § 440.10(a) be amended to prohibit any representation that hearing aids can help *most* of those who have a hearing problem?

(aa) Should § 440.10(b) and (c) be changed to require any advertisement which makes any representation that a hearing aid will enable a person with a hearing loss to understand conversation better in noisy (or group) situations to disclose that many of those who can benefit from the use of a hearing aid will still have difficulty understanding conversation in noisy (or group) situations?

(ab) Should the Rule be amended to provide that it would be an unfair act or practice for a hearing aid seller to fail to inform a potential buyer of the existence and role of the physician ear specialist and the audiologist prior to entering into purchase negotiations? If so, what should such a disclosure say? To help focus comment on this matter, the following draft rule provision has been developed:

A seller must make a clear and conspicuous disclosure of the precise statement set forth in paragraph (1) below in the manner set forth in paragraphs (2) and (3) below.

(1) "You should know that there are physicians specializing in diseases of the ear and audiologists who can provide valuable assistance in determining whether you can benefit from a hearing aid."

(2) The disclosure must be made clearly and conspicuously in each advertisement which is directed to consumers and in the written consent for a sales visit required by § 440.7(b).

(3) The disclosure must be made prior to the commencement of face-to-face purchase negotiations, whether or not it has already been made to the particular potential buyer involved through the manner set forth in Paragraph (2) above.

(4) The disclosure need not be made in situations in which State law requires the written authorization of both a physician specializing in problems of the ear and an audiologist before a hearing aid may be sold.

(5) The disclosure need not contain the reference to a physician specializing in diseases of the ear in situations in which State law requires the written authorization of a physician specializing in diseases of the ear before a hearing aid may be sold.

(6) The disclosure need not contain the reference to an audiologist in situations in which State law requires the written authorization of an audiologist before a hearing aid may be sold.

(7) In the event that the Food and Drug Administration requires a label disclosure concerning the advisability of obtaining a medical and or audiological evaluation prior to the purchase of a hearing aid, hearings will be held by the Federal Trade Commission to determine whether the disclosure set forth in paragraph (1) above should be superseded by such a label disclosure.

(ac) What economic effects can the Proposed Rule be expected to have on small business and consumers?

(ad) How prevalent are the acts or practices set forth in the Statement of Reason for the Rule and what is the manner and context in which such acts or practices may or may not be unfair or deceptive?

Issued: June 24, 1975.

By direction of the Commission.

(SEAL) CHARLES A. TOBIN
Secretary.

[FR Doc.75-16971 Filed 6-23-75;8:45 am]

APPENDIX II

FINAL NOTICE

FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

(The following has been reprinted from the Federal Register of December 30, 1975 - 40 F. R. 59746)

FEDERAL TRADE COMMISSION

[16 CFR Part 440]

HEARING AID INDUSTRY

Final Notice Regarding Proposed Trade Regulation Rule

On June 24, 1975, the Commission published in the FEDERAL REGISTER (40 FR 26646) an Initial Notice of a proposed trade regulation rule for the hearing aid industry pursuant to the Federal Trade Commission Act, as amended, 15 U.S.C. 41, et seq., the provisions of Part 1, Subpart B of the Commission's Procedures and Rules of Practice, 16 CFR 1.7, et seq., and § 553 of Subchapter II, Chapter 5, Title 5 of the U.S. Code (Administrative Procedure).

Now, pursuant to the same authority and more specifically to the authority of § 1.12 of the Commission's Procedures and Rules of Practice, the undersigned duly appointed Presiding Officer for this proceeding hereby gives Final Notice of proposed rulemaking, incorporating by reference the contents of the Initial Notice described above, including the proposed rule contained therein.

Written Comments. All interested persons are hereby notified that they may submit written data, views or arguments on any issue of fact, law, policy or discretion which may have some bearing upon the proposed rule. Such comments should be addressed to G. Martin Shepherd, Presiding Officer, Federal Trade Commission, Washington, D.C. 20580 no later than February 27, 1976. To assure prompt consideration comments should be identified as "HEARING AID INDUSTRY COMMENT" and submitted, if at all possible, in five copies.

