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

In the Matter of	
BASIC RESEARCH, L.L.C., **A.G. WATERHOUSE, L.L.C.,** **KLEIN-BECKER USA, L.L.C.,** **NUTRASPORT, L.L.C.,** **SOVAGE DERMALOGIC LABORATORIES, L.L.C.,** **BAN, L.L.C.,** **DENNIS GAY,** **DANIEL B. MOWREY, and** **MITCHELL K. FRIEDLANDER,**	**Docket No. 9318** **PUBLIC DOCUMENT**
Respondents.	

COMPLAINT COUNSEL'S MOTION FOR PROTECTIVE ORDER

Pursuant to RULE OF PRACTICE 3.22, Complaint Counsel moves for a *Protective Order* to limit the scope of Respondents' subpoenas *duces tecum* to two of Complaint Counsel's testifying experts; deny improper discovery demanded in 22 separate subpoenas *duces tecum* sent to Third Parties across the nation; and limit the scope of Respondent Dennis Gay's "Notice of Videotape Depositions" sent to 4 other Third Parties to protect these parties from annoyance, oppression, undue burden and expense. Respondents' subpoenas or notices are overbroad, unduly burdensome, harassing, seek information that is not reasonably expected to yield information relevant to this matter, and seek to gain expert testimony improperly. An *Order* limiting the scope of Respondents' subpoenas and depositions is appropriate.

BACKGROUND

The *Complaint* in this matter alleges, *inter alia*, that Basic Research and other related companies and individuals (collectively, "Respondents") marketed certain dietary supplements with unsubstantiated claims for fat loss and weight loss, and falsely represented that some of these products were clinically proven to be effective, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45 and 52.

The *Scheduling Order* in this matter set January 10, 2005, as the deadline for conducting all depositions, so the parties are preparing to depose witnesses while negotiating numerous outstanding discovery issues. In addition, the *Scheduling Order* set November 8, 2004, as the deadline for issuing subpoenas *duces tecum.*

Complaint Counsel has conferred with Respondents in an attempt to resolve the issues relating to the scope of these subpoenas discussed in this *Motion*. Although we were able to come to an agreement regarding two other testifying experts' subpoenas, Respondents declined to limit the two scientific substantiation experts' subpoenas *duces tecum* to areas of inquiry that the parties mutually agree are relevant and not unduly burdensome. Respondents further declined to withdraw their subpoenas to the 22 Third Parties, claiming that the inquiries are relevant to impeach one of Complaint Counsel's Expert Witnesses, Dr. Steven Heymsfield, regarding the use of double-blind clinical trials. As discussed below, the subpoenas seek documents that are completely outside the scope of the issues in this case. Finally, Respondents declined to limit the Notice of Videotape Depositions to the remaining 4 Third Parties to factual inquiry, as opposed to expert opinion. Respondents' positions necessitated the filing of the present *Motion*.

DISCUSSION

I. Scope of Discovery

"Parties may obtain discovery to the extent that it may be reasonably expected to yield information relevant to the allegations of the compliant, to the proposed relief, or to the defenses of any respondent." RULE OF PRACTICE 3.31(c)(1); *see FTC v. Anderson*, 631 F.2d 741, 745 (D.C. Cir. 1979). The Administrative Law Judge has the authority to quash or limit any subpoena that is unduly burdensome. *See* RULE OF PRACTICE 3.31(c)(1)(i) and (iii) (use of subpoena and other discovery methods "shall be limited by the Administrative Law Judge" where the "discovery sought is unreasonably cumulative or duplicative, or obtainable from some other source that is more convenient, less burdensome, or less expensive. . .; the burden and expense of the proposed discovery outweigh its likely benefit"); RULE OF PRACTICE 3.31(c)(2) (authorizing Administrative Law Judge to "enter a protective order denying or limiting discovery. . ."). Moreover, the ALJ has the power to deny discovery or modify a subpoena and limit the scope of permissible discovery "which justice requires to protect a party or other person from annoyance, embarrassment, oppression or undue burden or expense. . ." RULE OF PRACTICE 3.31(d)(1).

RULE 3.31(c)(4)(A) provides for discovery of an expert who is to testify at the trial. A party can require one who intends to use the expert to state the substance of the testimony that the expert is expected to give. The court may order further discovery, and has ample power to regulate its timing and scope and prevent abuse. "All data, documents, or information considered by a testifying expert witness in forming the opinions to be proffered in a case is discoverable." *Dura Lube Corp.*, No. 9292, 1999 F.T.C. Lexis 254 at *6 (Dec. 15, 1999)[1] *citing* Fed. R. Civ. P.

[1] Copies of all unpublished materials are attached as Exhibit A in alphabetical order.

26(a)(2)(B); 16 C.F.R. § 3.31(c)(4)(B); *Thompson Med. Co.*, 101 F.T.C. 385, 388 (1983). "Full disclosure of the basis of an expert opinion ensures the independence of the expert's conclusions." *Dura Lube* at *6. The RULES OF PRACTICE and this Court's *Scheduling Order* require that for each expert expected to testify at trial, the parties must exchange all documents reviewed, consulted, or examined by the expert in connection with forming his or her opinion on the subject on which he or she is expected to testify, regardless of the source of the document or whether a document was originally generated in another investigation or litigation. *Id.* at * 6-7. The scope of discovery is not limited to documents relied on by the expert in support of his or her opinions, but also extends to documents considered but rejected by the testifying expert in reaching those opinions. *Id.* at *7. An expert's prior opinions on the same subject matter may also be relevant to probe whether the expert has taken inconsistent positions. However, while a testifying expert's testimony from prior investigations or litigations must be produced, the documents "underlying" such testimony are not discoverable in subsequent litigation, "unless such documents were also relied upon or reviewed by a testifying expert in formulating an opinion in this case." *Id.* at *9. In addition, only those reports and documents prepared by any non-testifying experts which were relied upon or reviewed by a testifying expert in forming opinions in the instant case are discoverable *Id.*

In addition, under RULE 3.31(c)(4)(B), the Administrative Law Judge can order discovery of facts or opinions held by non-testifying or consulting experts who had been retained by the opposing party in anticipation of litigation only upon a showing of exceptional circumstances. The party seeking discovery from a non-testifying expert faces a heavy burden. *See Order Denying Basic Research's Motion to Compel* at 2 (Nov. 4, 2004); *Hoover v. Dep't. of Interior*, 611 F.2d 1132, 1142 n.13 (5th Cir. 1980).

II. Respondents' Subpoenas to Drs. Eckel and Heymsfield are Overbroad, Unduly Burdensome, and Seek Information Not Relevant to this Matter

After the close of business on November 8, 2004,[2] Respondents untimely served Complaint Counsel via email with copies of subpoenas *duces tecum* directed to two testifying scientific substantiation experts retained by Complaint Counsel, Dr. Steven B. Heymsfield, M.D., Executive Director of Clinical Sciences at Merck & Co., and Dr. Robert Eckel, M.D., a Professor at the University of Colorado and the President-elect of the American Heart Association.[3] Respondents' subpoenas consist of 22 identical specifications (and Heymsfield has 2 additional specifications), *not* including the 38 sub-specifications contained therein, which are designated by lower-case letters.

Complaint Counsel does not object to Specifications 1-7, and 20-22, which seek proper discovery, including a copy of the expert's file, correspondence with the FTC or any other individual relating to this case, all reports and drafts of reports prepared by the expert in connection with this case, all documents reviewed and all materials consulted or relied upon in forming any opinion in connection with this case, all documents which the FTC provided to the expert and all documents which the expert provided to the FTC, in connection with this case, and all notes of any meetings or telephone conversations with the FTC in connection with this matter. These specifications all properly demand documents which were prepared or used and relied upon by the experts in this case.

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[2] This service was at 5:19 p.m. and therefore pursuant to the *Scheduling Order*, past the November 8th 5:00 p.m. deadline for issuing written discovery requests not related to issues of authenticity and admissibility of exhibits. *See Scheduling Order* at p. 1, 3.

[3] Respondents' subpoenas *duces tecum* to our testifying experts are attached hereto as Exhibits B and C, respectively.

However, the remaining specifications, 8-19 and 23, are overbroad, unduly burdensome, seek information not reasonably expected to yield information relevant to this case, and seek materials that are outside of those relied upon by these experts in forming their opinions in this case. Accordingly, Complaint Counsel request that the Administrative Law Judge limit the scope of the subpoenas by striking these specifications.

A. Specifications Demanding a Library of Testifying Experts' Written Work

Specifications 8,[4] 9,[5] 10,[6] and 11[7] seek an overly broad range of documents and information which is readily discoverable by a reading of the experts' *curriculum vitae* (CV). On October 6, 2004, Complaint Counsel turned over our list of testifying experts, along with copies of their CVs. Dr. Eckel's CV includes a list of 94 speaking/participant events dating back to 1980, 136 publications, 18 letters and editorials, 32 chapters and books/reviews, and 183

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[4] Specification 8 seeks, "all documents that you have ever authored or contributed to regarding: a) obesity; b) weight loss; c) fat loss; d) the Federal Trade Commission; e) clinical trial protocol or procedures; f) the definition of 'competent and reliable scientific evidence'; g) Federal Trade Commission advertising rules and regulations; h) dietary supplements; i) weight loss or fat loss advertising."

[5] Specification 9 seeks, "all documents relating to lectures, speeches or testimony that you have ever given regarding: a) obesity; b) weight loss; c) fat loss; d) the Federal Trade Commission; e) clinical trial protocol or procedures; f) the definition of 'competent and reliable scientific evidence'; g) Federal Trade Commission advertising rules and regulations; h) dietary supplements; i) weight loss or fat loss advertising."

[6] Specification 10 seeks, "all documents relating to medical or clinical studies or tests that you have conducted or contributed to or participated relating to or involving: a) obesity; b) weight loss; c) fat loss; d) dietary supplements."

[7] Specification 11 seeks, "all patents and patent applications (whether or not published or pending review by the United States Patent and Trademark Office) in which you are named as an inventor or patent owner or assignee of any invention relating to: a) obesity; b) weight loss; c) fat loss; d) dietary supplements."

abstracts. Dr. Heymsfield's CVs includes a list of 312 original peer-reviewed articles, a number of articles in the Press, articles submitted, case reports, and reviews submitted in press, 110 book chapters/reviews, 4 books, 29 editorials/letters/book reviews, and patents.

Respondents requests seek an unlimited number of documents on unrelated matters involving different issues. Complaint Counsel have no objection to production of the documents that specifically relate to this case. Indeed, Complaint Counsel have turned all known materials requested in Specifications 1-7 and 20-22. That type of discovery is contemplated by the RULES and is clearly relevant. In addition, The RULES require Complaint Counsel to provide a "list of all publications authored by the witness within the preceding 10 years." RULE OF PRACTICE 3.31(b)(3). Complaint Counsel have complied with this rule and have gone further by providing each expert's CV which lists publications dating back further than 10 years. Nothing in the RULES requires that the experts provide copies of all of their publications.

Complaint Counsel have retained experts to address whether scientific support exists to substantiate the specific efficacy and establishment claims challenged in the Complaint given Respondents' specific products and their corresponding ingredients, dosage, composition and application. Respondents' subpoenas are so overbroad that they encompass thousands of pages of materials that do not relate to the issues or the claims and products challenged in this case. For example, Respondents are seeking all documents the experts have ever authored regarding nine broad areas. Documents that would be responsive to this subpoena would include, for example, documents regarding Dr. Eckel's participation in numerous articles and clinical studies relating to the study of metabolism and relationships between obesity, insulin and diabetes. Such studies and articles are not relevant to the purpose for which Dr. Eckel has been designated as an

expert. Moreover, the specifications seek "all documents" relating to lectures, speeches or testimony he has provided, "all documents" the expert has ever authored, and "all documents relating to" any clinical study the expert has ever been involved in regarding a) obesity, b) weight loss; c) fat loss, d) clinical trial protocol, and e) dietary supplements.[8] To the extent any documents are within the scope of expert discovery prescribed within the RULES OF PRACTICE and this Court's *Scheduling Order*, they have been produced. But Respondents' specifications far exceed the allowable scope of discovery. They specifically ask for all underlying documents, a request clearly beyond the permissible scope of discovery. *Compare Dura Lube* at *9 (in order to discover whether an expert has taken a prior inconsistent position, prior testimony must be produced, however the documents "underlying" the testimony are not discoverable in subsequent litigation, "unless such documents were also relied upon or reviewed by a testifying expert in formulating an opinion in this case")

Further, the Respondents are asking the experts to produce virtually their entire lives' work. Dr. Eckel's CV alone lists over 200 publications, and Dr. Heymsfield's CV lists over 400 publications. It is clear that many of the documents they seek are publicly available, and therefore equally available to all parties and may no longer be readily available to the experts without going to the same sources that Respondents would go to. The CVs already provide a list for Respondents. To require the experts, who are extremely busy with various professional obligations, to search for and produce every document relating to all of these broad areas in

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[8] Specifications 8 and 9 further seek all documents relating to the FTC and advertising law. These requests exceed the scope of Dr. Eckel and Heymsfield's expertise and hence are not relevant. Similarly seeking any patent information (specification 11) is not relevant to their expert opinions.

which these experts have spent numerous years of their lives studying and working, would be an arduous process, to say the least, and unduly burdensome.

These discovery requests are not tailored to discover information that is reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defenses of any Respondent. If Respondents wish to conduct such a fishing expedition, they should be prepared to expend their own time and resources, and not demand those of Third Parties, specifically our testifying experts, who are also medical doctors.

B. Specification Demanding Legal Documents

Specification 12[9] seeks information that is beyond the scope of discovery. Here, Respondents demand all documents relating to civil or criminal lawsuits in which the experts were named as a party. The RULES require that Complaint Counsel provide "a listing of any other cases in which the witness has testified as an expert at trial or by deposition within the proceeding four years." Complaint Counsel have complied with this requirement and will continue to supplement as more facts become available. However, Respondents' specification seeks documents not simply relating to the expertise of these witnesses; apparently, they are also seeking documents with which to impeach their credibility. Respondents are on a harassing fishing expedition to obtain anything to personally attack these expert witnesses, even separate and apart from their professional experience and opinions. This type of information can be obtained within reasonable limits by questioning the witnesses during their depositions. In fact, under the Federal Rules of Evidence, specific instances of conduct for the purpose of attacking

[9] Specification 12 seeks "all documents relating to lawsuits, whether criminal or civil, in which you were named as a party."

the witnesses' credibility, other than the conviction of certain crimes, may not be proved by extrinsic evidence. FED. R. EVID. 608(b). Respondents are simply not entitled to demand that the expert witnesses provide personal documentation regarding any civil or criminal lawsuits in which the experts were a party as opposed to testifying as an expert witness in their professional capacity. There is no provision in the RULES that would call for providing such information to Respondents and Respondents cannot show that such discovery would be reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defenses of any Respondent, much less that demanding such information is not unfairly prejudicial or harassing.[10]

C. Specifications Relating to Other Work and Compensation

Specifications 10,[11] and 13-19[12] all demand documents relating to other work the experts

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[10] If Respondents' counsel wishes to impeach our testifying experts by raising questions concerning their capacity for truthful testimony, as in the hypothetical case of damaging transcripts from divorce proceedings, then at the very least, Respondents should embark on their own safari, instead of demanding that others perform the work of the expedition. There are limits to admissible evidence. Unless there is evidence referring to character for truthfulness or untruthfulness, such evidence would be inadmissible under FED. R. EVID. 608(a) and likely unfairly prejudicial under FED. R. EVID. 403.

[11] See Footnote 6 for details of Specification 10.

[12] Specification 13 seeks, "all documents pertaining to work that you have performed for any company that manufactures, markets or sells pharmaceuticals or dietary supplements relating to: a) obesity; b) weight loss; c) fat loss." Specification 14 seeks, "all documents relating to weight loss or fat loss advertisements that you have authored, reviewed or approved relating to any weight loss or fat loss product." Specification 15 seeks, "all documents relating to requests for approval that you have made to the FDA, FTC or any other regulatory body, either on behalf of yourself or some other third party, relating to advertising or package labeling claims that you sought to make in relation to any weight loss or fat loss product." Specification 16 seeks, "all documents relating to efforts by you, either on your own behalf, or on behalf of any other third party or parties, to justify or substantiate advertising claims made in relation to any weight loss or fat loss product including but not limited to pharmaceutical products or dietary supplements."

performed either for other companies or for other government agencies in the broad areas in which make up their expertise, and thus, their entire professional careers. Respondents here are seeking documents that, once again, are so overreaching as to encompass areas which have no relationship to the issues in this case. These specifications are not tailored to the specific subject matter of the experts' testimony in this case. A search for all of these documents which span the careers of these experts would be an arduous and overly burdensome task.

