UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of	)	
DANIEL CHAPTER ONE, a corporation, and	)	DOCKET NO. 9329
JAMES FEIJO, Respondents.	)	

ORDER DENYING COMPLAINT COUNSEL'S MOTIONS *IN LIMINE* TO EXCLUDE OPINIONS FROM RESPONDENTS' PROPOSED EXPERT WITNESSES

I.

On March 16, 2009, pursuant to the Scheduling Order in this matter, Complaint Counsel submitted Motions *In Limine* to exclude Respondents' proposed expert witnesses, as follows: (1) Motion *In Limine* and Memorandum in Support to Exclude the Testimony and Report of Respondents' Expert Witness James Duke; (2) Motion *In Limine* and Memorandum in Support to Exclude the Testimony and Report of Respondents' Expert Witness Sally LaMont; and (3) Motion *In Limine* and Memorandum in Support to Exclude the Testimony and Reports of Respondents' Expert Witnesses Rustum Roy, Jay Lehr and Jim Dews (collectively, the "Motions"). Respondents submitted a single, consolidated Opposition to Complaint Counsel's Motions on March 26, 2009 ("Opposition").

Having fully considered all arguments in the Motions and the Opposition, and as discussed below, the Motions are DENIED.

II.

A. James Duke, Ph.D. ("Duke")

According to Respondents' witness list, Duke is offered to "provide substantiation for health claims about natural products generally and the use of herbs as medicine in the Bible." According to Duke's expert report, attached to Complaint Counsel's Motion *In Limine*, Duke's "scope of work" was to "[r]eview and offer opinion supported by

evidence and experience on the ingredients of the challenged products[1]; to review the science of herbal efficacy; and to clarify the complex nature of herbal science versus the relatively simple science of pharmaceuticals." Expert Report of James Duke, Ph.D. ("Duke Report"), p. 1.

According to the report, Duke has compiled a catalogue of information about herbs as remedies and has devised a rating system for the type and degree of support for various remedial claims for herbs, including claims for cancer, based upon Duke's searches of public databases. Duke Report, pp. 4-5, 11. Duke's report sets forth the following "Summary of Opinion":

1. There is a reasonable basis for the claims that the ingredients of 7 Herb Formula ". . . , fights [sic] tumor formation, and fights [sic] pathogenic bacteria."

2. There is a reasonable basis for the claims that the ingredients of GDU "contains [sic] natural proteolytic enzymes (from pineapple source bromelain) to help digest protein – even that of unwanted tumors and cysts. This formula also helps to relieve pain and heal inflammation. . . . GDU is also used for . . . and as an adjunct to cancer therapy. GDU possesses a wide range of actions including anti-inflammatory and antispasmodic activity. . ."

3. There is a reasonable basis for the claims that the ingredients of BioMixx "boosts [sic] the immune system, . . . to allow for natural healing. It is used to assist the body in fighting cancer and in healing the destructive effects of radiation and chemotherapy treatments."

Duke Report, p. 3.

As grounds for excluding Duke's report and testimony in advance of trial, Complaint Counsel contends that: (1) Duke is an economic botanist with no education or experience treating cancer and no scientific experience with any study to measure the anti-cancer effects of herbs. Therefore, Complaint Counsel argues, Duke is not qualified to give expert opinions regarding whether there is competent and reliable scientific evidence to support Respondents' claims that the Challenged Products prevent, treat or cure cancer; (2) Duke's opinions are irrelevant, because nothing in Duke's testimony will assist the Court in resolving the question of whether Respondents had competent and reliable scientific evidence to support their claims that the Challenged Products prevent, treat, or cure cancer; and (3) Duke's opinions are unreliable because they are not based on sufficient facts and data. Among other bases, Complaint Counsel notes that at his deposition, Duke testified that he had never heard of Daniel Chapter One ("DCO") before, did not know what the DCO products were, has never seen the challenged

[1] The "challenged products" are defined in the Complaint as the Daniel Chapter One products known as GDU, Bio*Shark, BioMixx and 7 Herb Formula. They are referred to collectively in this Order as the "Challenged Products."

advertising, never saw the products or their labels to view the quantities of herbs in the products, and erroneously believed at first that DCO was using only "Biblical" herbs.