Public hearing dates and places. Notice is also given that public hearings on the proposed rule will be held at the locations set forth below commencing on the dates and times specified at each location:

1. Public hearings will commence on April 12, 1976 at 9:45 a.m. in Washington, D.C.:

Room 332, Federal Trade Commission Building, 6th and Pennsylvania Avenue, N.W., Washington, D.C.

Persons desiring to present their views orally in Washington, D.C., should so inform the Commission representative listed below not later than March 22, 1976:

Mr. Steven D. Newburg-Rinn [(202) 724-1483.], Bureau of Consumer Protection, Division of National Advertising, Federal Trade Commission, Washington, D.C. 20580.

2. Public hearings will be held commencing on June 7, 1976 at 9:45 a.m. in Chicago, Illinois:

Room 347 A-B, John C. Kluczynski Federal Building, 230 South Dearborn Street, Chicago, Illinois.

Persons desiring to present their views orally in Chicago should so inform the Commission representative listed below not later than May 17, 1976:

Mr. Richard J. Toman [(312) 353-4430], Federal Trade Commission, Suite 1437, 55 East Monroe Street, Chicago, Illinois 60603.

3. Public hearings will be held commencing on August 2, 1976 at 9:45 a.m. in San Francisco, California:

Room 12138, Federal Building, 450 Golden Gate Avenue, San Francisco, California.

Persons desiring to present their views orally in San Francisco should so inform the Commission representative listed below not later than July 12, 1976:

Mr. Fred Austin [(415) 556-1270], Federal Trade Commission, 450 Golden Gate Avenue, San Francisco, California 94102.

INSTRUCTIONS TO WITNESSES

All prospective witnesses are advised that reasonable limitations on the time allotted to any person may be imposed and that these time periods may vary from witness to witness depending upon all the circumstances, including the needs of each witness, the complexity of the expected testimony, the number of parties represented by each witness and the cumulative nature of expected testimony. Witnesses will be expected to stay within the time allotted for their remarks and the Presiding Officer may allocate additional time for questioning. To the extent that individual views are not unduly suppressed, individual members of interested groups are encouraged to make their views known through group representatives. As a general rule, witnesses are expected to confine their prepared remarks to twenty minutes or less, unless an exception has been made, and to develop their testimony at greater length through their written submissions. Witnesses are entitled to testify only at one hearing site.

Persons wishing to deliver prepared statements are required to file such statements with the appropriate Commission representative listed above no later than March 22, 1976 for those witnesses appearing in Washington, D.C.; no later than May 17, 1976 for those witnesses appearing in Chicago, Illinois; and no later than July 12, 1976 for those witnesses appearing in San Francisco. If at all possible, witnesses should furnish ten copies of their statements. Any witness not intending to deliver a statement fully prepared in advance is required to file with the designated Commission representative (by the same date set forth above for the filing of written statements at the location where he expects to appear) a written detailed and comprehensive outline explaining the nature of his expected testimony including, but not limited to, a statement of each important fact, observation, conclusion, or opinion he anticipates presenting.

Advance submittal of statements and exhibits is required to apprise other interested parties of expected testimony so they may determine on the need for examination, including cross-examination, or rebuttal submissions. Such submittals will be made available for viewing by the Commission representatives designated above at the location where the witness intends to appear.

The Presiding Officer retains the discretion to require that any oral presentation be submitted in writing in advance of presentation and to deny the right to present oral testimony to any person who fails to file appropriate statements or comply with the advance notification requirements of this Notice.