The RULES require that Complaint Counsel provide "a listing of any other cases in which the witness has testified as an expert at trial or by deposition within the proceeding four years." The *Scheduling Order* goes further and provides that Complaint Counsel provide a list of "all prior cases in which the expert has testified or has been deposed." *Scheduling Order* at 5. Complaint Counsel have complied with this requirement and will continue to supplement as more facts become available. While testimony in the possession of Complaint Counsel or the expert, including deposition testimony, from prior investigations or litigation must be produced, the documents underlying such testimony are not discoverable in this subsequent litigation, unless such documents were also relied upon or reviewed by a testifying expert in formulating an opinion in this case. *See Dura Lube* at *9. Nevertheless, the documents that Respondents are seeking through these overbroad subpoenas, are far beyond that required by either the RULES or

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Specification 17 seeks, "all documents pertaining to work that you have performed for the Federal Trade Commission, The Food and Drug Administration or any other federal agency, whether as an expert, consultant or in any other capacity, relating to: a) obesity; b) weight loss; c) fat loss; d) the Federal Trade Commission; e) clinical trial protocol or procedures; f) the definition of 'competent and reliable scientific evidence'; g) Federal Trade Commission advertising rules and regulations; h) dietary supplements; i) weight loss or fat loss advertising." Specification 18 seeks, "all scientific and/or medical testing protocols you have authored." Specification 19 seeks, "all scientific and/or medical testing protocols on which you have provided comments, including your comments."

the *Scheduling Order*. Respondents will have the opportunity to question, within reasonable limits, these experts at depositions in this matter. However, demanding documents on matters that have no bearing on their opinions formed in this case, under these circumstances, with these particular products is an unreasonable and unduly burdensome task. There is no provision in the RULES that would call for providing such documentation to Respondents and Respondents cannot show that such discovery would be reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defenses of any respondent.

D. Specifications Relating to Other Products Not Made by Respondents or Challenged in the *Complaint* are Not Relevant and Unduly Burdensome

The subpoena *duces tecum* for Dr. Heymsfield includes two extra specifications[13] which seek all records and documents reflecting side effects experienced and comments about side effects experienced by subjects in control or placebo groups during a specific study titled, "Weight Control and Risk Factor Reduction in Obese Subjects Treated for 2 Years with Orlistat: A Randomized Controlled Trial." This is a study in which Dr. Heymsfield is listed as an author, along with 10 other doctors. These specifications call for documents that discuss side effects of Orlistat, a drug that is not at issue in this case, nor do any of the challenged products in this case contain any of the same active ingredients. Moreover, the side effects of a drug are only relevant

[13] Specification 23 seeks "all records and documents of whatever kind reflecting side effects experienced by subjects in control or placebo groups during the study titled Weight Control and Risk Factor Reduction in Obese Subjects Treated for 2 Years with Orlistat: A Randomized Controlled Trial . . . You may provide redacted records or documents redacting identifying information concerning the test subjects including but not limited to name, address, telephone number, social security number or similar." Specification 24 seeks "all records and documents of whatever kind reflecting comments by subjects concerning or related to any side effects experienced by subjects in control or placebo groups during the study titled Weight Control and Risk Factor Reduction in Obese Subjects Treated for 2 Years with Orlistat: A Randomized Controlled Trial . . ."

when discussing safety claims. The *Complaint* in this case does not allege any issues with regard to the safety of the challenged products, rather the allegations concern the efficacy of these products with respect to the claims made in the Respondents' promotional materials. Therefore, the specifications relating to side effects of participants in an unrelated study, having nothing to do with the issues in this case are completely irrelevant and certainly not reasonably calculated to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defenses of any respondent.

Respondents claim that such documents are relevant for the purposes of impeaching Dr. Heymsfield's testimony regarding the issue of double-blind clinical trials. This purpose is not facially evident from the specifications themselves, and the language of the specifications is broad enough to allow the Respondents to ask any question on side effects or safety. Moreover, compelling the expert to produce all documents relating to the study exceeds the scope of discovery for impeachment purposes. *See Dura Lube* at *9. Respondents could not offer such documents into evidence in order to impeach Dr. Heymsfield's testimony because such documents would be extrinsic evidence and not admissible. *See* FED. R. EVID. 608(b); *United States v. Boykoff*, 67 Fed. Appx. 15, 2003 U.S. App. LEXIS 9808 (2d Cir. 2003). Even without the documents, Respondents will have the opportunity to ask questions within reasonable limits at a deposition for impeachment purposes. Accordingly, a protective order is appropriate because the "burden . . . of the proposed discovery outweigh its likely benefit." 16 C.F.R. § 3.31(c)(1)(iii); *see also* 16 C.F.R. § 3.31(d).

III. Respondents' Subpoenas to the 22 Third Parties are Overbroad, Unduly Burdensome, Harassing, and Seek Information Not Reasonably Expected to Yield Information Relevant to this Matter

A. Respondents' Overreaching and Irrelevant Specifications

On November 9, 2004, after the general deadline for issuance of written discovery requests, Respondents served Complaint Counsel with emailed copies of *22* different subpoenas *duces tecum* that it issued to doctors, scientists, and custodians of records for various laboratories and research clinics who participated in one of two specified research studies regarding weight loss.[14] The letter attached to each of these subpoenas indicates that the subpoenas were sent on November 8, 2004 via First Class Mail.[15] Respondents' subpoenas directed to 18 of the 22 Third Parties seek all documents regarding *side effects* experienced by subjects during a study titled, "Weight Control and Risk Factor Reduction in Obese Subjects Treated for 2 Years with Orlistat: A Randomized Controlled Trial."[16] These specifications contain identical wording to Specifications 23 and 24 of Dr. Heymsfield's subpoena *duces tecum* as described above. This weight loss study involved a drug called Orlistat, which Respondents have never marketed or sold. Respondents' subpoenas directed to the remaining 4 Third Parties seek documents regarding *side effects* experienced by subjects during a different weight loss study entitled, "A

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[14] Respondents' cover letters and the first page of the subpoenas *duces tecum* to the 22 Third Parties are attached hereto as Exhibits D.

[15] These 22 subpoenas were sent along with a letter dated November 8, 2004, from a law firm called Manatt, Phelps &Phillips, LLP, and an attorney, Barrie Berman VanBrackle, that purportedly represents Respondents. Neither the attorney in question, nor the law firm, have filed a *Notice of Appearance* in this action.

[16] An example of the complete "Orlistat" study subpoena is attached at Exhibit E.

randomized double-blind placebo-controlled clinical trial of a product containing ephedrine, caffeine, and other ingredients from herbal sources for treatment of overweight and obesity in the absence of lifestyle treatment."[17]

B. A Protective Order is Appropriate

These specifications all seek documents reflecting the side effects of either Orlistat, a drug which does not involve any ingredients similar to the challenged products and which is not even relevant to the proceedings in this case, or a different ephedra/ caffeine product than that challenged in the *Complaint* in this case. As discussed above, the issue of side effects of a particular product is only relevant when discussing safety claims. The *Complaint* in this case does challenge any safety claims; rather the allegations concern whether the Respondents disseminated false and misleading advertising with respect to the efficacy claims made in the Respondents' promotional materials. Therefore, any documents relating to side effects of participants in an unrelated study,[18] having nothing to do with the issues in this case are completely irrelevant and certainly not reasonably calculated to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defenses of any respondent. As such these requests exceed the scope of expert discovery. *See Dura Lube* at *6-9. Respondents' foray into this area appears calculated to obtain evidence relevant to other proceedings, not this matter.

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[17] An example of the complete "ephedrine" study subpoena is attached at Exhibit F.

[18] The ephedra/caffeine study was not submitted by Respondents as part of their substantiation for the claims made in their promotional materials.

As discussed above, Respondents are apparently seeking discovery from these 22 individuals and entities in order to gather cross-examination impeachment material to use against Complaint Counsel's expert, Dr. Heymsfield, who participated in the Orlistat study. This is a harassing technique in which Respondents are attempting to use the subpoena power of this process to conduct onerous discovery upon Dr. Heymsfield's colleagues. Discovery should be granted "when the court is persuaded that the party seeking discovery is not abusing the procedure and the information sought would prove helpful in providing for a full and fair adjudication." *Thompson Medical Co.*, 101 F.T.C. 386 (Mar. 11, 1983) (citations omitted). These 22 subpoenas seek information unrelated to the allegations in the Complaint, the proposed relief, or the defenses of Respondents and hence are create an arduous, and harassing task for Third Parties who are not connected to this case. The discovery sought here is unreasonable, overly burdensome, and any tangential relation to impeachment of one of Complaint Counsel's expert witnesses is outweighed. Accordingly, justice requires that the Administrative Law Judge exercise his power to deny the discovery sought by these subpoenas to protect these 22 Third Parties from annoyance, embarrassment, oppression or undue burden or expense. *See* RULE OF PRACTICE 3.31(d)(1).

C. Respondents' Subpoenas *Duces Tecum* are Untimely

The *Scheduling Order* in this matter set November 8, 2004, as the deadline for issuing subpoenas *duces tecum*. The *Scheduling Order* further provides that the parties are required to "serve upon one another, at the time of issuance, copies of all subpoenas *duces tecum* . . ." *Scheduling Order* at 5. On November 9, 2004, Respondents sent to Complaint Counsel via electronic mail copies of the 22 subpoenas *duces tecum* that they issued to the 22 Third Parties.

The letter attached to each of these subpoenas asserts that the subpoenas were placed in the mail on November 8, 2004. At least two of the Third Parties notified Complaint Counsel that they received the subpoenas on November 15, 2004 (seven days later), and as of November 16, 2004, one of the Third Parties notified Complaint Counsel that it had not yet received the subpoena. In light of the date of service on Complaint Counsel and the fact that the Third Parties received the subpoenas significantly after the *Scheduling Order's* issuance deadline, it is questionable whether Respondents indeed issued the subpoenas before the close of business on November 8, 2004 as required and hence the Court should deem these subpoenas invalid.

V. Respondents' Subpoenas Ad Testificandum to the 4 Remaining Third Parties Should be Limited to Factual Inquiries and Should Prohibit Expert Opinion Inquiry

On November 10, 2004, Respondent Gay issued a "Notice of Videotape Deposition" for the following individuals and entities: George Bray, Frank Greenway, Dermtech International, Edward G. Fey, Dr. Bruce Frome, Ken Shirley, and Paul Lehman.[19] These individuals and entity either participated in, or have a relation to, studies submitted by Respondents as substantiation for the challenged products. Respondent listed the first 5 parties in its Preliminary Witness List as individuals or representatives "to testify as to the scientific support for the products and claims

[19] Greenway and Bray are individuals who conducted the studies regarding the challenged aminophylline gels; Frome is a lawyer and doctor who is mentioned in advertisements for the aminophylline gel products; Fey is a medical doctor whose name appeared in advertisements for some of the challenged products; Dermtech is the company that conducted the "cadaver studies" for the aminophylline gels; Lehman is an officer with Dermtech who conducted and approved the "cadaver studies"; and Shirley is president of BPI Labs, which formulated the aminophylline gels.

identified in the Complaint."[20] None were listed as expert witnesses. In fact, Respondents have listed only Respondent Daniel Mowrey as their testifying expert regarding the scientific substantiation. The remaining two individuals, Shirley and Lehman, were not listed in either party's Preliminary Witness List or Expert Witness list and Respondent has not supplemented their witness list to include them. The deadline imposed in the *Scheduling Order* for listing expert witnesses has passed (October 13, 2004). During discussions with Respondents' counsel, Respondents agreed to withdraw the notices for Bray, Greenway, and Frome because Complaint Counsel presently does not intend to call them as witnesses at the proceeding in this case. However, Respondents continue to refuse to withdraw the remaining 4 Notices.[21] Accordingly, Complaint Counsel seek an order limiting the depositions of these 4 Third Parties to factual inquiries relating to their own personal knowledge of factual information relating to this case, and prohibiting any expert opinion relating to the issues in this case.

Both Fey and Dermtech are listed in Complaint Counsel's Preliminary Witness List as parties who may be called "to testify as to the ingredients or attributes of the products identified in the Complaint. The testimony as listed, is limited to a factual inquiry within the party's personal knowledge. On the other hand, Respondents listed these Third Parties in their Preliminary Witness List as parties who may be called to "testify as to the scientific support for the products and claims identified in the Complaint." This type of testimony specifically calls for

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[20] In its Preliminary Witness List, Complaint Counsel listed 5 of these 7 parties as individuals or entities "to testify as to the ingredients or attributes of the products identified in the Complaint."

[21] Respondents' Notice of Videotape Depositions to the remaining 4 Third Parties are attached hereto as Exhibit G.

scientific expert opinion as to the competence and reliability of the substantiation provided by Respondents for their claims made in their promotional materials. This type of expert witness must be indicated as per the Court's *Scheduling Order* and as per the RULES OF PRACTICE. If Respondents are seeking to use these individuals for expert opinion testimony, they were required to identify the individuals, prepare and provide expert reports, and provide all other information required by the RULES. *See Scheduling Order*, at 1- 2, 5-6; RULES OF PRACTICE 3.31(b)(3). The *Scheduling Order* specifically provides that "fact witnesses shall not be allowed to provide expert opinions." *Scheduling Order* at 6.

Respondents' Expert Witness List only indicates one individual to testify as to the scientific substantiation - - Respondent Daniel Mowrey. Therefore, fact witnesses, such as Fey, Lehman, and Shirley cannot be called upon to provide expert opinion. It appears that instead of hiring an independent expert witness to opine on the substantiation submitted by Respondents, Respondents are attempting to obtain expert opinion testimony through the back door by deposing individuals involved in conducting the studies and promoting the aminophylline gels. Although Complaint Counsel have no objection to Respondents' right to depose witnesses listed on its *Preliminary Witness List* to gain discovery on facts within their personal knowledge, the contents of the subpoena suggest that the true purposes for these depositions is to gain expert testimony. For example, on the "List of Areas of Inquiry" specified on Dermtech's subpoena, aside from the factual areas listed, Respondents list "the results" of the studies and "the conclusions" of the studies. *See* Exhibit G at 4. In these areas, Respondents can only be seeking an expert's opinion. Respondents did not list the areas of inquiry for the remaining individuals, however, it is clear that they are seeking similar testimony which would likely call for expert

opinion.

Because none of these witnesses are listed on either Respondents or Complaint Counsel's expert witness list, Complaint Counsel seek a ruling to limit any deposition testimony to factual inquiries into areas within the witness' personal knowledge. This will protect the integrity of the discovery process and prevent any further abuse here by Respondents.

In addition, the *Scheduling Order* provides that "the preliminary and final witness lists shall represent counsels' good faith designation of all potential witnesses who counsel reasonably expect may be called in their case-in-chief. Parties shall notify the opposing party promptly of changes in witness lists to facilitate completion of discovery within the dates of the scheduling order." *Scheduling Order* at 5. Respondents failed to amend their preliminary witness list, nor did they notify Complaint Counsel of their intent to call Shirley and Lehman as witnesses. Instead, Respondents waited until the close of written discovery to send notices to Complaint Counsel that they wish to depose these Third Parties. Based on their failure to comply with the Administrative Law Judge's *Scheduling Order*, both Lehman and Shirley should be stricken as witnesses to be deposed by Respondents.

CONCLUSION

Respondents' abusive discovery tactics are unreasonable and inconsistent with the RULES OF PRACTICE and the *Scheduling Order* in this case. These overreaching, harassing, and overly burdensome subpoenas seek documents that are not likely to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defenses of any respondent. Respondents further seek to gain improper expert opinion from fact witnesses during the noticed depositions. For the reasons set forth above, and in the interest of judicial efficiency and economy, this Court should limit and deny Respondents' invalid and improper discovery.

