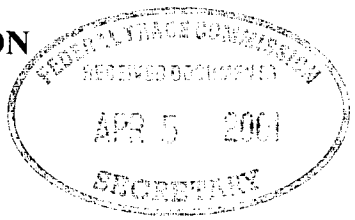
UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION



In the Matter of	)	
	)	**Docket No. 9294**
NATURAL ORGANICS, INC. **a corporation, and**	)	
GERALD A. KESSLER **individually and as an officer** **of the corporation**	)	

TO: The Honorable James P. Timony
Chief Administrative Law Judge

RESPONDENTS' ANSWER TO COMPLAINT COUNSELS' RENEWED MOTION TO LIMIT EXPERT WITNESSES

INTRODUCTION

On February 27, 2001, Complaint Counsel filed a Motion seeking to limit to six the number of expert witnesses Respondents may call at the hearing. On March 13, 2001, Your Honor denied that Motion as unripe. On March 28, 2001, Complaint Counsel renewed their Motion, asking Your Honor to limit Respondents to five experts ("renewed Motion"). For the reasons set forth below, Complaint Counsel's renewed Motion, like the original, should be denied. The motion is still not ripe and is otherwise without merit.

Respondents have been leaders in the dietary supplement industry for almost thirty years, during which time they have not been the subject of any other federal governmental proceeding alleging any violation of any law. The FTC has sought relief in its Complaint that, if granted, could have a devastating impact on Respondents' business.

Before the Complaint was filed, Respondents requested that the FTC allow their experts to meet with Respondents' experts to avoid litigation. Complaint Counsel answered that Respondents could present their case through their experts at the hearing.

Respondents have identified twelve preeminent scientific experts whose testimony will collectively demonstrate that the scientific data upon which Respondents relied to support advertising claims for Pedi-Active A.D.D. constitute a reasonable basis of substantiation. Now that Respondents have identified a number of renowned experts from a variety of scientific disciplines to support the advertising claims at issue in this case, Complaint Counsel have reversed course. Complaint Counsel have submitted two Motions in which they argue they should determine the number of experts that will support Respondents' defense, even before the close of discovery.

Complaint Counsel's Motion is still not ripe. According to Your Honor's Second Revised Scheduling Order, discovery will not close until April 27, 2001. Respondents are still in the process of developing the testimony of their experts to be presented at the hearing. Complaint Counsel and Respondents' Counsel are also in the process of scheduling the experts' depositions. The time for eliminating any testimony that might be potentially unnecessarily cumulative after stipulations or through other agreed-upon measures is weeks away. After the experts' depositions have been completed, Respondents are willing to work with Complaint Counsel to stipulate to any undisputed facts, to narrow and shorten expert testimony.

Complaint Counsel fail to cite a single FTC case that supports the relief requested in their renewed Motion. In fact, as discussed below, many prior FTC cases that are <u>not</u>

cited by Complaint Counsel establish that the number of experts Respondents have designated is reasonable and supported by precedent.

Even if their renewed Motion were ripe, Complaint Counsel's second attempt to gut Respondents' case ignores the FTC's own fundamental principle concerning substantiation, which centers on the opinions of experts in the relevant field.[1] The FTC guidance emphasizes the lack of a "fixed formula" concerning the quantity and quality of data needed to support dietary supplement advertising claims and that the proper inquiry is what experts in the relevant field consider adequate. There is nothing in the FTC guidance to support placing an arbitrary limit on the number of expert opinions that might be considered.

The nature of the allegations in the Complaint, as well as the complexity of the issues presented, warrant the presentation of testimony from a diverse group of scientific experts. At issue are dietary supplement advertising claims alleged to involve a condition known as "Attention Deficit/Hyperactivity Disorder (ADHD)," the nature of which is highly controversial. This fact is recognized by Complaint Counsel's own expert, Dr. L. Eugene Arnold, who admits in his report that there is disagreement among ADHD experts, particularly with respect to the biological basis and etiology of ADHD and substantiation. Respondents are prepared to present testimony from numerous experts with differing areas of scientific expertise to address the appropriate characterization of ADHD and substantiation. Although Complaint Counsel have chosen to rely on the

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[1] FTC, Dietary Supplements: An Advertising Guide for Industry (1998) ("FTC guidance").

testimony of only one expert on this subject, Respondents should not be forced to severely limit their expert testimony.