Prospective witnesses who plan to introduce documents or other written evidence as exhibits to their statements must furnish such documents or written evidence, properly identified with the witness' name and sequential number (i.e., Jackson Exhibit-1), by the same dates set out above for the filing of expected testimony, depending on the location at which the witness intends to appear, unless for good cause shown they can demonstrate why this could not have been done at that time.

All prospective witnesses may and, indeed, are encouraged to direct their statements towards any question of fact, law, policy or discretion relevant to the proposed rule, and, in this regard, the usual rules of evidence applicable to litigated proceedings will not apply. However, all prospective witnesses are advised that to the extent their statements may bear upon any of the designated issues set forth below, or to be later designated, they may be subject to limited cross-examination as to those issues by representatives of other interested parties, as designated by the Presiding Officer, or to cross-examination by the Presiding Officer on behalf of such representatives, or to direct rebuttal submissions. All witnesses will be subject to direct examination by the Presiding Officer and, subject to his control, to examination by such interested parties as he may within his discretion permit. Oral presentations will not be under oath unless the Presiding Officer expressly so provides.

DESIGNATED ISSUES

Set forth below are the issues which the Presiding Officer has determined to designate under § 1.13(d)(1) of the Commission's procedures and rules of practice as issues to be considered in accordance with § 1.13(d) (5) and (6) of said Procedures and Rules of Practice. Pursuant to statute and the Commission's rules of practice, testimony with respect to these issues may entitle designated representatives of other interested parties to conduct or have conducted such cross-examination as the Presiding Officer may determine to be appropriate and required for a full and true disclosure with respect to any issue so designated. In the alternative, the Presiding Officer may determine that full and true disclosure as to any issue may be achieved through rebuttal submissions or the presentation of additional oral or written statements.

The Presiding Officer may at any time on his own motion or pursuant to a written petition by interested persons, add to or modify any issues listed. No such petition shall be considered unless good cause is shown why such issue was not proposed during the time specified in the Initial Notice.

Interested persons who desire to avail themselves of the procedures described above with respect to designated issues must, by January 26, 1976, notify the Presiding Officer in writing of their particular interest with respect to each issue designated, including a general statement of their position with respect to such issues. In the event new issues are added interested persons must promptly notify the Presiding Officer to their particular interest with respect to each such issue in the same manner. Request to examine, including cross-examine, or to present rebuttal submissions, shall be accompanied by a specific justification therefor.

Before the hearings commence, the Presiding Officer will identify groups of persons with the same or similar interests in the proceeding. Such groups will be required to select a single representative for the purpose of examination, including cross-examination, and, if unable to agree, the Presiding Officer may select a representative of each such group. Any member of a group who is unable to agree upon group representation after a good faith effort to do so, and who seeks to present substantial and relevant issues which will not be adequately presented by the group representative, may be allowed to conduct or have conducted any

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examination, including cross-examination, or rebuttal submissions, to which he is entitled on issues designated for consideration in accordance with this Notice.

GENERAL ISSUES

1. As relevant to the Proposed Rule, what are the sales techniques employed by sellers (at any and/or all levels of distribution) in connection with the offering for sale and/or sale of hearing aids? In what respects could such techniques have the capacity or tendency to deceive consumers, and how might such techniques be unfair to consumers? How prevalent are such techniques?

2. How are hearing aid sellers trained, motivated, and controlled? How does that training, motivation, and control bear on whether consumers are subjected to selling abuses or whether consumers purchase hearing aids that provide no significant benefit?

3. In connection with the offering for sale and sale of hearing aids, are existing consumer protection measures (including, but not limited to those relating to cooling off periods) adequate to protect purchasers?

4. What will be the economic effect of the Rule, taking into account the effects on small business and consumers?

BUYER'S RIGHT TO CANCEL (§ 440.4)

5. Do a significant number of consumers buy hearing aids from which they receive no significant benefit (or no significant additional benefit if they are current hearing aid users buying a second hearing aid or a "better" hearing aid)?