Respectfully submitted,

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Division of Enforcement
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Dated: November 18, 2004

CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of November, 2004, I caused *Complaint Counsel's Motion for a Protective Order* to be served and filed as follows:

(1) the original, two (2) paper copies filed by hand delivery and one (1) electronic copy via email to:

Donald S. Clark, Secretary
Federal Trade Commission
600 Penn. Ave., N.W., Room H-159
Washington, D.C. 20580

(2) two (2) paper copies served by hand delivery to:

The Honorable Stephen J. McGuire
Administrative Law Judge
600 Penn. Ave., N.W., Room H-113
Washington, D.C. 20580

(3) one (1) electronic copy via email and one (1) paper copy by first class mail to the following persons:

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Laureen Kapin
COMPLAINT COUNSEL

EXHIBIT A

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

In the Matter of BASIC RESEARCH, LLC A.G. WATERHOUSE, LLC KLEIN-BECKER USA, LLC NUTRASPORT, LLC SOVAGE DERMALOGIC LABORATORIES, LLC BAN, LLC d/b/a BASIC RESEARCH, LLC OLD BASIC RESEARCH, LLC, BASIC RESEARCH, A.G. WATERHOUSE, KLEIN-BECKER USA, NUTRA SPORT, and SOVAGE DERMALOGIC LABORATORIES DENNIS GAY DANIEL B. MOWREY d/b/a AMERICAN PHYTOTHERAPY RESEARCH LABORATORY, and MITCHELL K. FRIEDLANDER, Respondents.	)	Docket No. 9318

ORDER DENYING BASIC RESEARCH'S MOTION TO COMPEL

I.

On September 10, 2004, Respondent Basic Research, L.L.C. ("Respondent") filed a motion to compel ("Motion"). On September 16, 2004, Respondent filed a Notice of Correction withdrawing one section of its Motion. On September 23, 2004, Complaint Counsel filed an unopposed motion for extension of time to file its opposition seeking an extension from September 27, 2004 to October 4, 2004. On October 4, 2004, Complaint Counsel filed its opposition to the Motion ("Opposition").

Complaint Counsel's motion for an extension is **GRANTED**. Upon consideration of the briefs and attachments, and for the reasons set forth below, Respondent's motion to compel is **DENIED**.

II.

Respondent seeks an order compelling Complaint Counsel to provide more complete answers to Respondent's First Set of Interrogatories. Motion at 1. Respondent identifies six interrogatories that it contends have not been answered completely and argues that Complaint Counsel's general objections are insufficient. Motion at 5-15. Complaint Counsel contends that it fully responded to each of the interrogatories and that Respondent has failed to demonstrate the circumstances necessary to breach the various privileges asserted. Opposition at 7-22.

III.

A.

Discovery sought in a proceeding before the Commission must be "reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defense of any respondent." 16 C.F.R. § 3.31(c)(1); *see FTC v. Anderson*, 631 F.2d 741, 745 (D.C. Cir. 1979). However, discovery may be limited if the discovery sought is unreasonably cumulative or duplicative or is obtainable from some other source that is more convenient, less burdensome or less expensive, or if the burden and expense of the proposed discovery outweigh its likely benefit. 16 C.F.R. § 3.31(c)(1). Further, the Administrative Law Judge may limit discovery to preserve privileges. 16 C.F.R. § 3.31(c)(2). The privileges regarding non-testifying experts, work product, and deliberative process are raised by Complaint Counsel.

Commission Rule 3.31(c)(4)(ii) provides that a party may discover facts known or opinions held by an expert who is not expected to be called as a witness "upon a showing of exceptional circumstances under which it is impracticable for the party seeking discovery to obtain facts or opinions on the same subject by other means." 16 C.F.R. § 3.31(c)(4)(ii). The party seeking discovery from a non-testifying retained expert faces a heavy burden. *Hoover v. Dep't of Interior*, 611 F.2d 1132, 1142 n.13 (5th Cir. 1980). Mere assertion that exceptional circumstances exist, without providing any facts in support of this contention, is not sufficient to compel the disclosure of nondiscoverable documents. *Martin v. Valley Nat'l Bank of Arizona*, 1992 U.S. Dist. LEXIS 11571, *13 (S.D.N.Y. 1992).

The well recognized rule of *Hickman v. Taylor*, 329 U.S. 495, 510 (1947), protects the work product of lawyers from discovery unless a substantial showing of necessity or justification is made. Under the Commission's rules, work product is discoverable "only upon a showing that the party seeking discovery has substantial need of the materials in the preparation of its case and that the party is unable without undue hardship to obtain the substantial equivalent of the materials by other means." 16 C.F.R. § 3.31(c)(3). Work product that reveals attorney client communications or the attorneys' mental processes in evaluating the communications "cannot be disclosed simply on a showing of substantial need and inability to obtain the equivalent without undue hardship." *Upjohn Co. v. United States*, 449 U.S. 383, 401 (1981).

The deliberative process privilege protects communications that are part of the decision-making process of a governmental agency. *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 150-152 (1975). This privilege permits the government to withhold documents that reflect advisory opinions, recommendations, and deliberations comprising part of a process by which government decisions and policies are formulated. *FTC v. Warner Communications, Inc.*, 742 F.2d 1156, 1161 (9th Cir. 1984). Assertion of the deliberative process privileges requires: (1) a formal claim of privilege by the head of the department having control over the requested information; (2) assertion of the privilege based on actual personal consideration by that official; and (3) a detailed specification of the information for which the privilege is claimed, with an explanation why it properly falls within the scope of the privilege. *Hoechst Marion Roussel*, 2000 FTC LEXIS 134, at *9; *Landry v. FDIC*, 204 F.3d 1125, 1135 (D.C. Cir. 2000). The deliberative process privilege is a qualified privilege and can be overcome where there is a sufficient showing of need. *In re Sealed Case*, 121 F.3d 729, 737 (D.C. Cir. 1997); *U.S. v. Farley*, 11 F.3d 1385, 1386 (7th Cir. 1993).

B.

Interrogatory 1(b) seeks information regarding "who interpreted the [p]romotional [m]aterial in question" and interrogatory 1(c) seeks information regarding "all extrinsic evidence . . . that was relied upon in determining what representations were conveyed." Motion at 5. Complaint Counsel argues that these persons fall within the deliberative process, non-testifying expert, and work product privileges, and that testifying experts will be identified as provided in the Scheduling Order. Opposition at 9-10. Respondent has not identified any basis to overcome the privileges claimed to this overly broad interrogatory. Moreover, use of an interrogatory to undermine the schedule established for the production of expert reports is not appropriate.

Interrogatory 1(d) seeks information regarding the substantiation that Complaint Counsel contends Respondents needed to have a reasonable basis for their representations. Motion at 6-7. Complaint Counsel contends that it answered this question by outlining specific sources of industry guidance, including specific reference to agency statements, Commission Policy Statements, caselaw and other information, including prior orders. Opposition at 11. Complaint Counsel further argues that the interrogatory requires speculation and that Complaint Counsel properly objected, asserting privilege with respect to information involving non-testifying experts, deliberative process, and work product. *Id.* Upon review of Complaint Counsel's Answer it is clear that Complaint Counsel provided an adequate response to the question asked. Complaint Counsel will not be required to provide a more speculative response.

Interrogatory 1(e) seeks information regarding the basis of Complaint Counsel's contention that Respondents did not have a reasonable basis to substantiate their representations. Motion at 8. Complaint Counsel does not respond to this allegation in their Opposition. However, it is presumed that Complaint Counsel intended its general objections and arguments raised regarding similar interrogatories to apply to this interrogatory. In addition, in reviewing Complaint Counsel's response to this interrogatory, Complaint Counsel raises the objections that

the interrogatory seeks information prepared in anticipation of litigation; protected by the deliberative process privilege; protected by the non-testifying witness privilege; and that expert witness materials would be provided at the appropriate time. Opposition, Attachment A at 6. In addition, Complaint Counsel responds that "the evidence submitted by Respondents does not amount to competent and reliable scientific evidence . . . ." *Id.* Respondent has not identified any basis to overcome the privileges claimed to this overly broad interrogatory. Moreover, use of an interrogatory to undermine the schedule established for the production of expert reports is not appropriate.

Interrogatory 2 seeks information regarding Complaint Counsel's analysis of the substantiation provided by Respondent. Motion at 9. Complaint Counsel argues that this question seeks the identity and opinions rendered by non-testifying experts; seeks prematurely the identity and opinions of expert witnesses; seeks information prepared in anticipation of litigation and attorney work product; seeks information protected by the deliberative process privilege; and is unduly burdensome. Opposition at 14. Complaint Counsel represents that Respondent provided over 284 different studies, analyses, and tests for the ephedra products alone. *Id.* Respondent has not identified any basis to overcome the privileges claimed to this overly broad interrogatory. Moreover, use of an interrogatory to undermine the schedule established for the production of expert reports is not appropriate.

Interrogatory 3 seeks identification of all market research or other evidence that is potentially relevant to determining consumer perceptions of Respondent's advertising. Motion at 10. Complaint Counsel responds that this interrogatory calls for expert opinions; that information related to testifying experts will be disclosed as required under the scheduling order; and that Complaint Counsel is not aware of any market research at this time. Thus, it appears that Complaint Counsel has provided a full and complete response to this interrogatory. Respondent has not identified any basis to overcome the privileges claimed to this overly broad interrogatory. Moreover, use of an interrogatory to undermine the schedule established for the production of expert reports is not appropriate.

Interrogatory 4 seeks the Commission's definition of the terms: visibly obvious, rapid, substantial, and causes. Motion at 11. Complaint Counsel argues that Respondents are presumed to understand the meaning of the words used in their advertising; additional information will be provided when expert discovery is provided; and the more than two single-spaces pages of responses to the interrogatory are sufficient. Reviewing Complaint Counsel's response along with their objections, it is clear that Complaint Counsel provided a sufficient response, including general objections, general comments, and over a single-spaced page providing facts regarding these four terms. *See* Opposition, Attachment A at 9.

Interrogatory 5 seeks information about materials provided to persons unaffiliated with the Commission, including information provided to the United States House of Representatives. Motion at 13. Complaint Counsel answered the interrogatory, disclosing that copies of the advertisements and Livieri study were disclosed but not provided to the minority and majority

counsel of the United States House of Representatives Committee on Energy and Commerce Subcommittee on Oversight and Investigations. Motion at 13-14; Opposition at 18. Respondent argues that the response is incomplete because it fails to "identify the persons" to whom such information was provided. Motion at 14. This argument is without merit – the persons to whom the material was disclosed have been provided.

Interrogatory 6 seeks information regarding why the Complaint was not filed prior to June 16, 2004. Motion at 14. Complaint Counsel argues that this information is not relevant to the allegations of the Complaint, to the proposed relief, or to the defenses of any respondent. Respondent's defense regarding delay has been stricken and the interrogatory is not relevant to any pending issues in the case. Moreover, the issue to be tried is whether Respondent disseminated false and misleading advertising, not the Commission's decision to file the Complaint. *Boise Cascade Corp. v. FTC*, 498 F. Supp. 772 (D. Del. 1980); *In re Exxon Corp.*, 1981 FTC LEXIS 113 (Jan. 19, 1981).

IV.

For the above-stated reasons, Respondent's motion to compel is **DENIED**.

ORDERED:

Stephen J. McGuire
Chief Administrative Law Judge

Date: November 4, 2004

67 Fed. Appx. 15, *; 2003 U.S. App. LEXIS 9808, **;
2003-1 U.S. Tax Cas. (CCH) P50,495; 91 A.F.T.R.2d (RIA) 2322

1 of 36 DOCUMENTS

UNITED STATES OF AMERICA, Appellee, - v - FRANKLIN BOYKOFF, Defendant-Appellant.

No. 02-1435

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

67 Fed. Appx. 15; 2003 U.S. App. LEXIS 9808; 2003-1 U.S. Tax Cas. (CCH) P50,495; 91 A.F.T.R.2d (RIA) 2322

May 21, 2003, Decided

NOTICE: [**1] RULES OF THE SECOND CIRCUIT COURT OF APPEALS MAY LIMIT CITATION TO UNPUBLISHED OPINIONS. PLEASE REFER TO THE RULES OF THE UNITED STATES COURT OF APPEALS FOR THIS CIRCUIT.

PRIOR HISTORY: Appeal from the United States District Court for the Southern District of New York (Colleen McMahon, Judge). *United States v. Boykoff, 186 F. Supp. 2d 347, 2002 U.S. Dist. LEXIS 1445 (S.D.N.Y., 2002)*

DISPOSITION: Affirmed.

LexisNexis(R) Headnotes

COUNSEL: Appearing for Appellant: KATHRYN KENEALLY, Fulbright & Jaworski L.L.P., New York, N.Y.

Appearing for Appellee: BARBARA GUSS, Assistant United States Attorney (James B. Comey, United States Attorney for the Southern District of New York, Meir Feder, Gary Stein, Assistant United States Attorneys, of counsel), New York, N.Y.

JUDGES: PRESENT: HON. FRED I. PARKER, HON. ROBERT D. SACK, Circuit Judges. *

* The Honorable Guido Calabresi of the United States Court of Appeals for the Second Circuit, who was originally a member of the panel, recused himself prior to oral argument. The appeal is being decided by the remaining two members of the panel, who are in agreement. See *2d Cir. R. § 0.14(b); Murray v. NBC, 35 F.3d 45, 46-48 (2d Cir. 1994)*, cert. denied, *513 U.S. 1082, 130 L. Ed. 2d 637, 115 S. Ct. 734 (1995).*

OPINION:

[*16] **SUMMARY ORDER**

UPON DUE CONSIDERATION, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the judgment of [**2] the district court be, and it hereby is, affirmed.

Defendant-appellant Franklin Boykoff appeals from a July 19, 2002, judgment after a jury trial, convicting him on fifteen counts of tax fraud and related offenses under *18 U.S.C. § 371* (conspiracy to defraud the United States), *26 U.S.C. § § 7201* (income tax evasion), *7206(1)* (subscribing false returns), *7206(2)* (aiding the preparation of false returns), *7212(a)* (interfering with the administration of the Internal Revenue Code), and acquitting him on the remaining eight counts of aiding the preparation of false returns under *26 U.S.C. § 7206(2)*. Boykoff was sentenced to fifty-seven months' imprisonment, three years' supervised release, a $ 75,000 fine, prosecution costs of $ 28,610.79, a $ 950 special assessment, and restitution to the Internal Revenue Service ("IRS") of $ 290,219. Boykoff makes numerous arguments of trial and sentencing errors, all of which are without merit.

[*17] The Exclusion of the Expert Psychiatric Testimony

Boykoff argues that the district court erred by excluding expert psychiatric testimony diagnosing him

with bipolar disorder and attention [**3] deficit disorder. Boykoff wanted to offer the testimony to show that he was disorganized, unfocused, and often late, consistent with his argument that any errors in the relevant tax returns were due to carelessness, not willfulness.

The district court excluded Zonana's testimony for two reasons. See *United States v. Boykoff, 186 F. Supp. 2d 347, 348-50 (S.D.N.Y. 2002)* ("Boykoff III"). First, the court found that Boykoff failed to demonstrate an adequate link between the proffered testimony and the specific intent of the crimes under *Fed. R. Evid. 702*. Second, the court concluded that the evidence would be more misleading to the jury than probative under *Fed. R. Evid. 403*.

We review decisions concerning expert testimony for abuse of discretion, according "broad discretion" to the district court in deciding whether to admit or exclude expert testimony. *United States v. Onunomu, 967 F.2d 782, 787 (2d Cir. 1992)* (internal quotation marks omitted). We also review evidentiary rulings for harmless error. *United States v. Diallo, 40 F.3d 32, 35 (2d Cir. 1994)*.

In this case, we need not reach the question of whether the district court [**4] abused its broad discretion by excluding the evidence under *Rules 702 and 403* because we conclude that the error, if any, was harmless. A jury could not reasonably have found that the excluded expert testimony negated the specific intent of willfulness. As the district court found, the evidence of willfulness was overwhelming. Numerous witnesses -- including Boykoff's longtime business partner, his clients, the investigating IRS agent -- gave testimony indicating that Boykoff committed substantial numbers of willful acts over an extended period of time. In addition, the expert expressly asserted that he had not consulted the relevant tax returns and therefore could not link the errors in the returns to Boykoff's medical condition. Moreover, Boykoff failed to identify particular errors in the tax returns that suggest transposed numbers or random, careless mistakes -- the kind of errors that could be caused by his attention-deficit disorder or bipolar disorder. Rather, the errors comprise additions of "round numbers" such as $ 10,000 and $ 50,000. Finally, we do not think that a jury would be persuaded that the asserted mental conditions could have been the cause of errors that only [**5] benefitted Boykoff and his clients. We therefore conclude with "fair assurance, after pondering all that happened without stripping the erroneous action from the whole, that the judgment was not substantially swayed by the error," if any error was committed. See *Kotteakos v. United States, 328 U.S. 750, 765, 90 L. Ed. 1557, 66 S. Ct. 1239 (1946)*.