Complaint Counsel are incorrect in asserting that Respondents' experts' testimony will be cumulative. Complaint Counsel attempt to shore up their Motion with allegations that Respondents are playing a "numbers game," attempting to proffer cumulative testimony and creating an undue burden with respect to deposition discovery.[2] In fact, the FTC has often entertained cases wherein numerous expert witnesses gave valuable and probative testimony without being cumulative. Respondents' right to be heard in this case should not be limited, nor should they be hampered in their defense because Complaint Counsel believe that the taking of depositions will be time-consuming or otherwise demanding, all the while conceding that "there is no magic number of appropriate experts in any litigation."[3]

THE MOTION IS STILL NOT RIPE

Respondents properly identified our potential witnesses on February 16, 2001, as required by Your Honor's Amended Schedule -- a list consisting of fourteen potential expert witnesses. Further, we provided thirteen experts' reports on March 14, 2001, and one on March 15. For reasons unrelated to Complaint Counsel's Motion, Respondents have subsequently decided to drop Dr. Richard Kunin from their expert witness list.

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2 See Renewed Motion at 4.

3 See Renewed Motion at 6.

Complaint Counsel have renewed their Motion without having taken the depositions of Respondents' experts. Because discovery has not closed, Complaint Counsel have not availed themselves of the opportunity to discover the opinions of Respondents' experts by questioning them. Hence, Complaint Counsel's renewed Motion is still unripe, because it is based on Complaint Counsel's hypothesis that the number of witnesses Respondents have named indicates that those witnesses' testimony will be cumulative.[4]

It is premature for Complaint Counsel to move for, and for Your Honor to grant, any ruling as to whether the testimony of Respondents' experts will be cumulative. As we indicated at the April 3, 2001 status conference, Respondents will endeavor to propose and enter into stipulations with Complaint Counsel that will minimize duplicative testimony. Complaint Counsel have not stipulated that if one expert renders an opinion, that opinion will be established as fact. Thus, Respondents may be required to present some duplication in order to establish a record that "experts" agree that Respondents' advertising claims for Pedi-Active A.D.D. were adequately substantiated.

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[4] Complaint Counsel discuss the reports of Respondents' experts in the renewed Motion, and predictably summarize them as cumulative. Complaint Counsel ignore the purpose of the expert reports, which do not establish the final testimony of the experts. Further, Complaint Counsel ignore information in these reports which shows that these experts, having diverse backgrounds, will present considerable non-cumulative and relevant testimony at the hearing.

COMPLAINT COUNSEL IGNORE RELEVANT FTC PRECEDENT

Complaint Counsel cite numerous federal cases to bolster their argument that cumulative testimony can be excluded from a proceeding.[5] However, Complaint Counsel fail to cite even one FTC case to support their position. The reason is obvious; the FTC precedent supports Respondents' position that Your Honor should not limit the number of expert witnesses we have designated.

It is not unusual in administrative cases brought by the FTC that both sides call multiple expert witnesses. Complaint Counsel assert that "[t]here is nothing unique about this case."[6] We agree with that statement, and the cases cited below illuminate that complaints brought by the FTC before its Administrative Law Judges often require the testimony of multiple experts, and that testimony from numerous experts is both probative and valuable to the process. Indeed, in cases Complaint Counsel did not cite, it was not unusual for Complaint Counsel or the Respondents to call as many or more experts as Respondents have designated in this case. For example:

- In In re Bristol-Myers Co., 102 F.T.C. 21, 1983 FTC LEXIS 63 (1983), petition for review denied sub nom., Bristol-Myers Co. v. F.T.C., 738 F.2d 554 (2d Cir. 1984), the FTC alleged Bufferin advertising lacked adequate substantiation. Complaint Counsel used twelve medical scientific experts and

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5 See Renewed Motion at 10, n.18.

6 See Renewed Motion at 2.

seventeen other experts, while Respondents used five medical scientific experts to testify at the Hearing;

- In In re Schering Corp., 1991 FTC LEXIS 427 (1991), the FTC alleged violations of Sections 5(a) and 12 of the Federal Trade Commission Act, arguing Schering did not have a reasonable basis for advertising claims concerning Fibre Trim. Complainant called five medical scientific experts and two other experts, while Respondents called ten medical scientific experts and four other experts to testify at the Hearing;
- In In re Sterling Drug, Inc., 102 F.T.C. 395, 1983 FTC LEXIS 65 (1983), order enforced sub nom., Sterling Drug, Inc. v. F.T.C., 741 F.2d 1146 (9th Cir. 1984), the case related to whether advertisements for Bayer aspirin had been adequately substantiated. Complaint Counsel called nine medical scientific expert witnesses, and Respondent called nine medical scientific experts and seven other experts to testify at the Hearing; and
- In In re Thompson Medical Co., 104 F.T.C. 648, 1984 FTC LEXIS 6 (1984), petition for review denied sub nom., Thompson Medical Co. v. F.T.C., 791 F.2d 789 (D.C. Cir. 1986), the FTC alleged that Respondent lacked adequate substantiation for the drug product Aspercreme. Respondent called ten medical scientific experts and five other experts to testify at the Hearing.