6. Is it necessary for a signfficant number of prospective hearing aid buyers to wear the selected hearing aid in a representative variety of actual use situations before it can be determined whether a significant benefit (or a significant additional benefit) will in fact be received?

7. Are there a significant number of prospective hearing aid buyers who cannot determine the relative importance to themselves of the advantages and limitations of a hearing aid without wearing the selected hearing aid in a representative variety of actual use situations?

8. Are the "cancellation charges" permitted by § 440.4(g)(1) high enough to effectively discourage casual or frivolous cancellations?

9. What would be an appropriate 30 day cancellation charge in situations where the sale of two hearing aids (one for each ear) is involved?

SELLING TECHNIQUES (§ 440.7)

10. Do "master hearing aids" or similar devices perform in a materially different manner from the actual performance (in actual use situations) of the hearing aids sold to consumers? To what extent are "master hearing aids" or similar devices utilized to demonstrate the performance a consumer can expect from a hearing aid? (§ 440.7(a))

11. Will the requirement that a seller obtain express written consent from prospective hearing air buyers, prior to making visits to their homes or places of business (for the purpose of selling hearing aids) enhance the ability of such buyers to protect themselves against deceptive or unfair acts or practices (including high pressure sales tactics) which might be used by the seller? (§ 440.7(b))

12. Does failure to disclose previous use of a hearing aid have the capacity or tendency to mislead consumers as to a fact material to them in making their decision as to whether to purchase the particular hearing aid? (§ 440.7(c))

13. Does the offering of a hearing test, without disclosure at the outset that the tester is a seller of hearing aids and may attempt to sell a hearing aid to the person being tested, have the capacity or tendency to mislead consumers as to (a) the status of the person doing the testing and/or (b) the true nature or purpose of the offer and test? (§ 440.7(d))

14. Does an advertisement which is not readily recognizable as an advertisement by the audience to whom it is addressed have the capacity or tendency to mislead consumers as to the nature and/or purpose of the communication? (§ 440.7(e))

PROHIBITED REPRESENTATIONS CONCERNING HEARING AID SELLERS (§ 440.8)

15. Does a representation by a seller of hearing aids (concerning hearing or hearing aids), without disclosure that such person is in fact a seller, have the capacity or tendency to lead consumers to believe (a) that such representation is not designed to effect the sale of a hearing aid, or (b) that the person making such representation is financially disinterested with respect to the matters covered in the representation? (§ 440.8(a))

16. Does the use of the terms set forth by way of example in § 440.8(b) have the capacity or tendency to lead consumers to believe that the organization being described is something other than a retail sales outlet (i.e., a governmental or other public service organization or a nonprofit medical, educational, or research institution)? (§ 440.8(b))

17. Does the representation that a seller of hearing aids (or the seller's employee, agent, salesperson, representative, or associate) is a physician or audiologist, when such is not the fact, have the capacity or tendency to mislead consumers as to (a) the training, skill, knowledge, specialty, and/or experience of such person, or (b) the nature of the enterprise engaged in by any such person? (§ 440.8(c) and (d))

18. Do the terms "counselor" and/or "consultant" have the capacity or tendency to lead consumers to believe that the individual so described can be relied upon to provide an expert and financially disinterested recommendation as to what should be done to deal with the consumer's perceived hearing problem? (§440.8(e))

PROHIBITED REPRESENTATIONS CONCERNING HEARING AIDS (§ 440.9)

19. Will any hearing aid restore or help restore normal or natural hearing, or enable wearers to hear sounds normally or naturally? (§ 440.9(a))

20. Do the expressions set forth by way of example in § 440.9(b) have the capacity or tendency to lead consumers to believe that any hearing aid will reverse, halt or retard the progression of hearing loss, or will help to do so? (§ 440.9(b))

21. Does the word "new", when used to describe hearing aid models, or features thereof, which have been on the market for more than one year, have the capacity or tendency to mislead consumers? (§ 440.9(c))