The Appearance of Bias

The defendant argues that the district court gave the appearance of improper bias under *United States v. Edwardo-Franco, 885 F.2d 1002 (2d Cir. 1989)*. The district judge noted at several points that her family experience with attention-deficit disorder informed her view that attention-deficit disorder would not prevent someone from forming criminal intent. While those comments arguably may have been relevant to the question of the district court's ability dispassionately to decide the admissibility of Dr. Zonana's testimony, we do not reach the question of its admissibility, for the reasons discussed above. The comments do not otherwise bear on the court's fairness and impartiality. This case is very different from, and therefore [*18] not controlled by, Edwardo-Franco, where [**6] the court expressly disparaged people of the defendants' nationality, Colombian. *Id. at 1005*. By contrast, the district court's comments in this case did not indicate bias against any group of which Boykoff is a member.

The Admission of IRS Agent Dennehy's Testimony

Boykoff argues that the district court erred by permitting the expert testimony of IRS Agent Dennehy, who testified about his analysis of the defendant's improper reporting of certain personal expenses as business expenses. Boykoff contends that the agent's testimony was improperly admitted as summary, rather than substantiated, evidence under *United States v. Greenberg, 280 F.2d 472, 476-77 (1st Cir. 1960)* ("Greenberg I"), and *United States v. Greenberg, 295 F.2d 903, 908-09 (1st Cir. 1961)* ("Greenberg II"). But the crux of the First Circuit's decision in the Greenberg cases was that the agent's testimony was impermissibly based on hearsay. See *Greenberg II, 295 F.2d at 908*. This case does not present a similar hearsay problem. Boykoff's argument under the Greenberg cases therefore fails.

Boykoff also contends that Agent Dennehy's [**7] testimony improperly shifted the burden of proof to Boykoff, effectively converting his criminal prosecution into a civil tax audit. But Agent Dennehy was not the trier of fact, and the district court made clear to the jury that Agent Dennehy was testifying only about his opinion, that the jury was responsible for deciding whether each item was a proper business deduction, and that this criminal prosecution differed from a civil audit in that the government was required to prove the defendant's guilt beyond a reasonable doubt and the defendant was not required to prove anything. Moreover, as the court pointed out in the jury charge, the

government was not required to prove beyond a reasonable doubt "each and every item that it claims was income to Franklin Boykoff" or "the exact amount of the tax deficiency"; rather, the government needed only to "prove[] beyond a reasonable doubt that there was a substantial tax deficiency." (Tr. of Proceedings before Hon. Colleen McMahon in the United States District Court for the Southern District of New York, on Jan. 27 - Feb. 8, 2002, at 1802. ("Tr.").) In sum, the district court did not abuse its "broad discretion," *Onunomu, 967 F.2d at 787,* [**8] by admitting Agent Dennehy's expert testimony.

The Jury Charge: Burden-shifting

The defendant also argues that the district court impermissibly shifted the burden of proof to the defendant by stating in the jury charge that taxpayers are legally required to keep records documenting the information shown on their tax returns. The defendant did not object to this aspect of the charge at trial, so we review it for plain error, that is, for "(1) error, (2) that is plain, and (3) that affects substantial rights." *Johnson v. United States, 520 U.S. 461, 467, 137 L. Ed. 2d 718, 117 S. Ct. 1544 (1997)* (internal punctuation omitted). If those three conditions are met, we may exercise our discretion to notice a forfeited error, "but only if (4) the error seriously affects the fairness, integrity, or public reputation of judicial proceedings." Id. (internal punctuation omitted).

It appears that there is no error here, much less a plain one. The court correctly stated the law. See *26 C.F.R. § 1.6001-1.* And the defendant has pointed to no binding authority holding that it is error to refer to these requirements in a criminal tax case. [**9] The defendant merely cites a First Circuit case that observes in a footnote that evidence that a defendant failed to file a return was improperly admitted, [*19] because there was no evidence that the particular defendant even owed a tax. See *Greenberg I, 280 F.2d at 474 n.2.* In addition, the Supreme Court precedent relied on by *Greenberg I, Spies v. United States, 317 U.S. 492, 87 L. Ed. 418, 63 S. Ct. 364 (1943),* did not hold that a jury may not draw inferences from a taxpayer's failure to file a return or pay a tax; Spies held only that the combined failure to pay and failure to file are not sufficient to prove criminal tax evasion. See *Spies, 317 U.S. at 500.* Thus, in the case at bar, even if there was error in the district court's instruction about the record-keeping requirements of the Internal Revenue Code -- which seems very unlikely -- that error was not plain.

Moreover, immediately after instructing the jury about the record-keeping requirements, the court explained the burden of proof in a criminal case and distinguished this criminal case from a civil audit. Even if the record-keeping instruction was mistaken, then, [**10] any prejudice engendered by it was minimal.

The Jury Charge: The Explanation of an Accountable Plan

Boykoff argues that the court misstated a specific matter of tax law in the charge to the jury: whether an employee's expenses, when paid directly by the employer, count as income to the employee.

We review jury charges de novo. *United States v. Dyer, 922 F.2d 105, 107 (2d Cir. 1990).* When reviewing a jury instruction, we consider the disputed charge "within the context of the district court's charges in their entirety." *United States v. Feliciano, 223 F.3d 102, 120 (2d Cir. 2000),* cert. denied, *532 U.S. 943, 149 L. Ed. 2d 348, 121 S. Ct. 1406 (2001)* (citing *United States v. Caban, 173 F.3d 89, 94 (2d Cir.),* cert. denied, *528 U.S. 872, 145 L. Ed. 2d 147, 120 S. Ct. 174 (1999)).* "An appellant bears the burden of showing that the requested instruction accurately represented the law in every respect and that, viewing as a whole the charge actually given, he was prejudiced." *United States v. Abelis, 146 F.3d 73, 82 (2d Cir. 1998)* (internal quotation marks omitted), cert. denied, *525 U.S. 1147, 143 L. Ed. 2d 51, 119 S. Ct. 1044 (1999).* [**11]

In this case, the district court gave the parties a copy of the jury charge in advance and gave the parties an opportunity to challenge any aspect of it on the morning of its delivery. In the original charge distributed to the parties for review, the district court made two separate statements about the tax status of business expenses -- in one part explaining that direct payment of expenses by an employer counts as income to the employee, and in another part explaining that, in certain circumstances, reimbursement of business expenses by an employer constitutes an "accountable plan" under which the expenses do not count as income to the employee. For the purposes of this discussion, we accept that the charge, as written, was misleading. See *26 U.S.C. § 62(a); 26 C.F.R. § 1.62-2(c);* 1 Boris I. Bittker & Lawrence Lokken, Federal Taxation of Income, Estates and Gifts P 2.1.3 (3d ed. 1999).

Although we review jury instructions de novo, *Dyer, 922 F.2d at 107,* "'no party may assign as error any portion of the charge or omission therefrom unless that party objects thereto before the jury retires to consider its verdict, [**12] stating distinctly the matter to which that party objects and the grounds of the objection.'" *United States v. Crowley, 318 F.3d 401, 412 (2d Cir. 2003)* (quoting *Fed. R. Crim. P. 30*). Despite having been given

a printed copy of the charge the day before and being present when the government proposed a modification to precisely the paragraph defense counsel later challenged, defense [*20] counsel did not object to the charge before it was delivered to the jury. Although defense counsel objected before the jury began deliberating, he did not "distinctly" state "the grounds of the objection." *Crowley, 318 F.3d at 412*. When the court asked defense counsel to "show me something" to support defense counsel's claim about the law of direct payments, defense counsel failed to do so. (Tr. at 1842.) The judge cannot be expected to correct an instruction when the objecting party fails to explain or to offer support for his objection. Cf. *United States v. Phillips, 522 F.2d 388, 390-91 (8th Cir. 1975)* (rejecting the defendant's argument that "he complied with *Rule 30* by tendering to the trial court the standard cautionary informer instruction . . . and [**13] stating that he had no objection to the court's chosen instruction 'other than' that the defendant's requested charge 'better state(s) the law as regards to credibility of witnesses in this case'" (footnote omitted)). Since the defendant failed to comply with the requirements of *Rule 30*, we review for plain error only. See *Crowley, 318 F.3d at 414*.

The error, if any, was not plain. The defendant does not argue on appeal that the jury instruction was erroneous; he argues only that "the tax law is not as absolute as the trial court set out." Appellant's Br. at 38. Defense counsel's proposed alternative instruction was "just a simple statement that 'I instructed you that a direct payment by the employer of an expense is income to the employee. That's incorrect. It's not income." (Tr. at 1841.) If the problem with the court's charge is that it was too absolute, as the defendant argues on appeal, then the defendant's proposed jury instruction also did not "accurately represent[] the law in every respect." *Abelis, 146 F.3d at 82*. Not only did defense counsel fail to distinguish the "expenses" in his charge as business expenses, defense counsel also [**14] represented the relevant tax law as absolute by asking the court to say that its prior instruction was "incorrect" and to assert the direct opposite. (Tr. at 1841.)

Finally, the prejudice, if any, was minimal. The key question before the jury was whether the relevant expenses were business expenses rather than personal expenses. Because the jury clearly found that the relevant expenses were for personal matters, whether or not the defendant properly declined to report them as income under an accountable plan does not bear upon his conviction for misrepresenting personal expenses as business expenses.

Denial of Discovery of the IRS Agent's Report

The defendant argues that he was entitled to discovery of the IRS Special Agent's Report (the "Report") on all of his clients' returns under *Brady v. Maryland, 373 U.S. 83, 10 L. Ed. 2d 215, 83 S. Ct. 1194 (1963)*, and *United States v. Sternstein, 596 F.2d 528 (2d Cir. 1979)* ("Sternstein I"), because the Report would help him show that any errors in the few clients' returns at issue in the indictment were careless. The district court considered this argument and rejected it in two written decisions. [**15] United States v. Boykoff, No. 01 Cr. 493 (S.D.N.Y. Dec. 7, 2001) ("Boykoff I"); United States v. Boykoff, No. 01 Cr. 493 (S.D.N.Y. Dec. 12, 2001) ("Boykoff II").

"The management of discovery lies within the sound discretion of the district court, and the court's rulings on discovery will not be overturned on appeal absent an abuse of discretion." *Grady v. Affiliated Cent., Inc., 130 F.3d 553, 561 (2d Cir. 1997)*, cert. denied, *525 U.S. 936, 142 L. Ed. 2d 288, 119 S. Ct. 349 (1998)*. Moreover, "evidence of noncriminal conduct to negate the [*21] inference of criminal conduct is generally irrelevant." *United States v. Grimm, 568 F.2d 1136, 1138 (5th Cir. 1978)*. And the defendant acknowledged to the district court that the type of material he requested is generally not discoverable in a criminal tax case.

As the defendant points out, Sternstein I carves out an exception to this rule. *596 F.2d at 529-31*. There, we reversed a district court's decision to deny a defendant discovery of an IRS agent's report on the defendant's clients who were not named in the indictment. *Id. at 531*. Like Boykoff, Sternstein argued that this report [**16] would show that errors were found in only a few of his clients' reports, thereby bolstering his argument that those errors were careless. *Id. at 529*. We held that the report was important to Sternstein's defense against the government's claim that he falsified returns in order to retain his clients. *Id. at 530-31*.

In Sternstein I, the district failed to conduct an in camera appraisal of the value of the evidence. *Id. at 529*. Though we ordered release of the report to the defendant on remand, the purpose of our remand was to permit the district court to "determine whether the Special Agent's report reveals that a substantial number of the returns prepared by appellant which were investigated showed no error." *Id. at 531*. In Boykoff's case, by contrast, the trial court did review the Report in camera and issued a brief written decision that the Report did not contain exculpatory material. The court found that the Special Agent was unable to draw final conclusions in most cases because he lacked underlying records for many of the taxpayers, and the court concluded that "the Special Agent's tentative observations [**17] after looking over

(but not auditing) other returns prepared by Mr. Boykoff were far from exculpatory." Boykoff II, No. 01 Cr. 493, slip op. at 1. As we observed in Sternstein I, "the firsthand appraisal of the trial judge is essential in determining the materiality of withheld evidence." *596 F.2d at 531* (citing *United States v. Agurs, 427 U.S. 97, 114, 49 L. Ed. 2d 342, 96 S. Ct. 2392 (1976)).* Because the district court in this case conducted the necessary examination and found that the Report did not offer exculpatory material, the court committed no error in denying discovery of the Report. See *Sternstein I, 596 F.2d at 531*; see also *United States v. Sternstein, 605 F.2d 672, 673 (2d Cir. 1979)* (per curiam) ("Sternstein II") (observing that the trial court's findings "establish that no errors were found in only 8 of the 134 tax returns actually audited by [the] IRS and prepared by the appellant" so the probative value of the materials was "at best negligible" and a new trial was not warranted).

Exclusion of Certain Testimony the Defendant Proffered as Relevant to the Counts of Aiding and Abetting [**18] Dr. Cimmino

The defendant argues that the district court improperly excluded testimony by the brother of Dr. Cimmino -- who prepared Dr. Cimmino's medical partnership books -- that Dr. Cimmino deceptively withheld tax-related information from Boykoff. Boykoff wanted to elicit from Cimmino's brother testimony that Dr. Cimmino told his brother not to send certain annual summaries and checks to Boykoff. The district court permitted Boykoff to elicit testimony that Dr. Cimmino's brother did not send the records, but excluded testimony as to what Dr. Cimmino told his brother.

The court rejected the evidence on two grounds. First, the court rejected the defendant's proffer of the testimony to impeach the credibility of Dr. Cimmino's earlier testimony that he did not remember if [*22] he sent the records. This decision was a straightforward application of *Rule 608(b)*, which prohibits the introduction of extrinsic evidence (other than criminal convictions) to impeach the credibility of a witness. See *Fed. R. Evid. 608(b)*; *United States v. Moskowitz, 215 F.3d 265, 270 (2d Cir.)*, cert. denied, *531 U.S. 1014, 148 L. Ed. 2d 489, 121 S. Ct. 571 (2000).*

Second, [**19] the court rejected as collateral the testimony about why Cimmino's brother did not send the records. The court determined that the only matter relevant to whether Boykoff was deceived about Dr. Cimmino's tax situation was whether Boykoff received the records, not why he did or did not receive them. Thus, the court permitted Boykoff to question Cimmino's brother about whether he sent the records to Boykoff, but not why. Cimmino's brother then gave inconsistent testimony, variously asserting that he did not send the annual statements to Boykoff and that he did not remember if he sent them. (Tr. 1171-72.) In light of all the evidence before the district court, particularly the defendant's initial proffer of the evidence for improper impeachment purposes under *Rule 608(b)*, we conclude that the district court did not abuse its discretion by excluding testimony by Dr. Cimmino's brother that Dr. Cimmino told him not to send the disputed records. See *United States v. Pascarella, 84 F.3d 61, 70 (2d Cir. 1996).*

Count Twenty-Three: Whether the Obstruction of Justice Charge Is Time-Barred

Count twenty-three charged Boykoff with obstructing the IRS's audit of Dr. Weiser, [**20] Boykoff's client, by providing false expense receipts and writing false entries in Dr. Weiser's diaries to substantiate improper deductions claimed on Dr. Weiser's individual tax returns for 1990 through 1992. The defendant was charged with obstruction of justice under *26 U.S.C. § 7212(a)*, for which the statute of limitations is defined by *26 U.S.C. § 6531. Section 6531* provides for a three-year statute of limitations except in enumerated situations, such as a conviction under *section 7212(a).* See *26 U.S.C. § 6531(6).* The defendant argues that the six-year statutory period applied to *section 7212(a)* under *section 6531(6)* does not apply to his offense because he was not charged with "intimidation of officers and employees of the United States," as named in a parenthetical in *section 6531(6).* Rather, he was charged with the aspect of *section 7212(a)* that covers corrupt interference with the administration of the Internal Revenue laws, the so-called omnibus clause of *section 7212(a).*

The application of a statute of limitations is a matter of law that we review de novo. *Corcoran v. New York Power Authority, 202 F.3d 530, 542 (2d Cir. 1999),* [**21] cert. denied, *529 U.S. 1109, 146 L. Ed. 2d 794, 120 S. Ct. 1959 (2000).* Courts have uniformly held that the parenthetical in *section 6531(6)* is explanatory, not limiting, and applies to all conduct under *section 7212(a).* See, e.g., *United States v. Kassouf, 144 F.3d 952, 959 (6th Cir. 1998)*; *United States v. Workinger, 90 F.3d 1409, 1413-14 (9th Cir. 1996)*; see also *United States v. Kelly, 147 F.3d 172, 177 (2d Cir. 1998)* (rejecting the defendant's argument on plain error review). We therefore conclude that the district court properly rejected the defendant's argument. (Tr. 1145.)