B. Sally LaMont, N.D. ("LaMont")

According to Respondents' witness list, LaMont "will provide pre-claim substantiation for Respondents' challenged claims; substantiation for health claims about natural products generally; [and] contradict FTC claims of the safety and effectiveness of conventional cancer treatments, including the inadequacy of the 'scientific method' in evaluating the usefulness of nutritional supplements and natural healing." According to her report, attached to Complaint Counsel's Motion *In Limine*, LaMont is a naturopathic doctor and acupuncturist. She has practiced naturopathic medicine since 1981, and has incorporated Chinese herbal medicine into her practice. Report of Expert Witness Sally LaMont ("LaMont Report"), p. 1. LaMont's scope of work was to provide opinions "on the use of nutrition supplements and botanical medicines in the prevention and treatment of illness, including but not limited to cancer." She was also asked to review the evidence that exists regarding the "mechanisms of action of the major constituents of" the Challenged Products. LaMont Report, p. 3. She was provided with the Challenged Products' labels, and the literature and summary of medical evidence which she understood to have been provided to the FTC. She states that, to form her opinion, she searched various sources of published literature regarding herbal medicines. She also drew on her experience as a practicing naturopathic doctor and acupuncturist who utilizes dietary supplements and botanical medicines in daily practice. LaMont Report, pp. 3-4. The LaMont Report's "Summary and Conclusions" state:

1. There is a reasonable basis to claim that the ingredients of GDU contain bromelain, a source of natural proteolytic enzymes from the pineapple, which helps digest unwanted proteins. GDU also contains tumeric, feverfew and quercitin, which help to reduce inflammation and relieve pain. Next, it is reasonable to claim that these ingredients as a whole may be used as an adjunct to cancer therapy, and that the ingredients possess a wide range of actions as anti-inflammatory agents.

2. There is a reasonable basis to claim that the ingredients of 7 Herb Formula fight tumor formation, and fight pathogenic bacteria.

3. There is a reasonable basis to claim that the ingredients of BioMixx boost the immune system, build lean body mass and support healing. It is also reasonable to claim that these ingredients assist the body in fighting cancer, cachexia and in healing the destructive effects of radiation and chemotherapy treatments.

4. There is a reasonable basis for the claims that pure skeletal tissue of sharks provides a protein that inhibits angiogenesis – the formation of

new blood vessels. It is also reasonable to claim that angiogenesis has been demonstrated to inhibit tumor growth in some studies.

LaMont Report, p. 40.

Complaint Counsel's arguments for excluding LaMont are substantially the same as those it made regarding Duke -- that LaMont is unqualified, and that her opinions are irrelevant and unreliable as not supported by sufficient facts or data. In summary, Complaint Counsel contends that: (1) LaMont is unqualified because she has never served as an expert, and is not a trained doctor or oncologist; (2) LaMont's testimony is irrelevant because she relies on "traditional use" evidence rather than on scientific evidence; and her opinions refer to the ingredients of the Challenged Products, rather than to the Challenged Products themselves. Therefore, according to Complaint Counsel, LaMont's opinions will not assist the court in evaluating whether there was competent and reliable scientific evidence to substantiate Respondents' "serious cancer claims" and "disease claims" about the Challenged Products; and (3) LaMont's opinions are unreliable because she has only limited knowledge of the DCO products, has not studied the medical records of anyone who has taken them to cure cancer, and could not state the recommended doses of the products.

C. Rustum Roy ("Roy")

According to Respondents' witness list, Roy is expected to testify regarding the "inappropriateness of relying on and the lack of scientific validity of randomly-controlled trials to evaluate whole person healing; the science of homeopathy; and the scientific validity of traditional testing of herbal medicines." According to Roy's expert report, submitted by Complaint Counsel with its Motion *In Limine*, Roy has been an active professional scientist and educator in the physical sciences for over six decades, and in integrative medicine for nearly three decades. Expert Report of Rustum Roy ("Roy Report"), p. 2. Roy's "Summary of Opinions" states as follows:

1. It is inappropriate to use traditional randomly controlled double blind studies to evaluate whole person healing approaches.