22. Do representations that a hearing aid possesses a general or specific feature or characteristic, or that it embodies any particular concept or principle, have the capacity or tendency to lead consumers to believe that (with respect to such feature, characteristic, concept, or principle) the advertised hearing aid will (a) provide some significant benefit(s) to the wearer (b) regardless of the wearer's particular type of hearing impairment? (§ 440.9(e))

23. Do representations in which a particular hearing aid is being compared to any other hearing aid(s) have the capacity or tendency to (a) mislead consumers as to what hearing aid(s) the particular hearing aid is being compared to when the representation is in the form of a dangling (incomplete) comparison; or (b) lead consumers to believe that the particular hearing aid is superior with respect to any characteristic being compared? (§ 440.9(e)(6))

24. Do representations that a hearing aid model is unique, special, or revolutionary, with respect to some particular characteristic, have the capacity or tendency to lead consumers to believe that the advertised model is being compared to all other hearing aid models with respect to such characteristic? (§ 440.9(f))

25. When a hearing aid is represented as being "smaller" than other hearing aids, would the fact that it produces sound of less quality and range than those with which it is being compared be a material fact which might influence the potential purchaser's decision of whether to purchase it? (§ 440.9(g))

26. Do the terms "prescribe" and "prescription" when used in connection with hearing aids, have the capacity or tendency to mislead consumers as to the extent to which hearing aids can correct hearing loss? (§ 440.9(h))

27. Do the words and phrases set forth by way of example in § 440.9(j), when used to describe a hearing aid or part thereof, have the capacity or tendency to lead consumers to believe that the hearing aid, or part thereof, so described is hidden or cannot be seen? (§ 440.9(j))

28. Do the words and phrases set forth by way of example in § 440.9(k) have the capacity or tendency to lead consumers to believe that the hearing aid so described can be worn without any visible cord or wire? (§ 440.9(k))

29. Do the words and phrases set forth by way of example in § 440.9(l) have the

capacity or tendency to lead consumers to believe that the hearing aid so described can be worn without any button or other receiver in the ear? (§ 440.9(l))

30. Can any hearing aid or feature thereof enable the wearer to eliminate all or most unwanted noises? (§ 440.9 (m))

31. What effect does a representation that a hearing aid can operate without batteries have on consumer beliefs or perceptions as to the operation of the particular hearing aid? (§ 440.9(n))

ADVERTISING REPRESENTATIONS THAT MUST BE QUALIFIED (§ 440.10)

32. Would many of those who think they have a hearing problem (and, therefore, might buy a hearing aid) not be able to receive any significant benefit from the use of any hearing aid? (§ 440.10(a))

33. Would many of those who can benefit from the use of a hearing aid still have difficulty understanding conversation in noisy situations? (§ 440.10 (b))

34. Would many of those who can benefit from the use of a hearing aid still have difficulty understanding conversation in group situations? (§ 440.10 (c))

35. Would many persons with a hearing loss in both ears fail to receive greater benefits from the use of two hearing aids, one in each ear, than from the use of one hearing aid? (§ 440.10(d))

SUMMARY OF CLOSING DATES

1. Notification of interest; January 26, 1976.

2. All written comments; February 27, 1976.

3. Witnesses' prepared statements (or comprehensive summaries) and exhibits for:

(a) Washington, D.C. hearing; March 22, 1976;

(b) Chicago hearing; May 17, 1976;

(c) San Francisco hearing; July 12, 1976.

SUMMARY OF HEARING DATES

1. Washington, D.C.; April 13, 1976.
2. Chicago, Illinois; June 7, 1976.
3. San Francisco, California; August 2, 1976.

Issued: December 23, 1975.

O. MARTIN SHEPHERD,
Presiding Officer.

[FR Doc.75-35021 Filed 12-29-75;8:45 am]

APPENDIX III

RECORD FORMAT

APPENDIX III

Outline of Public Record 215-44.
Proposed Trade Regulation Rule
for the Hearing Aid Industry

§1 Public Notices, Petitions, Motions, and Answers Thereto (and certain other documents related to the conduct of the proceeding).