Count Twenty-Three: Admission of Statements to Agent Monachino

Boykoff argues that the district court erred by denying his motion to suppress statements made by him and Dr. Weiser during the July 13, 1995, interview of Dr. Weiser conducted by IRS Agent Monachino. The defendant argues that his rights were violated because Agent Monachino [*23] was actually conducting a criminal investigation under the auspices of a civil audit. Judge McMahon conducted a hearing on the matter on the fir 21st day of trial and, in a decision dated January 23, 2002, concluded [**22] that the statements were admissible because Agent Monachino was not acting as an agent of the Criminal Investigation Division, see *Boykoff III, 186 F. Supp. 2d at 352*, and the statements were obtained during a non-custodial interrogation without threats or promises, *id. at 353*.

When reviewing a district court's ruling on a motion to suppress, we review the factual findings for clear error and the legal conclusions de novo. *United States v. Casado, 303 F.3d 440, 443 (2d Cir. 2002)*; *United States v. Peterson, 100 F.3d 7, 11 (2d Cir. 1996)*. We stated in *United States v. Squeri, 398 F.2d 785 (2d Cir. 1968)*, that, "even if the IRS had contemplated criminal proceedings against [the defendant], there would be no merit to the claim of deception; the information that a taxpayer's returns are under audit gives sufficient notice of the possibility of criminal prosecution regardless of whether the agents contemplate civil or criminal action when they speak to him," *id. at 788*. See also *United States v. Kontny, 238 F.3d 815, 819-20 (7th Cir.)*, cert. denied, *532 U.S. 1022, 149 L. Ed. 2d 758, 121 S. Ct. 1964 (2001)*. [**23] We conclude that the district court committed no error by admitting the testimony of Agent Monachino.

Sentencing

Boykoff argues that his sentence should be vacated because the district court erred 1) in applying an enhancement for sophisticated concealment under U.S.S.G. § 2T1.4(b)(2), and 2) in calculating his tax loss for purposes of determining his base offense level.

U.S.S.G. § 2T1.4(b)(2) provides for a 2-level increase in the defendant's offense level if the offense of aiding tax fraud involved sophisticated concealment. We review de novo the district court's decision regarding the sophisticated-concealment enhancement, giving due deference to the district court's Guidelines application. See *United States v. Lewis, 93 F.3d 1075, 1080 (2d Cir. 1996)*.

At sentencing and on appeal, the government argued that the sophisticated-concealment enhancement was appropriate because of Boykoff's conduct in helping a client who was being audited to fabricate restaurant receipts and expense journal entries, and in paying personal expenses from business accounts and characterizing those expenses as business expenses. In applying the sophisticated-concealment [**24] enhancement, the district court observed that "the Weiser scheme alone constitutes sophisticated concealment. The fabrication of receipts and expense journals is the very essence of sophisticated concealment, because it relies on Mr. Boykoff's knowledge of what the taxpayer would need to justify the expenses." (Tr. of Proceedings before Hon. Colleen McMahon in the United States District Court for the Southern District of New York, on June 24, 2002, at 31.)

As we stated in Lewis,

> even though this tax-evasion scheme cannot be described as singularly or uniquely sophisticated, it is more complex than the routine tax-evasion case in which a taxpayer reports false information on his 1040 form to avoid paying income taxes . . . or asserts he paid taxes that he did not pay . . . . Even if each step in the planned tax evasion was simple, when viewed together, the steps comprised a plan more complex than merely filling out a false tax return.

93 F.3d at 1082, 1083 (overturning a district court's decision not to apply a sophisticated-concealment enhancement where [*24] the defendant claimed fraudulent deductions by writing checks to non-existent entities drawn [**25] on his bank account, which were deposited into other accounts from which the defendant paid his personal expenses). In the case at bar, fabricating receipts and expense journal entries involved "a plan more complex than merely filling out a false tax return." *Id. at 1082*; see also *Kontny, 238 F.3d at 821*. We therefore conclude that the district court did not err in applying the enhancement for sophisticated enhancement.

We review de novo the district court's calculation of the "tax loss" attributable to the defendant. *United States v. Bove, 155 F.3d 44, 46-47 (2d Cir. 1998)*. Having reviewed the tax-loss calculation and the defendant's arguments challenging it, we conclude that the district court committed no error.

For the foregoing reasons, the judgment of the district court is hereby AFFIRMED.

LEXSEE 1999 FTC LEXIS 254

In the Matter of DURA LUBE CORPORATION, AMERICAN DIRECT MARKETING, INC., HOWE LABORATORIES, INC., CRESCENT MANUFACTURING, INC., NATIONAL COMMUNICATIONS CORPORATION THE MEDIA GROUP, INC., corporations, and HERMAN S. HOWARD, SCOTT HOWARD, individually and as officers of the corporations

Docket No. 9292

Federal Trade Commission

1999 FTC LEXIS 254

ORDER ON RESPONDENTS' MOTION TO COMPEL TESTIMONY AND PRODUCTION OF DOCUMENTS

December 15, 1999

ALJ: [*1]

D. Michael Chappell, Administrative Law Judge

ORDER:

ORDER ON RESPONDENTS' MOTION TO COMPEL TESTIMONY AND PRODUCTION OF DOCUMENTS

I.

On December 6, 1999, pursuant to Commission Rule 3.38(a), Respondents filed a motion for an order to compel testimony and production of documents in unredacted form. Complaint Counsel filed its Opposition to Respondents' Motion to Compel Testimony and Production of Documents ("Opposition") on December 14, 1999. Respondents filed a reply in support of the motion on December 15, 1999. For the reasons set forth below, Respondents' motion is GRANTED in part and DENIED in part.

II.

Respondents' motion has three objectives. First, Respondents assert that Complaint Counsel has refused to produce reports and documents relating to Frederic Litt. Complaint Counsel had designated Litt as an expert witness in its preliminary witness list on August 10, 1999, but subsequently indicated that Litt would not testify as an expert witness. Complaint Counsel has not produced an expert report for Litt. Respondents seek production of all of Complaint Counsel's correspondence and documents relating to Litt. Second, Respondents assert that reports and written communications [*2] relating to FTC cases against other after-market additive manufacturers which were authored by Norbert Nann and Lyle Bowman have been redacted to such an extent that these documents are unintelligible. Respondents seek production of these documents in unredacted form. Third, Respondents assert that Complaint Counsel directed its expert Nann not to answer a number of questions relating to (a) work that he did for the FTC in cases brought against other after-market additive manufacturers, on grounds of work product privilege; (b) opinions that he rendered on what he thought were Dura Lube documents, on grounds that the documents may have related to another case; and (c) his employment in the additives research lab at Texaco, on grounds of a confidentiality provision in his termination agreement with Texaco. Respondents seek an order compelling this testimony from Nann.

III.

A. Reports and documents relating to Litt

Respondents seek to compel production of reports and documents relating to Litt, first under Commission Rule 3.31(c)(4)(i) which allows "discovery of facts known and opinions held by experts . . . acquired or developed in anticipation of litigation or for hearing[.]" [*3] 16 C.F.R. § 3.31(c)(4)(i). Although Complaint Counsel originally listed Litt as a testifying expert in this case, Complaint Counsel no longer intends to call Litt as an expert and Respondents have not offered a sufficient explanation to justify continued treatment of Litt as a testifying expert. The rationale for liberal discovery of testifying experts is to enable the opposing party to prepare an effective cross-examination. In re Thompson Med. Co., Inc., 101 F.T.C. 385, 387 (1983). Once a party has removed an individual from the list of expert witnesses expected to testify at trial, the rationale for compelling production of documents relied upon by that expert no longer applies. Furniture World, Inc. v. D.A.V. Thrift Stores, Inc., 168 F.R.D. 61, 63 (D.N.M. 1996); In re Shell Oil Refinery, 132 F.R.D. 437, 440-41 (D.C. La. 1990); Mantolete v. Bolger, 96 F.R.D. 179, 181 (D. Az. 1982). Because Complaint Counsel does not intend to call Litt as an expert at trial, Litt is not treated as a testifying expert and Litt's documents are not subject to production under Commission Rule 3.31(c)(4)(i).

Respondents next seek to compel production of reports and documents relating to Litt under Commission [*4] Rule 3.31(c)(4)(ii) which provides that a party may discover facts known or opinions held by an expert who is not expected to be called as a witness "upon a showing of exceptional circumstances under which it is impracticable for the party seeking discovery to obtain facts or opinions on the same subject by other means." 16 C.F.R. § 3.31(c)(4)(ii).

The party seeking discovery from a non-testifying retained expert faces a heavy burden. Hoover v. Dep't of Interior, 611 F.2d 1132, 1142 n.13 (5th Cir. 1980); Bank Brussels Lambert v. Chase Manhattan Bank, 175 F.R.D. 34, 44 (S.D.N.Y. 1997). Mere assertion that exceptional circumstances exist, without providing any facts in support of this contention, is not sufficient to compel the disclosure of nondiscoverable documents. Martin v. Valley Nat'l Bank of Arizona, 1992 U.S. Dist. LEXIS 11571, *13 (S.D.N.Y. 1992). Those cases that do allow discovery from non-testifying experts often involve information about destroyed or non-available materials or situations in which the expert might also be viewed as a fact witness regarding material matters at issue. Wright, Miller & Marcus, Federal Practice and Procedure: Civil 2d § 2032. The Court is not [*5] persuaded that exceptional circumstances exist which make it impracticable for Respondents to obtain facts or opinions on the same subject. Accordingly, except as described below, Respondents are not entitled to discovery of reports and documents relating to or prepared by Litt.

However, any documents prepared by Litt, or any other non-testifying expert, which were relied upon or reviewed by Complaint Counsel's testifying experts in forming opinions in the instant case are discoverable, as set forth below. United States v. City of Torrance, 163 F.R.D. 590, 593-94 (C.D. Cal. 1995); Eliasen v. Hamilton, 1986 U.S. Dist. LEXIS 24509, *4-5 (N.D. Ill. 1986); Heitmann v. Concrete Pipe Mach., 98 F.R.D. 740, 743 (E.D. Mo. 1983). See also Fed. R. Civ. Pro. 26(a)(2) & (4).

B. Reports and documents relating to Nann and Bowman

Respondents seek reports and written communications authored by Nann, Bowman, and Litt that relate to FTC cases against other after-market additive manufacturers. Documents authored by Litt are governed by Rule 3.31(c)(4)(ii), and based on the holding above are not subject to discovery, unless they were relied upon or reviewed by Nann or Bowman in formulating an [*6] opinion in this case.

Nann and Bowman are testifying experts. Therefore, documents authored by them are governed by Commission Rule 3.31(c)(4)(i) which entitles parties to "discovery of facts known and opinions held by experts . . . acquired or developed in anticipation of litigation or for hearing" and by the Pretrial Scheduling Order entered in this case on June 10, 1999 ("Scheduling Order") which entitles parties to "documents and other written materials relied on by the expert in his/her analysis and conclusions."

To clarify the law regarding disclosure of expert testimony and information, all data, documents, or information considered by a testifying expert witness in forming the opinions to be proffered in a case is discoverable. Fed. R. Civ. Pro. 26(a)(2)(B); 16 C.F.R. § 3.31(c)(4)(B); Thompson Med. Co., 101 F.T.C. at 388. Full disclosure of the basis of an expert opinion ensures the independence of the expert's conclusions. FDIC v. First Heights Bank, FSB, 1998 U.S. Dist. LEXIS 21506, *9-10 (E.D. Mich. 1998). Therefore, for each expert expected to testify at trial, the parties must exchange all documents reviewed, consulted, or examined by the expert in connection with forming [*7] his or her opinion on the

subject on which he or she is expected to testify, regardless of the source of the document or whether a document was originally generated in another investigation or litigation against another after-market additive manufacturer. See In re Shell Oil Refinery, 1992 U.S. Dist. LEXIS 4896, *2 (E.D. La. 1992). The scope of discovery is not limited to documents relied on by the expert in support of his or her opinions, but extends to documents considered but rejected by the testifying expert in reaching those opinions. Torrance, 163 F.R.D. at 593-94. Any document considered by an expert in forming an opinion, whether or not such document constitutes work product or is privileged, is discoverable. Musselman v. Phillips, 176 F.R.D. 194, 199 (D. Md. 1997); B.C.F. Oil Refining, Inc. v. Consolidated Edison Co., 171 F.R.D. 57, 63 (S.D.N.Y. 1997); Karn v. Rand Ingersoll, 168 F.R.D. 633, 639 (N.D. Ind. 1996).

Complaint Counsel has represented that "Mr. Nann and Mr. Bowman prepared their reports and based their opinions strictly on information relating to Dura Lube and not on other product information or testing." Opposition at p.8. Considering this representation, [*8] issues regarding protection of trade secrets, work product, proprietary information, and information subject to protective orders in other investigations or litigation are not dispositive. The dispositive issue becomes what data, documents, or information has been reviewed or relied upon by Nann or Bowman in forming any opinion in the instant case. If an expert offers an opinion which includes or is based upon a comparative analysis or an opinion relating to general industry standards and the type of testing needed to substantiate particular claims, all data, documents, or other information supporting that opinion is discoverable.

An opposing party is entitled to know if an expert has taken an inconsistent position in another investigation or other litigation. Fundamental fairness dictates that any testifying expert who is asked whether he or she has ever taken a position or given an opinion inconsistent with an opinion asserted or position taken in the instant case must disclose such information. Karn. 168 F.R.D. at 640. See also Herrick Co., Inc. v. Vetta Sports, Inc., 1998 U.S. Dist. LEXIS 14544, *7 (S.D.N.Y. 1998)("Prior inconsistent opinions by [an expert] on the same subject [*9] matter would be highly relevant material."). The Scheduling Order requires exchange of materials fully describing all prior cases in which the expert has testified or has been deposed and transcripts of such testimony. It follows that the opposing party is entitled to opinions held and positions taken in those prior cases. See Thompson Med. Co., 101 F.T.C. at 388-89 (It is well within the broad discretion of Administrative Law Judges to order the disclosure of prior statements of expert witnesses.). However, while reports and testimony, including deposition testimony, from prior investigations or litigation must be produced, the documents underlying such reports or testimony are not discoverable in this subsequent litigation, unless such documents were also relied upon or reviewed by a testifying expert in formulating an opinion in this case.

C. Testimony from Nann

Respondents assert that Complaint Counsel improperly directed its expert Nann not to answer a number of questions during his deposition. To the extent that Nann received information from General Motors, or through his previous employment with Texaco, or through work that he performed for the FTC in cases brought [*10] against other after-market additive manufacturers, if that information forms the basis of an opinion that Nann proffers in this litigation, Respondents are entitled to testimony or discovery from Nann on such information. Should Nann offer an opinion in this case on the amount of money Respondents should spend on testing, and bases his opinion in comparison to the amount Texaco spent on testing, Respondents are entitled to such information from Nann. In addition, if Nann reviewed or relied upon the disputed document referred to in his deposition testimony at pages 165-173 in proffering an opinion in this case, Respondents are entitled to testimony on such document.

IV.

Pursuant to my Order on Request for Expedited Consideration on Respondents' Motion to Compel, dated December 8, 1999, Complaint Counsel produced to the undersigned for in camera inspection unredacted expert reports and written communications that had previously been produced to Respondents in redacted form authored by Nann and Bowman. Without knowledge of the expert opinions at issue, an analysis of what should be disclosed or redacted would be speculative. Based upon the rulings herein. Complaint Counsel is hereby [*11] ordered to review these documents, as well as other written communications authored by Nann and Bowman in connection with their work for FTC staff relating to automotive engine treatments that were not previously provided to Respondents in any form, to determine if any of the documents are discoverable in accordance with this Order. Complaint Counsel shall produce any such documents to Respondents as soon as possible, but no later than noon on Friday, December 17, 1999.

Complaint Counsel may retrieve its documents from my office at its convenience. All copies that were made for the Court's review have been destroyed.

It is SO ORDERED.

EXHIBIT B

RONALD F. PRICE
ATTORNEY AT LAW

PETERS SCOFIELD PRICE
A PROFESSIONAL CORPORATION

rfp@psplawyers.com

8 November 2004

VIA FEDERAL EXPRESS

Steven B. Heymsfield, M.D.
St. Luke's-Roosevelt Hospital
Obesity Research Center
1090 Amsterdam Ave. #14C
New York, NY 10025

Re: *In re Basic Research, LLC, et al.*, Docket No. 9318

Dear Dr. Heymsfield:

Please find enclosed a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Thank you for your cooperation.