2. Homeopathy is an empirical science based health modality and its practitioners are knowledgeable about what constitutes an effect on the structure and function of the whole person, the true approach to healing as distinct from using a drug to cure the symptoms of a disease.

3. Herbal medicines have been tested epidemiologically by nature over thousands of years and hundreds of human generations, in many different peoples. Humans have evolved side by side with the natural substances in herbs, so they are not new chemicals to us. New chemicals, like those in pharmaceuticals, are totally new to the very complex body, and we have no way of really knowing their systemic

and long term effects, which may take decades, and in some cases, generations, to become clear.

4. Cancer is a particular instance where whole body healing approaches make far more scientific sense than relying solely on pharmaceutical approaches.

5. There is no conflict between science and religion, because they are incommensurable.

6. The health modalities that have the greatest impact on public health are known to be those that affect the whole person: diet, exercise, clean water.

Roy Report, pp. 1-2.

Complaint Counsel contends that Roy's opinions are: (1) irrelevant, because randomly controlled double blind studies are required to support serious health claims; (2) unreliable under Rule 702 of the Federal Rules of Evidence, because Roy has not conducted any studies to support his opinion that double blind controlled studies are inappropriate, contending that under *Daubert*, an important indicia or reliability is whether an expert is proposing to testify about matters growing naturally and directly out of research the expert has conducted independent of the litigation or whether the expert has developed his or her own opinions expressly for purposes of testifying; and, (3) unreliable, because Roy has no knowledge of the Challenged Products, what ingredients they contain, or Respondents' communications about the products that are at issue in the case.

D. Jay Lehr ("Lehr")

Respondents' witness list states that Lehr will "provide pre-claim substantiation of Respondents' challenged claims." According to the deposition transcript submitted by Complaint Counsel[2]: Lehr is a Ph.D. environmental scientist, Lehr Deposition Transcript, p. 9 (hereafter "Lehr Tr., p. ___); Lehr has written a book on health and fitness, Lehr Tr., p. 10; Lehr has known Respondent James Feijo for approximately 10 years, Lehr Tr., p. 16; Lehr takes Daniel Chapter One products to enhance his athletic performance, Lehr Tr., pp. 16-17; and, one week prior to the deposition, Lehr started taking GDU, one of the Challenged Products, for an arthritic hip. Lehr Tr., p. 18.

Complaint Counsel argues that Lehr's testimony should be excluded because, according to his deposition testimony, he is not a cancer expert and has no opinions concerning whether the Challenged Products prevent, treat or cure cancer. Complaint Counsel states that Lehr's opinion is that, because the athletic products Lehr takes were effective for him, and because Respondent Feijo appears to Lehr to be knowledgeable about performance enhancing herbal products, then Respondents' other products must be

[2] Neither party submitted an expert report for Lehr.

effective as well. According to Complaint Counsel, Lehr has done no literature searches concerning substantiation for Respondents' claims that the Challenged Products prevent, treat or cure cancer, and his "testing" is limited to the personal experience of him and his wife in taking DCO's products other than the Challenged Products. Complaint Counsel argues that Lehr cannot provide any substantiation of any kind for the Challenged Products, and his testimony should therefore be excluded.