§2 Recommendations as to Disputed Issues of Material Facts.

§3 Industry Comments (Written).

§4 Consumer Comments (Written).

§5 Scientific and Technical Comments (Written).

§6 Government Agencies (Federal, State, Local, etc.) (Written).

§7 General Comments (Written) (Unclassified sources).

§8 Commission Staff Submissions.

§9 Presiding Officer's Report, Staff Report, and Comments Thereon.

§10 Advance Statements for Hearings.

§11 Hearing Aid Users Opposed to Rule (Written).

§12 Transcript of Hearing and Exhibits.
A. Hearing Exhibits
B. Physical Exhibits
C. Transcript

§13 Rebuttal Submissions (Post-hearing).

§14 Excluded Evidence.

§15 Evidence In Camera

NOTE: Each Section has its own pagination starting with page 1.

APPENDIX IV

EXTENSION NOTICE.

FEDERAL TRADE COMMISSION

WASHINGTON, D. C. 20580

(The following has been reprinted from the Federal Register of August 19, 1975 - 40 FR 36145)

[16 CFR Part 440]

HEARING AID INDUSTRY

Change in Closing Date To Propose Issues of Fact in Proposed Trade Regulation Rule

Notice of opportunity to propose issues of specific fact regarding the proposed Trade Regulation Rule concerning the Hearing Aid Industry was published in the FEDERAL REGISTER on June 24, 1975 (40 FR 26646). The time for filing such proposals was August 25, 1975.

The Commission has now finalized the rules of procedure governing trade regulation rule proceedings and has determined that all interested parties should be afforded additional time for filing such proposals, or to amend or supplement proposals previously filed, taking into consideration the final procedural rules adopted. Accordingly, the record in this proceeding will remain open for that purpose until September 24, 1975.

Proposed issues of fact concerning the proposed Rule may be filed with the Special Assistant Director for Rulemaking, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

Issued: August 19, 1975.

By the Commission.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-21679 Filed 8-18-75;8:45 am]

APPENDIX V

ADDENDUM

Appendix V

Addendum

This report was in final form prior to disposition of two motions from two industry associations. Therefore, this addendum became necessary.

The first of these motions was entitled:

MOTION OF THE NATIONAL HEARING AID SOCIETY (NHAS) TO REOPEN THE...RULEMAKING PROCEEDING FOR THE RECEPTION OF FURTHER EVIDENCE. R-1-D320.

Submitted with this motion were certain recently generated documents which were offered as rebuttal evidence and were alleged to "bear directly upon the veracity and credibility" of (1) the only spokesman in this proceeding sponsored by the American Speech and Hearing Association (ASHA), Kenneth O. Johnson, Ph.D., now Executive Director of ASHA; (2) Richard J. Dowling, Esq., Counsel for ASHA during this proceeding--but not a witness; (3) the President of ASHA, Daniel Van Hattum, Ph.D., who was not a witness; and (4) the large number of audiologists who were members of ASHA and "who testified in these proceedings and who also may have been the object of ASHA schemes."

The second motion was submitted on behalf of the Hearing Aid Industry Conference (HAIC) under its recently changed name, Hearing Industries Association (HIA). R-1-D322. HIA joined in the NHAS motion and, in addition, requested reconsideration and expansion of motions previously submitted on behalf of HAIC (HIA). Those previous motions sought extensive discovery and were denied as has been noted in the relevant discussion in Part I of this report at pages 24-30.