Best regards,

PETERS SCOFIELD PRICE
A Professional Corporation

Ronald F. Price

F:\Data\RFP\Basic Research\Mowrey\Corres. 2004\11.08.04 Dr. Heymsfield.wpd

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO	2. FROM
Steven B. Heymsfield, M.D. St. Luke's-Roosevelt Hospital Obesity Research Center 1090 Amsterdam Avenue #14C New York, NY 10025	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION ~~OR INSPECTION~~ XXXXXXXXX	4. MATERIAL WILL BE PRODUCED TO
Peters Scofield Price 111 East Broadway, Suite 340 Salt Lake City, Utah 84111	Peters Scofield Price A Professional Corporation
	5. DATE AND TIME OF PRODUCTION OR INSPECTION Monday, December 6, 2004

6. SUBJECT OF PROCEEDING

In the Matter of Basic Research, LLC, et. al., Docket No. 9318

7. MATERIAL TO BE PRODUCED SEE EXHIBIT A

In lieu of production at the above place, documents may be produced by return mail on or before December 6, 2004, to Ronald F. Price, at Peters Scofield Price, 111 East Broadway, Suite 340, Salt Lake City, UT 84111.

8. ADMINISTRATIVE LAW JUDGE	9. COUNSEL REQUESTING SUBPOENA
The Honorable Stephen J. McGuire Federal Trade Commission Washington, D.C. 20580	Peters Scofield Price A Professional Corporation

DATE ISSUED	SECRETARY'S SIGNATURE
10/12/2004	Donald S. Clark

GENERAL INSTRUCTIONS

APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

MOTION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any motion to limit or quash this subpoena be filed within the earlier of 10 days after service or the time for compliance. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission, accompanied by an affidavit of service of the document upon counsel listed in Item 9, and upon all other parties prescribed by the Rules of Practice.

TRAVEL EXPENSES

The Commission's Rules of Practice require that fees and mileage be paid by the party that requested your appearance. You should present your claim to counsel listed in Item 9 for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from counsel listed in Item 9.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

RETURN OF SERVICE

I hereby certify that a duplicate original of the within subpoena was duly served: (check the method used)

○ *in person.*

○ *by registered mail.*

○ *by leaving copy at principal office or place of business, to wit:*

---

on the person named herein on:

(Month, day, and year)

(Name of person making service)

(Official title)

EXHIBIT A

1. Your complete file related to this matter.

2. All correspondence with the Federal Trade Commission concerning this matter regardless of whether you were the author, addressee or copy recipient.

3. All correspondence with any individual or entity other than the Federal Trade Commission concerning this matter regardless of whether you were the author, addressee or copy recipient.

4. All reports prepared by you in connection with your work on this matter.

5. All drafts of all reports prepared by you in connection with your work on this matter.

6. All documents reviewed by you in connection with your work on this matter.

7. All materials consulted by you or relied on by you in forming any opinion in connection with this matter.

8. All documents that you have ever authored or contributed to regarding:

a. obesity
b. weight loss
c. fat loss
d. the Federal Trade Commission
e. clinical trial protocol or procedures
f. the definition of "competent and reliable scientific evidence"
g. Federal Trade Commission advertising rules and regulations
h. dietary supplements
i. weight loss or fat loss advertising.

9. All documents relating to lectures, speeches or testimony that you have ever given relating to:

a. obesity
b. weight loss
c. fat loss
d. clinical trial protocol or procedures
e. the Federal Trade Commission

f. the definition of "competent and reliable scientific evidence"
g. Federal Trade Commission advertising rules and regulations
h. dietary supplements
I. weight loss or fat loss advertising.

10 All documents relating to medical or clinical studies or tests that you have conducted or contributed ton or participated relating to or involving:

a. obesity
b. weight loss
c. fat loss
d. dietary supplements

11. All patents and patent applications (whether or not published or pending review by the United States Patent and Trademark Office) in which you are named as an inventor or patent owner or assignee of any invention relating to:

a. obesity
b. weight loss
c. fat loss
d. dietary supplements

12. All documents relating to lawsuits, whether criminal or civil, in which you were named as a party.

13. All documents pertaining to work that you have performed for any company that manufactures, markets or sells pharmaceuticals or dietary supplements relating to:

a. obesity
b. weight loss
c. fat loss

14. All documents relating to weight loss or fat loss advertisements that you have authored, reviewed or approved relating to any weight loss or fat loss product.

15. All documents relating to requests for approval that you have made to the FDA, FTC or any other regulatory body, either on behalf of yourself or some other third party, relating to advertising or package labeling claims that you sought to make in relation to any weight loss or fat loss product.

16. All documents relating to efforts by you, either on your own behalf or on behalf of any other third party or parties, to justify or substantiate

advertising claims made in relation to any weight loss or fat loss product including but not limited to pharmaceutical products or dietary supplements.

17. All documents pertaining to work that you have performed for the Federal Trade Commission, The Food and Drug Administration or any other federal agency, whether as an expert, consultant or in any other capacity, relating to:

a. obesity
b. weight loss
c. fat loss
d. the Federal Trade Commission
e. clinical trial protocol or procedures
f. the definition of "competent and reliable scientific evidence"
g. Federal Trade Commission advertising rules and regulations
h. dietary supplements
I. weight loss or fat loss advertising.

18. All scientific and/or medical testing protocols you have authored.

19. All scientific and/or medical testing protocols on which you have provided comments, including your comments.

20. All documents which the Federal Trade Commission, including Complaint Counsel in this matter, has provided to you in connection with this matter.

21. All documents, including drafts, which you have provided to the Federal Trade Commission, including Complaint Counsel in this matter, in connection with this matter.

22. All notes of any meetings and/or telephone conversations and/or any other communications you have had with the Federal Trade Commission, including Complaint Counsel in this matter, and/or any other entity or person, in connection with this matter.

23. All records and documents of whatever kind reflecting side effects experienced by subjects in control or placebo groups during the study titled Weight Control and Risk Factor Reduction in Obese Subjects Treated for 2 Years with Orlistat: A Randomized Controlled Trial a copy of which is attached as Exhibit A. You may provide redacted records or documents redacting identifying information concerning the test subjects including but not limited to name, address, telephone number, social security number or similar.

24. All records and documents of whatever kind reflecting comments by subjects concerning or related to any side effects experienced by subjects in the control or placebo group during the study titled Weight Control and Risk Factor Reduction in Obese Subjects Treated for 2 Years with Orlistat: A Randomized Controlled Trial a copy of which is attached as Exhibit A. You may provide redacted records or documents redacting identifying information concerning the test subjects including but not limited to name, address, telephone number, social security number or similar.

EXHIBIT C

RONALD F. PRICE
ATTORNEY AT LAW

PETERS SCOFIELD PRICE
A PROFESSIONAL CORPORATION

rfp@psplawyers.com

8 November 2004

VIA FEDERAL EXPRESS

Robert H. Eckel, MD
12801 East 17th Avenue, Suite 7103
Aurora, CO 80010

Re: *In re Basic Research, LLC, et al.*, Docket No. 9318

Dear Dr. Eckel:

Please find enclosed a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Thank you for your cooperation.

Best regards,

PETERS SCOFIELD PRICE
A Professional Corporation

Ronald F. Price

F:\Data\RFP\Basic Research\Mowrey\Corres. 2004\11.08.04 Dr. Eckel.wpd

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO	2. FROM
Robert H. Eckel, M.D. 12801 East 17th Avenue, Suite 7103 Aurora, Colorado 80010	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION ~~OR INSPECTION~~	4. MATERIAL WILL BE PRODUCED TO
Peters Scofield Price 111 East Broadway, Suite 340 Salt Lake City, Utah 84111	Peters Scofield Price A Professional Corporation
	5. DATE AND TIME OF PRODUCTION OR INSPECTION Monday, December 6, 2004

6. SUBJECT OF PROCEEDING

~~In the Matter of Basic Research, LLC, et al., Docket No. 9318~~

In the Matter of Basic Research, LLC, et. al., Docket No. 9318

7. MATERIAL TO BE PRODUCED SEE EXHIBIT A

In lieu of production at the above place, documents may be produced by return mail on or before December 6, 2004, to Ronald F. Price, at Peters Scofield Price, 111 East Broadway, Suite 340, Salt Lake City, UT 84111.

8. ADMINISTRATIVE LAW JUDGE	9. COUNSEL REQUESTING SUBPOENA
The Honorable Stephen J. McGuire Federal Trade Commission Washington, D.C. 20580	PETERS SCOFIELD PRICE A Professional Corporation

DATE ISSUED	SECRETARY'S SIGNATURE
10/12/2004	Donald S. Clark

GENERAL INSTRUCTIONS

APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

MOTION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any motion to limit or quash this subpoena be filed within the earlier of 10 days after service or the time for compliance. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission, accompanied by an affidavit of service of the document upon counsel listed in Item 9, and upon all other parties prescribed by the Rules of Practice.

TRAVEL EXPENSES

The Commission's Rules of Practice require that fees and mileage be paid by the party that requested your appearance. You should present your claim to counsel listed in Item 9 for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from counsel listed in Item 9.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

RETURN OF SERVICE

I hereby certify that a duplicate original of the within subpoena was duly served: (check the method used)

O *In person.*

O *by registered mail.*

O *by leaving copy at principal office or place of business, to wit:*

---

on the person named herein on:

(Month, day, and year)

(Name of person making service)

(Official title)

EXHIBIT A

1. Your complete file related to this matter.

2. All correspondence with the Federal Trade Commission concerning this matter regardless of whether you were the author, addressee or copy recipient.

3. All correspondence with any individual or entity other than the Federal Trade Commission concerning this matter regardless of whether you were the author, addressee or copy recipient.

4. All reports prepared by you in connection with your work on this matter.

5. All drafts of all reports prepared by you in connection with your work on this matter.

6. All documents reviewed by you in connection with your work on this matter.

7. All materials consulted by you or relied on by you in forming any opinion in connection with this matter.

8. All documents that you have ever authored or contributed to regarding:

a. obesity
b. weight loss
c. fat loss
d. the Federal Trade Commission
e. clinical trial protocol or procedures
f. the definition of "competent and reliable scientific evidence"
g. Federal Trade Commission advertising rules and regulations
h. dietary supplements
i. weight loss or fat loss advertising.

9. All documents relating to lectures, speeches or testimony that you have ever given relating to:

a. obesity
b. weight loss
c. fat loss
d. clinical trial protocol or procedures
e. the Federal Trade Commission

f. the definition of "competent and reliable scientific evidence"
g. Federal Trade Commission advertising rules and regulations
h. dietary supplements
I. weight loss or fat loss advertising.

10 All documents relating to medical or clinical studies or tests that you have conducted or contributed ton or participated relating to or involving:

a. obesity
b. weight loss
c. fat loss
d. dietary supplements

11. All patents and patent applications (whether or not published or pending review by the United States Patent and Trademark Office) in which you are named as an inventor or patent owner or assignee of any invention relating to:

a. obesity
b. weight loss
c. fat loss
d. dietary supplements

12. All documents relating to lawsuits, whether criminal or civil, in which you were named as a party.

13. All documents pertaining to work that you have performed for any company that manufactures, markets or sells pharmaceuticals or dietary supplements relating to:

a. obesity
b. weight loss
c. fat loss

14. All documents relating to weight loss or fat loss advertisements that you have authored, reviewed or approved relating to any weight loss or fat loss product.

15. All documents relating to requests for approval that you have made to the FDA, FTC or any other regulatory body, either on behalf of yourself or some other third party, relating to advertising or package labeling claims that you sought to make in relation to any weight loss or fat loss product.

16. All documents relating to efforts by you, either on your own behalf or on behalf of any other third party or parties, to justify or substantiate

advertising claims made in relation to any weight loss or fat loss product including but not limited to pharmaceutical products or dietary supplements.

17. All documents pertaining to work that you have performed for the Federal Trade Commission, The Food and Drug Administration or any other federal agency, whether as an expert, consultant or in any other capacity, relating to:

a. obesity
b. weight loss
c. fat loss
d. the Federal Trade Commission
e. clinical trial protocol or procedures
f. the definition of "competent and reliable scientific evidence"
g. Federal Trade Commission advertising rules and regulations
h. dietary supplements
I. weight loss or fat loss advertising.

18. All scientific and/or medical testing protocols you have authored.

19. All scientific and/or medical testing protocols on which you have provided comments, including your comments.

20. All documents which the Federal Trade Commission, including Complaint Counsel in this matter, has provided to you in connection with this matter.

21. All documents, including drafts, which you have provided to the Federal Trade Commission, including Complaint Counsel in this matter, in connection with this matter.

22. All notes of any meetings and/or telephone conversations and/or any other communications you have had with the Federal Trade Commission, including Complaint Counsel in this matter, and/or any other entity or person, in connection with this matter.

EXHIBIT D

manatt
manatt | phelps | phillips

Barrie Berman VanBrackle
Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Michael H. Davidson, MD
c/o Chicago Center for Clinical Research
515 North State Street
Chicago, IL . 60610

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Davidson:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie VanBrackle

Barrie Berman VanBrackle

30172847.3

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

Michael H. Davidson, M.D.
c/o Chicago Center for Clinical Research
515 North State Street
Chicago, IL 60610

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION

FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

4. MATERIAL WILL BE PRODUCED TO

Christopher P. Demetriades

5. DATE AND TIME OF PRODUCTION OR INSPECTION

November 23, 2004

6. SUBJECT OF PROCEEDING

In the Matter of Basic Research, LLC, et. al., Docket No. 9318

7. MATERIAL TO BE PRODUCED

See attached Exhibit A

8. ADMINISTRATIVE LAW JUDGE

The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

Nov. 8, 2004

SECRETARY'S SIGNATURE

Richard C. Donohue, Acting Secretary

GENERAL INSTRUCTIONS

APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

MOTION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any motion to limit or quash this subpoena be filed within the earlier of 10 days after service or the time for compliance. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission, accompanied by an affidavit of service of the document upon counsel listed in Item 9, and upon all other parties prescribed by the Rules of Practice.

TRAVEL EXPENSES

The Commission's Rules of Practice require that fees and mileage be paid by the party that requested your appearance. You should present your claim to counsel listed in Item 9 for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from counsel listed in Item 9.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

manatt
manatt | phelps | phillips

Barrie Berman VanBrackle
Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Charles H. Halstead, MD
506 Jerome Street
Davis, CA 95616

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Halstead:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie VanBrackle

Barrie Berman VanBrackle

30172849.7

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

Charles H. Halstead, M.D.
506 Jerome Street
Davis, CA 95616

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION

FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

4. MATERIAL WILL BE PRODUCED TO

Christopher P. Demetriades

5. DATE AND TIME OF PRODUCTION OR INSPECTION

November 23, 2004

6. SUBJECT OF PROCEEDING

In the Matter of Basic Research, LLC, et. al., Docket No. 9318

7. MATERIAL TO BE PRODUCED

See attached Exhibit A

8. ADMINISTRATIVE LAW JUDGE

The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

Nov. 8, 2004

SECRETARY'S SIGNATURE

Richard C. Donohue, Acting Secretary

GENERAL INSTRUCTIONS

APPEARANCE

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This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

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manatt | phelps | phillips

Barrie Berman VanBrackle
Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

John P. Forcyt, Ph.D.
c/o Baylor College of Medicine
Nutrition Research Clinic
1100 Bates Street
Houston, TX 77030

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Forcyt:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie VanBrackle led

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

John P. Forcyt, Ph.D.
c/o Baylor College of Medicine
Nutrition Research Clinic
1100 Bates Street
Houston, TX 77030

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION

FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

4. MATERIAL WILL BE PRODUCED TO

Christopher P. Demetriades

5. DATE AND TIME OF PRODUCTION OR INSPECTION

November 23, 2004

6. SUBJECT OF PROCEEDING

In the Matter of Basic Research, LLC, et. al., Docket No. 9318

7. MATERIAL TO BE PRODUCED

See attached Exhibit A

8. ADMINISTRATIVE LAW JUDGE

The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

Nov. 8, 2004

SECRETARY'S SIGNATURE

Richard C. Donohue, Acting Secretary

GENERAL INSTRUCTIONS

APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

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This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

manatt
manatt | phelps | phillips

Barrie Berman VanBrackle
Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Custodian of Records
Baylor College of Medicine
Nutrition Research Clinic
1100 Bates Street
Houston, TX 77030

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Custodian of Records:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie VanBrackle

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO	2. FROM
Custodian of Records Baylor College of Medicine Nutrition Research Clinic 1100 Bates Street Houston, TX 77030	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION	4. MATERIAL WILL BE PRODUCED TO
FeldmanGale, P.A. 201 S. Biscayne Blvd. Miami, FL 33131	Christopher P. Demetriades
	5. DATE AND TIME OF PRODUCTION OR INSPECTION
	November 23, 2004