Even more telling is Your Honor's ruling in In re R.J. Reynolds Tobacco Co., 1998 FTC Lexis 182 (1998), another case Complaint Counsel did not cite in their

renewed motion. There, Your Honor denied Complaint Counsel's Motion to Strike Expert Witnesses, ruling:

> Complaint counsel have not shown that the expected testimonies of these witnesses are cumulative, nor have complaint counsel shown that they will be unduly burdened by having to take the depositions of these experts and cross examine them at trial.[7]

Your Honor rejected the very argument Complaint Counsel makes here -- that they would be unduly burdened by having to take the experts' depositions.

As we noted in response to the earlier Motion, Complaint Counsel are not forced to depose each of Respondents' experts. Rather, they have opted to exercise their right to do so. Moreover, Complaint Counsel are free to take some or all of these depositions by telephone. Their choice to take all of these depositions, and to take them in person, is not required by the Rules. Having made this choice, Complaint Counsel are not in a position to blame Respondents for the costs involved. Surely, Respondents' right to present highly relevant evidence that goes to the heart of our defense outweighs any self-imposed financial burdens on Complaint Counsel.

Your Honor's two week extension of the close of discovery considerably weakens Complaint Counsel's argument that taking Respondents' experts' depositions is overly burdensome. Complaint Counsel and Respondents have nearly worked out a schedule that will allow Complaint Counsel to take the depositions they desire. Having brought this case, Complaint Counsel must now dedicate the necessary resources to prosecute the

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[7] In re R.J. Reynolds Tobacco Co., 1998 FTC Lexis 182, at *1 (1998).

case, consistent with the Respondents' right to have a full and fair opportunity to be heard in their presentation of relevant evidence.

Complaint Counsel should concentrate their efforts on presenting sufficient evidence to carry their burden of proving the allegations in the Complaint, rather than seek to dictate to Respondents and Your Honor how we present our defense. Complaint Counsel's repetitive motions to limit Respondents' case are diverting the attention of Respondents' counsel from the difficult task at hand of preparing for the upcoming hearing.

FTC'S OWN GUIDANCE DEFEATS THE MOTION

Complaint Counsel's renewed Motion goes against FTC's own guidance that was issued to clarify the substantiation standard for advertisers of dietary supplements. FTC's guidance, titled "Dietary Supplements: An Advertising Guide for Industry" states that FTC requires dietary supplement claims concerning safety or efficacy to be supported with:

> 'competent and reliable scientific evidence,' defined in FTC cases as 'tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.'[8]

[8] FTC guidance at 9 (emphasis added).

The guidance further states that "[t]here is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration"[9] and that "[a] guiding principle of determining the amount and type of evidence that will be sufficient is what experts in the relevant area of study would generally consider to be adequate."[10] Moreover, the guidance emphasizes that, in making a determination concerning the amount of substantiation that experts in the field believe is reasonable, the FTC "consults with experts from a wide variety of disciplines."[11] Complaint Counsel never even mention this FTC guidance.

Thus, the FTC's guidance contemplates the use of multiple experts in a substantiation case. The words "professionals" and "experts" appear in the plural, not in the singular. This indicates the FTC's contemplation that the opinions of perhaps many professionals and experts would be consulted to determine the substantiation of a claim regarding a dietary supplement's effectiveness. While Complaint Counsel may freely decide to use a single expert witness to support their case, Respondents are under no obligation to limit their experts, as demanded in the renewed Motion.

Second, the FTC's policy guidance states that there is "no fixed formula" for studies, sample size, duration, or other parameters for substantiation. Similarly, there is no "fixed formula" with regard to the number of experts Respondents will need to defend

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9 Id.

10 Id. at 10 (emphasis added).

11 Id. at 9.

their advertising claims at issue. Yet, Complaint Counsel attempt to "fix" a formula for Respondents' case, arbitrarily deciding that Respondents should be limited first to six, and now to five, experts. In their renewed Motion, Complaint Counsel go even further and attempt to micro-manage Respondents' defense by asserting "One good expert can perform this task as well as one hundred."[12] They ask that Respondents' scientific experts be limited to "2 experts to discuss the effects of DMAE and/or other product ingredients" and "one expert to discuss ADHD."[13] As the FTC's guidance and prior FTC case law indicate, "there is no magic number"[14] with regard to establishing substantiation. In short, Respondents must be allowed to properly prepare their case, within the bounds of previously issued FTC guidance and case law precedent.