E. Jim Dews ("Dews")

Respondents' witness list states Dews will "provide pre-claim substantiation of Respondents' challenged claims." According to Dews' deposition, submitted by Complaint Counsel,[3] Dews manufactures pharmaceuticals and "nutraceuticals," which comprise chemical extracts from one or more herbs, such as Vitamin C tablets. Dews Deposition Transcript, pp. 17-18 (hereafter, "Dews Tr., p. _"). He has done so for 35 years. Dews Tr., p. 55. Dews also consults for others in the creation of nutraceuticals, and analyzes and certifies the chemical composition of nutraceuticals formulated by others. Dews Tr., pp. 21-28. Dews testified that about 15 to 20 years ago, he advised an individual named Bill McLean who wanted to make an herb formula, and he later learned that McLean eventually started manufacturing 7 Herb Formula. Dews Tr. pp. 34-36, 76. Dews' opinions will center on the ingredients of Respondents' 7 Herb Formula and substantiation for the effectiveness of various herbs as remedies, including for reducing inflammation, supporting the immune system, and/or purifying the blood. *E.g.*, Dews Tr. pp. 5, 41-54. Dews bases his opinions on various sources of information about herbs and nutraceuticals that he uses for his business, including a Physicians' Desk Reference and various German and British reference compilations. *E.g.*, Dews Tr., pp. 69-75.

Complaint Counsel argues that Dews is unqualified to testify as an expert because he has no college degree, is not a clinician or health care practitioner, and his main role in making nutraceuticals for customers is to formulate a blend that is probably safe for its intended use. Complaint Counsel also contends that Dews' opinions are unreliable because Dews had never heard of 7 Herb Formula until he was contacted regarding the present lawsuit, and is familiar only with the component ingredients. Because he cannot offer any opinions as to whether 7 Herb Formula prevents, treats or cures cancer, Complaint Counsel argues, his testimony should be excluded.

F. Respondents' Opposition

As noted above, Respondents filed a single, consolidated opposition to Complaint Counsel's Motions. As to all their proposed experts, Respondents contend that they need not be qualified to testify about claims that the Challenged Products prevent, treat or cure cancer, because Respondents deny they make such claims. Respondents state that their experts are offered to provide information and give opinions on the quality and quantity of substantiation that exists for Respondents' claims about the constituent ingredients within the Challenged Products, and the nature of the science that supports those claims, not the claims alleged by Complaint Counsel. Respondents submit that it is not necessary

[3] Complaint Counsel did not submit an expert report for Dews.

for their experts to testify that the Challenged Products are effective for cancer. Respondents further argue that under the FTC Dietary Supplements Guide, the appropriate level of substantiation is flexible and it is appropriate to consider the opinions of those with experience in botanicals and traditional medicines. Respondents assert that they "believe that the body has innate healing capabilities that the products they make available assist. It is to cast light on these and related facts in the case that Respondents proffer" their experts. Opposition, p. 8.

In addition, Respondents state that their experts' opinions are relevant to public policy considerations, which they contend are relevant under Section 5(n) of the FTC Act, 15 U.S.C. § 45(n). That section states:

> (n) Definition of unfair acts or practices. The Commission shall have no authority under this section or section 18 [15 USCS § 57a] to declare unlawful an act or practice on the grounds that such act or practice is unfair unless the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition. In determining whether an act or practice is unfair, the Commission may consider established public policies as evidence to be considered with all other evidence. Such public policy considerations may not serve as a primary basis for such determination.

Finally, Respondents assert that Complaint Counsel's objections go to the weight, not the admissibility, of the evidence.

As to Duke, Respondents contend that he is a renowned botanist who is widely published and recognized as one the most knowledgeable individuals in the world on the nature of herbs. Respondents further assert that Duke is thoroughly familiar with all the herbal ingredients in Respondents' products, that Duke was asked to evaluate the claims made for the DCO products and the information available to support them, and that Duke's opinions support what Respondents state are "dietary supplement claims." Opposition, p. 9.

Respondents specify as to LaMont that she is trained to and does treat patients with herbs and is familiar with herbal science literature; that she was provided the substantiation materials upon which Respondents relied in making their claims and was asked to evaluate them, as well as other supporting literature; and that her testimony illuminates and corroborates what Respondents state are Respondents' "dietary supplement claims." Opposition, p. 9.

With regard to Roy, Respondents argue that he is a world-renowned materials scientist and a member of the National Academy of Engineering, among other organizations; has worked to apply principles of physics and engineering to health; has conducted research on the mechanisms of homeopathy; and has years of experience in participating in, conducting and overseeing the construction of scientific studies in accordance with the principles of science. They contend that Roy has specifically

reviewed the pitfalls of relying on single entity chemical testing for herbs, and that his opinions about the structure of science and the role it plays in addressing various facts about health, herbs, and claims is crucial to understanding the case.