6. SUBJECT OF PROCEEDING

In the Matter of Basic Research, LLC, et. al., Docket No. 9318

7. MATERIAL TO BE PRODUCED

See attached Exhibit A

8. ADMINISTRATIVE LAW JUDGE	9. COUNSEL REQUESTING SUBPOENA
The Honorable Stephen J. McGuire Federal Trade Commission Washington, D.C. 20580	Christopher P. Demetriades FeldmanGale, P.A. 201 S. Biscayne Blvd. Miami, FL 33131

DATE ISSUED	SECRETARY'S SIGNATURE
Nov. 8, 2004	Richard C. Donohue, Acting Secretary

GENERAL INSTRUCTIONS

APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

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manatt
manatt | phelps | phillips

Barrie Berman VanBrackle
Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Jain Chung, Ph.D.
c/o Hoffman LaRoche
340 Kingsland Street
Nutley, NJ 07110

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Chung:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie VanBrackle

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

Jain Chung, Ph.D.
c/o Hoffman LaRoche
340 Kingsland Street
Nutley, N.J. 07110

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION

FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

4. MATERIAL WILL BE PRODUCED TO

Christopher P. Demetriades

5. DATE AND TIME OF PRODUCTION OR INSPECTION

November 23, 2004

6. SUBJECT OF PROCEEDING

In the Matter of Basic Research, LLC, et. al., Docket No. 9318

7. MATERIAL TO BE PRODUCED

See attached Exhibit A

8. ADMINISTRATIVE LAW JUDGE

The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

Nov. 8, 2004

SECRETARY'S SIGNATURE

Richard C. Donohue, Acting Secretary

GENERAL INSTRUCTIONS

APPEARANCE

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manatt
manatt | phelps | phillips

Barrie Berman VanBrackle
Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Custodian of Records
University of California, Davis
Clinical Nutrition Research Unit
One Shields Ave
Davis, CA 95616

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Custodian of Records:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie VanBrackle

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

Custodian of Records
University of California, Davis
Clinical Nutrition Research Unit
One Shields Avenue
Davis, CA 95616

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION

FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

4. MATERIAL WILL BE PRODUCED TO

Christopher P. Demetriades

5. DATE AND TIME OF PRODUCTION OR INSPECTION

November 23, 2004

6. SUBJECT OF PROCEEDING

In the Matter of Basic Research, LLC, et. al., Docket No. 9318

7. MATERIAL TO BE PRODUCED

See attached Exhibit A

8. ADMINISTRATIVE LAW JUDGE

The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

Nov. 8, 2004

SECRETARY'S SIGNATURE

Richard C. Donohue, Acting Secretary

GENERAL INSTRUCTIONS

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This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

manatt
manatt | phelps | phillips

Barrie Berman VanBrackle
Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Custodian of Records
c/o William Beaumont Hospital
3601 West 13 Mile Road
Royal Oak, MI 48073

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Custodian of Records:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie VanBrackle/cd

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO	2. FROM
Custodian of Records William Beaumont Hospital 3601 West 13 Mile Road Royal Oak, MI 48073	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION	4. MATERIAL WILL BE PRODUCED TO
FeldmanGale, P.A. 201 S. Biscayne Blvd. Miami, FL 33131	Christopher P. Demetriades
	5. DATE AND TIME OF PRODUCTION OR INSPECTION November 23, 2004

6. SUBJECT OF PROCEEDING

In the Matter of Basic Research, LLC, et. al., Docket No. 9318

7. MATERIAL TO BE PRODUCED

See attached Exhibit A

8. ADMINISTRATIVE LAW JUDGE	9. COUNSEL REQUESTING SUBPOENA
The Honorable Stephen J. McGuire Federal Trade Commission Washington, D.C. 20580	Christopher P. Demetriades FeldmanGale, P.A. 201 S. Biscayne Blvd. Miami, FL 33131

DATE ISSUED	SECRETARY'S SIGNATURE
Nov. 8, 2004	Richard C. Donohue, Acting Secretary

GENERAL INSTRUCTIONS

APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

MOTION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any motion to limit or quash this subpoena be filed within the earlier of 10 days after service or the time for compliance. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission, accompanied by an affidavit of service of the document upon counsel listed in Item 9, and upon all other parties prescribed by the Rules of Practice.

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Barrie Berman VanBrackle
Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Charles P. Lucas, MD
21 Arlena Terrace
Ramsey, NJ 07446

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Lucas:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie VanBrackle

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

Charles P. Lucas, M.D.
21 Arlena Terrace
Ramsey, NJ 07446

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

Nov. 8, 2004

SECRETARY'S SIGNATURE

Richard C. Donohue, Acting Secretary

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Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Custodian of Records
University of California, Los Angeles
Center for Nutrition
900 Veteran Ave., Room 1-2-217
Los Angeles, CA 90095-1742

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Custodian of Records:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

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Thank you for your cooperation.

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University of California,
Los Angeles
Center for Nutrition
900 Veteran Avenue, Rm. 1-2-217
Los Angeles, CA 90095-1742

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Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
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201 S. Biscayne Blvd.
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DATE ISSUED

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Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Douglas C. Heimburger, MD
c/o UAB Kirklin Clinic
2000 6th Ave South
Birmingham, AL 35233

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Heimburger:

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Douglas C. Heimburger, M.D. c/o UAB Kirklin Clinic 2000 6th Avenue South Birmingham, AL 35233	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

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The Honorable Stephen J. McGuire Federal Trade Commission Washington, D.C. 20580	Christopher P. Demetriades FeldmanGale, P.A. 201 S. Biscayne Blvd. Miami, FL 33131

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Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Mario DiGirolamo, MD
Emory University, School of Medicine
1440 Clifton Road, N.E.
Atlanta, GA 30322

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. DiGirolamo:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie Berman VanBrackle

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

Mario DiGirolamo, M.D.
Emory University School
of Medicine
1440 Clifton Road, N.E.
Atlanta, GA 30322

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

Nov. 8, 2004

SECRETARY'S SIGNATURE

Richard C. Donohue, Acting Secretary

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Direct Dial: (202) 585-6530
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November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Jonathan Hauptman, MD
666 N. Monroe Street
Ridgewood, NJ 07450-1227

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Hauptman:

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Ridgewood, NJ 07450-1227

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Federal Trade Commission
Washington, D.C. 20580

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FeldmanGale, P.A.
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Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

David C. Robbins, MD
c/o Medical Laboratories
Mediantic Research Institute
650 Pennsylvania Ave.
Washington, DC 20003

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Robbins

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David C. Robbins, M.D. c/o Penn Medical Laboratories Mediantic Research Institute 640 Pennsylvania Avenue Washington, D.C. 20003	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

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Chicago Center for Clinical Research
515 North State Street
Chicago, IL . 60610

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manatt
manatt | phelps | phillips

Barrie Berman VanBrackle
Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Mario DiGirolamo, MD
Emory University, School of Medicine
1440 Clifton Road, N.E.
Atlanta, GA 30322

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. DiGirolamo:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

Mario DiGirolamo, M.D.
Emory University School
of Medicine
1440 Clifton Road, N.E.
Atlanta, GA 30322

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION

FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

4. MATERIAL WILL BE PRODUCED TO

Christopher P. Demetriades

5. DATE AND TIME OF PRODUCTION OR INSPECTION

November 23, 2004

6. SUBJECT OF PROCEEDING

In the Matter of Basic Research, LLC, et. al., Docket No. 9318

7. MATERIAL TO BE PRODUCED

See attached Exhibit A

8. ADMINISTRATIVE LAW JUDGE

The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

Nov. 8, 2004

SECRETARY'S SIGNATURE

Richard C. Donohue, Acting Secretary

GENERAL INSTRUCTIONS

APPEARANCE

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Barrie Berman VanBrackle
Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Jonathan Hauptman, MD
666 N. Monroe Street
Ridgewood, NJ 07450-1227

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Hauptman:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie VanBrackle

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

Jonathan Hauptman, M.D.
666 N. Monroe Street
Ridgewood, NJ 07450-1227

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

Nov. 8, 2004

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Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

David C. Robbins, MD
c/o Medical Laboratories
Mediantic Research Institute
650 Pennsylvania Ave.
Washington, DC 20003

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Robbins

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie VanBrackle

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

David C. Robbins, M.D.
c/o Penn Medical Laboratories
Mediantic Research Institute
640 Pennsylvania Avenue
Washington, D.C. 20003

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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8. ADMINISTRATIVE LAW JUDGE

The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

Nov. 8, 2004

SECRETARY'S SIGNATURE

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Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Custodian of Records
Chicago Center for Clinical Research
515 North State Street
Chicago, IL . 60610

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Custodian or Records:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie VanBrackle

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

Custodian of Records
Chicago Center for Clinical Research
515 North State Street
Chicago, IL 60610

2. FROM

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FEDERAL TRADE COMMISSION

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Miami, FL 33131

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8. ADMINISTRATIVE LAW JUDGE

The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

Nov. 8, 2004

SECRETARY'S SIGNATURE

Richard C. Donohue, Acting Secretary

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E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Custodian of Records
Emory University, School of Medicine
1440 Clifton Road, N.E.
Atlanta, GA 30322

Re: ***Basic Research LLC, et al., Docket No. 9318***

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The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

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Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Custodian of Records
c/o Penn Medical Laboratories
Mediantic Research Institute
650 Pennsylvania Ave.
Washington, DC 20003

Re: ***Basic Research LLC, et al., Docket No. 9318***

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Barrie Berman VanBrackle

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Mediantic Research Institute
650 Pennsylvania Avenue
Washington, D.C. 20003

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Miami, FL 33131

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The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

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Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

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Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

David Heber, MD
900 Veteran Ave., Room 1-2-217
Los Angeles, CA 90095-1742

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Heber:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie VanBrackle/ed

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO	2. FROM
David Heber, M.D. 900 Veteran Avenue, Rm. 1-2-217 Los Angeles, CA 90095-1742	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

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3. PLACE OF PRODUCTION OR INSPECTION	4. MATERIAL WILL BE PRODUCED TO
FeldmanGale, P.A. 201 S. Biscayne Blvd. Miami, FL 33131	Christopher P. Demetriades
	5. DATE AND TIME OF PRODUCTION OR INSPECTION
	November 23, 2004

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7. MATERIAL TO BE PRODUCED

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8. ADMINISTRATIVE LAW JUDGE	9. COUNSEL REQUESTING SUBPOENA
The Honorable Stephen J. McGuire Federal Trade Commission Washington, D.C. 20580	Christopher P. Demetriades FeldmanGale, P.A. 201 S. Biscayne Blvd. Miami, FL 33131

DATE ISSUED	SECRETARY'S SIGNATURE
Nov. 8, 2004	Richard C. Donohue, Acting Secretary

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Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Custodian of Records
Hoffman LaRoche
340 Kingsland Street
Nutley, NJ 07110

Re: ***Basic Research LLC, et al., Docket No. 9318***

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Barrie Berman VanBrackle

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Hoffman LaRoche
340 Kingsland Street
Nutley, NJ 07110

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Federal Trade Commission
Washington, D.C. 20580

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Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

C.S. Coffey
c/o Dept of Biostatistics
University of Alabama, Birmingham
Alabama Ryals Public Health Bldg. 327
1665 University Blvd.
Birmingham, AL 35294

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Coffey:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO	2. FROM
C.S. Coffey Department of Biostatistics University of Alabama Alabama Ryals Public Health Bldg. 327 1665 University Boulevard Birmingham, AL 35294	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

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FeldmanGale, P.A. 201 S. Biscayne Blvd. Miami, FL 33131	Christopher P. Demetriades
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7. MATERIAL TO BE PRODUCED

See attached Exhibit A

8. ADMINISTRATIVE LAW JUDGE	9. COUNSEL REQUESTING SUBPOENA
The Honorable Stephen J. McGuire Federal Trade Commission Washington, D.C. 20580	Christopher P. Demetriades FeldmanGale, P.A. 201 S. Biscayne Blvd. Miami, FL 33131

DATE ISSUED	SECRETARY'S SIGNATURE
Nov. 8, 2004	Richard C. Donohue, Acting Secretary

GENERAL INSTRUCTIONS

APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

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Barrie Berman VanBrackle
Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

D. Steiner
Research Testing Laboratories
225 Great Neck Road
Great Neck, NY 11021

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Steiner:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO	2. FROM
D. Steiner Research Testing Laboratories 255 Great Neck Road Great Neck, NY 11021	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION	4. MATERIAL WILL BE PRODUCED TO
FeldmanGale, P.A. 201 S. Biscayne Blvd. Miami, FL 33131	Christopher P. Demetriades
	5. DATE AND TIME OF PRODUCTION OR INSPECTION November 23, 2004

6. SUBJECT OF PROCEEDING

In the Matter of Basic Research, LLC, et. al., Docket No. 9318

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Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

B.A. Baker
Section on Statistical Genetics
University of Alabama, Birmingham
Alabama Ryals Public Health Bldg. 327
1665 University Blvd.
Birmingham, AL 35294

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Baker:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie VanBrackle

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

B.A. Baker
Section of Statistical Genetics
University of Alabama
Alabama Ryals Public Health Bldg. 327
1665 University Boulevard
Birmingham, AL 35294

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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Miami, FL 33131

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Christopher P. Demetriades

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The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

Nov. 8, 2004

SECRETARY'S SIGNATURE

Richard C. Donohue, Acting Secretary

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Barrie Berman VanBrackle
Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

D.B. Allison
Clinical Nutrition Research Unit
University of Alabama, Birmingham
Alabama Ryals Public Health Bldg. 327
1665 University Blvd.
Birmingham, AL 35294

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Allison:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie VanBrackle

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO	2. FROM
D.B. Allison Clinical Nutrition Research Unit University of Alabama Alabama Ryals Public Health Bldg. 327 1665 University Boulevard Birmingham, AL 35294	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

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FeldmanGale, P.A. 201 S. Biscayne Blvd. Miami, FL 33131	Christopher P. Demetriades
	5. DATE AND TIME OF PRODUCTION OR INSPECTION
	November 23, 2004

6. SUBJECT OF PROCEEDING

In the Matter of Basic Research, LLC, et. al., Docket No. 9318

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The Honorable Stephen J. McGuire Federal Trade Commission Washington, D.C. 20580	Christopher P. Demetriades FeldmanGale, P.A. 201 S. Biscayne Blvd. Miami, FL 33131

DATE ISSUED	SECRETARY'S SIGNATURE
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EXHIBIT E

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Barrie Berman VanBrackle
Manatt, Phelps & Phillips, LLP
Direct Dial: (202) 585-6530
E-mail: bvanbrackle@manatt.com

November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

Michael H. Davidson, MD
c/o Chicago Center for Clinical Research
515 North State Street
Chicago, IL . 60610

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Davidson:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie Berman VanBrackle

30172847.3

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

Michael H. Davidson, M.D.
c/o Chicago Center for Clinical Research
515 North State Street
Chicago, IL 60610

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

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8. ADMINISTRATIVE LAW JUDGE

The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

Nov. 8, 2004

SECRETARY'S SIGNATURE

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EXHIBIT A

INSTRUCTIONS FOR COMPLIANCE BY DELIVERY OF DOCUMENTS

If documents are delivered by hand, overnight delivery service, mail, or electronic means, your response shall be accompanied by an affidavit, executed by you, that provides:

1. The names, addresses, positions, and organizations of all persons whose files were searched and all persons who participated in or supervised the collection of the documents, and a brief description of the nature of the work that each person performed in connection with collecting the documents;

2. A statement that the search was complete and that all responsive documents are being produced;

3. A statement as to whether the documents were made and kept in the course of your regularly conducted business, and whether it was your regular practice to make and keep such documents; and

4. A statement as to whether any document called for by the subpoena has been misplaced, lost, or destroyed. If any document has been misplaced, lost, or destroyed, identify: the type of document; the date (or approximate date) of the document; subject matter of the document; all persons to whom it was addressed, circulated, or shown; its date of destruction, or when it was lost or misplaced; the reason it was destroyed, lost, or misplaced; and the custodian of the document on the date of its destruction, loss or misplacement.

If the affidavit is incomplete, or additional information is necessary, you may be compelled to appear and testify.

Specifications

1. All records and documents of whatever kind reflecting side effects experienced by subjects in control or placebo groups during the study titled *Weight Control and Risk Factor Reduction in Obese Subjects Treated for 2 Years with Orlistat: A Randomized Controlled Trial* a copy of which is attached as Exhibit A. You may provide redacted records or documents redacting identifying information concerning the test subjects including but not limited to name, address, telephone number, social security number or similar.