SCIENTIFIC TESTIMOMY OF RESPONDENTS' EXPERTS IS ESSENTIAL AND IS NOT CUMULATIVE

The very nature of ADHD requires testimony of experts from a wide array of scientific disciplines -- as recognized by the FTC's own expert, Dr. L. Eugene Arnold, and several of Respondents' experts. In his expert report for Complaint Counsel, Dr. Arnold gives an in-depth discourse about the history and nature of ADHD. In doing so, he admits that there is disagreement among ADHD experts, particularly with respect to the biological basis and etiology of ADHD.

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12 Renewed Motion at 6.

13 Renewed Motion at 4.

14 See Renewed Motion at 6.

Respondents will offer expert testimony concerning the controversial nature of ADHD. In light of this fact, it is essential to the fair resolution of this proceeding that Your Honor hear from experts with a variety of scientific backgrounds and expertise. This is particularly critical in this case since there is no "accepted norm" among scientific experts with respect to the characterization of ADHD. Thus, Complaint Counsel's suggestion that Respondents should be limited to "one expert to discuss ADHD"[15] is patently absurd.

Complaint Counsel wrongly assume that Respondents' experts will testify in a cumulative fashion. It appears that Complaint Counsel are basing this erroneous assertion on the fact that Respondents did not ask their experts to consider "sub-topics."[16] Complaint Counsel misunderstand the rationale for the testimony of these different experts and the manner in which their testimony will fit together.

While Respondents have compiled a comprehensive list of scientific experts, the experts are a diverse group, specializing in differing areas of science and offering particular expertise in addressing the symptoms associated with ADHD.[17] Respondents are prepared to present substantial testimony at the hearing that the scientific data in their possession was more than sufficient to constitute a reasonable basis on which to make the claims in the advertisements for Pedi-Active A.D.D. To that end, and in consideration of

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15 Renewed Motion at 4.

16 Renewed Motion at 3.

17 See Respondents' Statement of the Case at 12-13.

Complaint Counsel's outright rejection of the scientific evidence presented by Respondents' former counsel in negotiations prior to the issuing of the Complaint, Respondents should be permitted to fully develop expert testimony necessary to their defense.

In their renewed Motion, Complaint Counsel attach as Exhibit C their "Summary of Respondents' Expert Reports" which overly simplifies and mischaracterizes Respondents' expert reports. Apparently, because Complaint Counsel have not yet deposed these witnesses, they assume that the testimony will be cumulative and repetitive, when, in fact, Respondents have no intention to burden Your Honor in that manner. As established above, the FTC's own guidance encourages and appears to require testimony from a variety of experts.

Further, as explained above, Respondents are still developing their testimony for the hearing through experts who have reviewed scientific data relevant to this case and who have used the ingredients in Pedi-Active A.D.D. in their practices to address children's attention, focus, and learning issues. We will work closely with those experts to narrowly tailor their testimony to avoid unnecessary duplication. Further, we will propose stipulations to Compliant Counsel which, if agreed upon, will limit the scope of their testimony and potentially the need to call one or more of these experts to testify at the hearing.

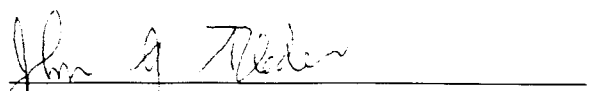
CONCLUSION

During the status conference held on April 3, 2001, Complaint Counsel stated that "the [Respondents'] expert depositions are key to this case." It is time to take those depositions, unhindered by Complaint Counsel's premature and artificial efforts to limit their testimony.

For the foregoing reasons, Complaint Counsel's Renewed Motion to Limit Expert Witnesses should be denied with prejudice.

Dated: April 6, 2001

Respectfully Submitted,



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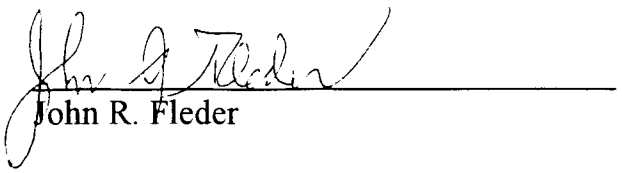
CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of April 2001, a copy of the foregoing Respondents' Answer to Complaint Counsel's Renewed Motion to Limit Expert Witnesses was served by facsimile and by overnight delivery, on Matthew D. Gold and Kerry O'Brien, Federal Trade Commission, 901 Market Street, Suite 570, San Francisco, CA 94310.



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