As to Lehr, Respondents assert that he has many years of science experience and experience with scientific studies, and that he will offer opinions and testimony about the structure of science and the role it plays in addressing various facts about health, herbs and claims.

Finally, with regard to Dews, Respondents claim that he is a world-renowned manufacturer of herbal and other health-related products, with nearly 40 years as an herbal product manufacturer, who has the knowledge, training, skill, and education in herbal supplements to testify to their effects and the scientific basis for herbal usage. Respondents further note that Dews advised the manufacturer of 7 Herb Formula as to how it could be formulated. Therefore, Respondents claim, he can describe how he created the formula, the standard of knowledge about each of its ingredients as contained in monographs and the herbal Physicians' Desk Reference, and will corroborate Respondents' claims. According to Respondents, Dews can also testify about the cost and quantity of substantiation for dietary supplements and their constituent ingredients.

III.

A. *In Limine* Standard

"Motion *in limine*" refers "to any motion, whether made before or during trial, to exclude anticipated prejudicial evidence before the evidence is actually offered." *Luce v. United States*, 469 U.S. 38, 40 n.2 (1984); *see also In re Motor Up Corp.*, Docket 9291, 1999 FTC LEXIS 207, at *1 (August 5, 1999). Although the Federal Rules of Evidence do not explicitly authorize *in limine* rulings, the practice has developed pursuant to the court's inherent authority to manage the course of trials. *Luce*, 469 U.S. at 41 n.4. The practice has also been used in Commission proceedings. *E.g.*, *In re Telebrands Corp.*, Docket 9313, 2004 FTC LEXIS 270 (April 26, 2004); *In re Dura Lube Corp.*, Docket 9292, 1999 FTC LEXIS 252 (Oct. 22, 1999).

Motions *in limine* are generally used to ensure evenhanded and expeditious management of trials by eliminating evidence that is clearly inadmissible. *Bouchard v. American Home Products Corp*, 213 F. Supp. 2d 802, 810 (N.D. Ohio 2002); *Intermatic Inc. v. Toeppen*, No. 96 C 1982, 1998 U.S. Dist. LEXIS 15431, at *6 (N.D. Ill. February 28, 1998). Evidence should be excluded on a motion *in limine* only when the evidence is clearly inadmissible on all potential grounds. *Hawthorne Partners v. AT&T Technologies, Inc.*, 831 F. Supp. 1398, 1400 (N.D. Ill. 1993); *see also Sec. Exch. Comm'n v. U.S. Environmental, Inc.*, No. 94 Civ. 6608 (PKL)(AJP), 2002 U.S. Dist. LEXIS 19701, at *5-6 (S.D.N.Y. October 16, 2002). Courts considering a motion *in limine* may reserve judgment until trial, so that the motion is placed in the appropriate factual context. *U.S. Environmental*, 2002 U.S. Dist. LEXIS 19701, at *6; *see, e.g., Veloso v. Western Bedding Supply Co., Inc.*, 281 F. Supp. 2d 743, 750 (D.N.J.

2003). *In limine* rulings are not binding on the trial judge, and the judge may change his mind during the course of a trial. *Ohler v. United States.*, 529 U.S. 753, 758 n.3 (2000); *Luce*, 469 U.S. at 41 (stating that a motion *in limine* ruling "is subject to change when the case unfolds, particularly if the actual testimony differs from what was contained in the defendant's proffer"). "Denial of a motion *in limine* does not necessarily mean that all evidence contemplated by the motion will be admitted at trial. Denial merely means that without the context of trial, the court is unable to determine whether the evidence in question should be excluded." *Noble v. Sheahan*, 116 F. Supp.2d 966, 969 (N.D. Ill. 2000); *Knotts v. Black & Decker, Inc.*, 204 F. Supp.2d 1029, 1034 n.4 (N.D. Ohio 2002).