Succintly stated, NHAS recently requested and acquired certain documents under the Freedom of Information Act from the Food and Drug Administration (FDA). NHAS alleges that those documents (which are attached to the subject motion) show that ASHA, through certain of its officers, engaged in a surreptitious scheme to send a "bogus press release" to FDA (in an effort to determine if FDA would "leak" the information therein to NHAS) and then made (or confirmed) false statements to FDA officials concerning the matter. According to NHAS, this new evidence, taken with other evidence in the FTC rulemaking record relating to a meeting ASHA officials held with a group of ASHA members who were potential witnesses at the hearings in this proceeding, demonstrates that all ASHA officials and members participating in this proceeding (in support of the rule) are not trustworthy. (It is assumed that NHAS does not question the credibility of the many audiologists who are members of ASHA but who testified in opposition to the rule under the

sponsorship of the manufacturers or dealers.) HIA concurs with NHAS.

Copies of these motions were forwarded to ASHA with invitation to respond. R-1-D321. Response was received and entered in the record (R-1-D323) along with the industry's motions.

In the ASHA response, Mr. Dowling noted that, "Industry counsel offer an allegation regarding ASHA's interest in an FDA proceeding that is unrelated to the issues before the [Federal Trade] Commission." Also, he stated that he had made an "inappropriate and incorrect" "spur-of-the-moment" statement to FDA officials in an "awkward, ill-conceived attempt to discover how the release had come into the trade group's possession" -- a statement for which he later apologized. Further, ASHA discussed the allegations that ASHA might have somehow coerced its members to accept its position concerning the rule, but ASHA denied such allegations and compared its own conduct with the conduct of other associations in regard to sponsorship and preparation of witnesses.

ASHA also made certain counter-allegations concerning the tactics employed by NHAS and, after citing various examples, concluded:

> We have demonstrated how the NHAS counsel has attempted to mislead the reader of the record with strained inferences and misquotations. And we have shown that this attempt is characteristic of the manner in which he chooses to represent his client. We have also shown that the principal objective of this, the most recent exercise of his characteristic approach, is a clouding of the impact which the combined testimony of audiologists and other witnesses who supported the proposed rule is bound to have on the reader of the record. Industry counsel have shown that ad hominem argument may serve their purposes where relevant facts fail.

It would appear that ASHA's counter-allegations are at least as related to this FTC rulemaking proceeding as were the industry's allegations and, therefore, worthy of at least as much consideration. However, in the Presiding Officer's summary report he found it preferable, indeed necessary, to avoid what would have been an extremely lengthy discussion presenting the bases for evaluating, on an individual basis, the testimony of over 200 (mostly expert) witnesses -- no one of whom presented evidence of an outcome determinative nature on any issue. Such analyses, to be adequate, would require much more time and another book.

Likewise, the Presiding Officer endeavored to avoid, wherever practicable, cluttering the record with side issues or repetitious and irrelevant materials born of the obviously growing and bitter competition between dealer-salesmen and latter-day audiologists who not only test hearing but, more recently, dispense hearing aids at cost-plus-overhead. Clearly, this industry is undergoing its own version of the good old American free enterprise system. The Presiding Officer has also avoided a detailed evaluation of counsel participants because, except where some procedural issues are involved, it would add very little of particular importance to this report.

In the same vein of thought, there appears to be no need to discuss further the details of the allegations and counter-allegations presented by the two subject motions and the response thereto. Those documents are on the record for the meticulous reviewer's own analysis. Suffice it to say, except for tangential considerations of credibility, the allegations add very little to this record.

In summary, the Presiding Officer considered the motions and response thereto in the light of the record as a whole and of all other circumstances, including observations made by him during the hearings. He then determined to place the three documents with attachments in the record but concluded that, even in the most sinister possible view of the facts, there is insufficient reason to rephrase any statements, findings, or conclusions in his report, including those statements relevant to biases, credibility, reliability, and objectivity of witnesses (i.e., see pages 37-38 of this report). He also determined that there is insufficient reason to further extend this proceeding for any other purpose at this time. R-1-D324.

* U.S. GOVERNMENT PRINTING OFFICE : 1977 O-229-966/1509