B. Standard Applicable to Expert Testimony

To be admissible, evidence must be relevant, material, and reliable, pursuant to Commission Rule 3.43(b)(1). When ruling on the admissibility of expert opinions, courts traditionally consider whether the expert is qualified in the relevant field and examine the methodology the expert used in reaching the conclusions at issue. *See, e.g.*, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and the many cases applying *Daubert*, including *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 153-54 (1999).

Rather than excluding expert testimony, the better approach under *Daubert* in a bench trial is to permit the expert testimony and allow "vigorous cross-examination, presentation of contrary evidence" and careful weighing of the burden of proof to test "shaky but admissible evidence." *The Ekotek Site PRP Committee v. Self*, 1 F. Supp. 2d 1282, 1296 n.5 (D. Utah 1998) (citing *Fierro v. Gomez*, 865 F. Supp. 1387, 1396 n.7 (N.D. Cal. 1994) (quoting *Daubert*, 509 U.S. at 596)). *See also Clark v. Richman*, 339 F. Supp. 2d 631, 648 (M.D. Pa. 2004) (stating that "[a]s this case will be a bench trial, the court's 'role as a gatekeeper pursuant to *Daubert* is arguably less essential.'") (citation omitted); *Albarado v. Chouest Offshore, LLC*, Civil Action No. 02-3504 Section "J"(4), 2003 U.S. Dist. LEXIS 16481, at *2-3 (E.D. La. Sept. 5, 2003) (stating that "[g]iven that this case has been converted into a bench trial, and thus that the objectives of *Daubert* . . . are no longer implicated, the Court finds that defendant's motion should be denied at this time. Following the introduction of the alleged expert testimony at trial, the Court will either exclude it at that point, or give it whatever weight it deserves.").

IV.

Applying the foregoing standards, Complaint Counsel's Motions, at this stage of the proceedings, are denied. First, *United States v. 99.66 Acres of Land*, 970 F.2d 651 (9th Cir. 1992) does not mandate precluding Respondents' proposed experts' opinions at this stage of this case. That case held that the trial court did not abuse its discretion in excluding testimony from an accountant regarding a land development feasibility study where the accountant had no experience as an appraiser and had relied upon data that was provided to him, rather than upon data which the accountant himself had generated.

In addition, Complaint Counsel's contention that the proposed experts are insufficiently knowledgeable about cancer, the Challenged Products, or Respondents' communications about the Challenged Products, to render reliable opinions, addresses the weight, rather than the admissibility of the experts' opinions, and is best addressed through "[v]igorous cross-examination, [and] presentation of contrary evidence." *Daubert*, 509 U.S. at 596.

Finally, Complaint Counsel's argument -- to be relevant and reliable, Respondents' experts' opinions must address "competent and reliable scientific evidence" substantiating claims that Respondents' products "prevent, treat, or cure cancer" -- does not support precluding Respondents' experts' opinions in advance of trial. Complaint Counsel's argument is based on its contentions that Respondents expressly or impliedly claimed their products "prevent, treat or cure cancer" and that there must be competent, scientific evidence, in the form of double-blind, placebo-controlled studies, for there to be adequate substantiation of those claims. However, the messages that were in fact conveyed by Respondents' communications about their products, as well as the type and amount of substantiation required for those claims, are matters that have not yet been resolved. Accordingly, it cannot be determined, as a preliminary matter outside the context of trial, that Respondents' experts' opinions regarding substantiation should be excluded. *See In Re Basic Research, LLC*, Docket No. 9318, 2005 FTC LEXIS 152, *2-3 (December 1, 2005) (denying motion *in limine* that appeared to seek to exclude evidence "about the very issue that must be decided after receipt of the evidence in this case").

Accordingly, after full consideration of all arguments in the Motions and the Opposition, Complaint Counsel's Motions *in Limine* to Exclude the Testimony and Reports of Respondents' Expert Witnesses James Duke, Sally LaMont, Rustum Roy, Jay Lehr and Jim Dews, are each DENIED. Nothing herein shall be construed as a ruling on the admissibility of opinions or evidence that may be offered through these witnesses at trial.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: April 20, 2009