2. All records and documents of whatever kind reflecting comments by subjects concerning or related to any side effects experienced by subjects in the control or placebo group during the study titled *Weight Control and Risk Factor Reduction in Obese Subjects Treated for 2 Years with Orlistat: A Randomized Controlled Trial* a copy of which is attached as Exhibit A. You may provide redacted records or documents redacting identifying information concerning the test subjects including but not limited to name, address, telephone number, social security number or similar.

ORIGINAL CONTRIBUTION

Weight Control and Risk Factor Reduction in Obese Subjects Treated for 2 Years With Orlistat

A Randomized Controlled Trial

Michael H. Davidson, MD
Jonathan Hauptman, MD
Mario DiGirolamo, MD
John P. Foreyt, PhD
Charles H. Halsted, MD
David Heber, MD
Douglas C. Heimburger, MD
Charles P. Lucas, MD
David C. Robbins, MD
Jain Chung, PhD
Steven B. Heymsfield, MD

Context Orlistat, a gastrointestinal lipase inhibitor that reduces dietary fat absorption by approximately 30%, may promote weight loss and reduce cardiovascular risk factors.

Objective To test the hypothesis that orlistat combined with dietary intervention is more effective than placebo plus diet for weight loss and maintenance over 2 years.

Design Randomized, double-blind, placebo-controlled study conducted from October 1992 to October 1995.

Setting and Participants Obese adults (body mass index [weight in kilograms divided by the square of height in meters], 30–43 kg/m^2) evaluated at 18 US research centers.

Intervention Subjects received placebo plus a controlled-energy diet during a 4-week lead-in. On study day 1, the diet was continued and subjects were randomized to receive placebo 3 times a day or orlistat, 120 mg 3 times a day, for 52 weeks. After 52 weeks, subjects began a weight-maintenance diet, and the placebo group (n = 133) continued to receive placebo and orlistat-treated subjects were rerandomized to receive placebo 3 times a day (n = 138), orlistat, 60 mg (n = 152) or 120 mg (n = 153) 3 times a day, for an additional 52 weeks.

Main Outcome Measures Body weight change and changes in blood pressure and serum lipid, glucose, and insulin levels.

Results A total of 1187 subjects entered the protocol, and 892 were randomly assigned on day 1 to double-blind treatment. For intent-to-treat analysis, 223 placebo-treated subjects and 657 orlistat-treated subjects were evaluated. During the first year orlistat-treated subjects lost more weight (mean ± SEM, 8.76 ± 0.37 kg) than placebo-treated subjects (5.81 ± 0.67 kg) (P<.001). Subjects treated with orlistat, 120 mg 3 times a day, during year 1 and year 2 regained less weight during year 2 (3.2 ± 0.45 kg; 35.2% regain) than those who received orlistat, 60 mg (4.26 ± 0.57 kg; 51.3% regain), or placebo (5.63 ± 0.42 kg; 63.4% regain) in year 2 (P<.001). Treatment with orlistat, 120 mg 3 times a day, was associated with improvements in fasting low-density lipoprotein cholesterol and insulin levels.

Conclusions Two-year treatment with orlistat plus diet significantly promotes weight loss, lessens weight regain, and improves some obesity-related disease risk factors.

JAMA. 1999;281:235-242 www.jama.com

OBESITY, WHICH AFFECTS AN increasing number of Americans,[1] poses a therapeutic challenge to the clinician. Conventional nonpharmacological interventions based on diet and exercise have limited long-term success in producing sustained weight loss.[2,3] Obesity induces multiple metabolic abnormalities that contribute to the pathogenesis of diabetes mellitus and cardiovascular disease[4,5] and is associated with increased morbidity and mortality risk.[6,7] A need therefore exists for new and effective therapeutic tools.

A potentially promising approach is induction of negative energy balance and weight loss by drug-mediated inhibition of nutrient absorption. Orlistat (Xenical, Hoffman La Roche Inc, Nutley, NJ), a minimally absorbable (<1%) agent that inhibits activity of pancreatic and gastric lipases, blocks gastrointestinal uptake of approximately 30% of ingested fat.[8] Assuming incomplete energy compensation, the treated subject consuming an average American diet should gradually lose weight and maintain weight loss. The primary aim of this investigation was to test this hypothesis in a large-scale, 2-year, randomized, double-blind, placebo-controlled study.

For editorial comment see p 278.

Author Affiliations and Funding are listed at the end of this article.
Corresponding Author and Reprints: Steven B. Heymsfield, MD, Obesity Research Center, St Luke's-Roosevelt Hospital, Columbia University College of Physicians and Surgeons, 1090 Amsterdam Ave, New York, NY 10025 (e-mail: SBH2@Columbia.edu).

While weight loss is an important end point in obesity treatment, the primary concern in medical management of obesity is morbidity and mortality risk reduction by improving underlying cardiovascular and metabolic risk factors: high blood pressure, atherogenic dyslipidemia, and insulin resistance. A widely held view, which has not been subjected to rigorous critical evaluation in large-scale prospective studies, is that modest (approximately 5%-10%) intentional weight loss is associated with significant improvements in obesity-related cardiovascular and metabolic abnormalities.[9,10] A secondary aim of this study was to examine the effectiveness of 2-year orlistat administration in improving blood pressure, lipid, and carbohydrate metabolism abnormalities, which often occur in obesity.

METHODS

Subjects

Subjects were recruited, evaluated, and monitored at 18 clinical research centers in the United States. Entry criteria included age older than 18 years, body mass index (weight in kilograms divided by the square of height in meters) of 30 to 43 kg/m^2, adequate contraception in women of childbearing potential, and absence of weight loss (>4 kg) in the previous 3 months. Subjects were excluded if they frequently changed smoking habits or had stopped smoking within the past 6 months, had a history or presence of substance abuse, excessive intake of alcohol, significant cardiac, renal, hepatic, gastrointestinal (GI), psychiatric, or endocrine disorders, drug-treated type 2 diabetes mellitus, or the concomitant use of medications that alter appetite or lipid levels.

Study Design

The hypothesis that orlistat is an effective antiobesity agent for weight management was evaluated in a 2-year, double-blind, randomized, placebo-controlled study. Subjects began a controlled-energy diet that provided 30% of energy intake as fat during a 4-week, single-blind, placebo lead-in period. Energy intake was prescribed for each subject on the basis of estimated daily maintenance energy requirement (1.3 × calculated basal metabolic rate) minus 2100 to 3360 kJ/d. All vitamin and mineral preparations were discontinued 8 weeks prior to beginning the study.

Weight change during the 4-week lead-in period was used as a measure of weight loss potential and subjects were stratified accordingly at randomization to ensure an even distribution between treatment groups of individuals who lost less than 2 kg or 2 kg or more during the run-in period. After the 4-week placebo lead-in, subjects who had a treatment compliance of 75% or more, assessed by counting placebo capsules taken during lead-in, were randomized for the 2 full years of study on day 1 to receive placebo (25% of subjects) or orlistat 120 mg capsules (75% of subjects) for 52 weeks. The study drug was administered with the subjects' 3 main meals and the controlled-energy diet was continued.

Medication compliance was assessed by counting the number of pills returned at the time of specified clinic visits. Subjects were considered noncompliant if cumulative capsule consumption was less than 70%. Orlistat-treated subjects who completed 1 year of treatment with a compliance of more than 70% moved to the next phase of their initial randomization to 1 of 3 groups: placebo, orlistat 120 mg, or orlistat 60 mg, for an additional 52 weeks. Subjects randomized to placebo in the first year who had 70% or higher compliance remained taking placebo for another 52 weeks. Subjects began a weight-maintenance diet during year 2, which was designed to help prevent or diminish weight regain rather than to produce further weight loss. If a subject was still losing weight during the last 3 months of year 1, an increased energy intake of 840 to 1260 kJ/d was prescribed. For all other subjects, no change in diet was made.

Dietitians at each site periodically provided instruction on dietary intake recording procedures as part of a behavior modification program and then later used the subject's food diaries for counseling. During year 1, there were 4 behavior modification sessions on weight-loss strategies followed during year 2 by 4 seminars on weight-maintenance strategies. Individuals were encouraged to increase their physical activity by walking briskly for 20 to 30 minutes 3 to 5 times per week. The recommended changes in physical activity throughout the study were not assessed.

Each subject provided written informed consent before entry into the trial. The study protocol was reviewed and approved by the institutional review boards of each investigation site.

Assessments

The initial screening visit included a medical history taking, physical examination, body weight evaluation, electrocardiogram, and clinical chemistry, thyroid function, hematology, and urinalysis laboratory tests. Blood and urine samples were analyzed at a central laboratory.

Fasting serum lipid levels were evaluated according to standard procedures with low-density lipoprotein cholesterol (LDL-C) measured directly by ultracentrifugation. Abnormal serum lipid levels were considered LDL-C higher than 3.36 mmol/L (129.9 mg/dL), untreated; high-density lipoprotein cholesterol lower than 0.9 mmol/L (34.8 mg/dL); and triglycerides higher than 2.54 mmol/L (98.2 mg/dL), untreated.

Fasting serum glucose and insulin levels were measured, and a 3-hour glucose tolerance test (75 g oral glucose load) was performed at the time of randomization and at the end of years 1 and 2 of double-blind treatment. Impaired glucose tolerance and diabetes mellitus were defined according to the National Diabetes Data Group criteria.[11] Fasting serum insulin levels higher than 90 pmol/L were considered abnormal.

Body weight, the primary efficacy measure, was evaluated every 2 weeks until week 16, every 4 weeks until the end of year 1, then every 8 weeks thereafter. The last body weight measurement was recorded at week 104. Standing waist circumference, a measure of adipose tissue distribution and cardiovascular disease risk,[3,6] was determined with a Gulick anthropometric spring-loaded tape measure (Model 5829, Bell Medical Services, Neptune, NJ) and blood pressure was recorded at every visit using a mercury sphygmomanometer. Fat-soluble vitamins A (retinol), D (25-hydroxyvitamin D), and E (alpha tocopherol), prothrombin time (as

a marker for vitamin K), and beta carotene were monitored regularly. If serum vitamin values decreased to below the reference range on 2 consecutive visits, during year 1 only, subjects received a once-daily multivitamin preparation (Centrum) that contained all fat-soluble vitamins. Subjects were instructed to take vitamin supplements at least 2 hours before or after the evening medication dose.

Statistical Analysis

An analysis of the intent-to-treat population was applied to the data from subjects who received at least 1 dose of orlistat or placebo during double-blind treatment and who had at least 1 body weight measurement before and after randomization. The intent-to-treat population thus includes all randomized medication-treated subjects who had at least 1 follow-up body weight measurement. As recommended in the CONSORT guidelines,[12] the last value carried-forward technique was used for years 1 and 2 analyses. The last value carried-forward analysis method uses all follow-up data, including that obtained from subjects who withdrew prematurely, with the last recorded data point used in statistical analysis. All reported data are the actual observed values rather than derived data from carrying forward the last recorded values.

The hypothesis that the mean change in body weight from randomization after 1 year of double-blind treatment is the same for the placebo group and orlistat 120 mg group was tested using analysis of variance or covariance models.[13] These models were also used to test the hypothesis that the expected weight change in subjects receiving orlistat 120 mg in year 1 is the same in year 2, when these subjects were treated with either placebo, orlistat 60 mg, or orlistat 120 mg. The 95% confidence interval of the placebo-adjusted effect of orlistat treatment based on the least squares mean was determined. An analysis of covariance model was used to evaluate changes in risk factor measures from the start of treatment, using baseline values as covariates. Data are presented as mean ± SEM. Categorical analyses of the frequency distributions of weight loss were performed with the use of the χ^2 statistic. For all statistical analyses, $P<.05$ was considered statistically significant.

RESULTS

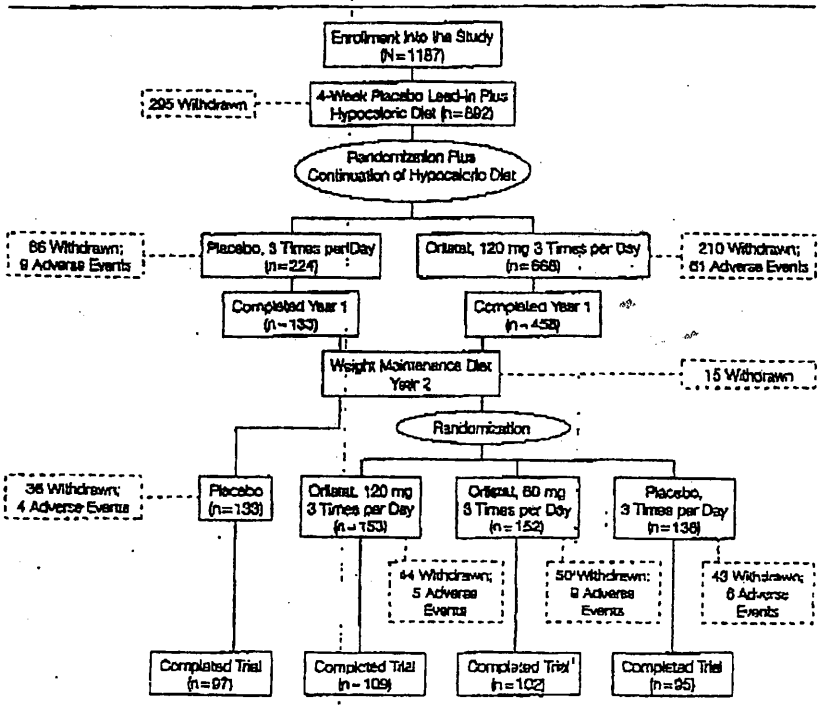
Participation

A total of 1187 subjects were enrolled into the study, of whom 892 completed the 4-week placebo lead-in and were randomized to double-blind treatment with placebo (n = 224) or orlistat 120 mg (n = 668). The intent-to-treat population, presented in the figures and tables, includes the 223 subjects in the placebo group and 657 subjects in the orlistat 120 mg group. One subject in the placebo group and 11 in the orlistat group were withdrawn without at least 1 follow-up measurement. Thus, the intent-to-treat population of 880, which is presented below, is 12 subjects smaller than the randomized population of 892.

The study design and disposition of the subjects over 2 years are shown in Figure 1. The characteristics of the study population at randomization were similar in the 2 treatment groups (Table 1). Oral glucose tolerance was abnormal (impaired or diabetic) in approximately 11% of subjects.

A total of 591 subjects completed the first year: 133 (59%) placebo-treated subjects and 458 (69%) orlistat-treated subjects (Figure 1). Fifteen subjects who completed treatment with orlistat 120 mg did not enter the second year. Of the remaining orlistat subjects, 138 received placebo, 152 received orlistat 60 mg, and 153 received orlistat 120 mg in the second year. The numbers of subjects who completed the second year are also shown in Figure 1 along with those who withdrew because of adverse events. A total of 403 subjects (43%) completed 2 full years of treatment with a total study 2-year completion rate of 45% (403/892) for all study participants. The completion rate was not significantly different among treatment groups. The main reasons for withdrawal (Table 2) were not different between treatment groups.

Figure 1. Flow and Disposition of Subjects Entered Into the Study



Weight Loss

During the 4-week placebo lead-in, subjects in both treatment arms lost approximately 2.3 kg or 2.3% of initial body weight. Following randomization on study day 1, both treatment groups continued to lose weight, but the orlistat 120 mg group achieved a more rapid and significantly greater weight loss compared with the placebo group (FIGURE 2). At the end of the first year of lost 8.76 ± 0.37 kg compared with treatment, the orlistat 120 mg subjects 5.81 ± 0.67 kg in the placebo group (least squares mean difference, $P<.001$). Identical results were obtained when the statistical analyses were applied to the data expressed in absolute form or as a percent change from initial values. When expressed as a percentage, the groups lost 8.8% ± 0.4% vs 5.8% ± 0.7%, respectively ($P<.001$). In addition, 65.7% of orlistat-treated subjects lost more than 5% of their initial body weight compared with 43.6% of placebo-treated subjects ($P<.01$) at the end of the first year, and 38.9% in the orlistat group lost more than 10% of initial weight compared with only 24.8% in the placebo group ($P = .004$).

Of the subjects treated with orlistat 120 mg during the first year, those who also received 120 mg during year 2 regained significantly less of their first-year weight loss (3.2 ± 0.45 kg; 35.2% regain) than those who received orlistat 60 mg (4.26 ± 0.57 kg; 51.3% regain) or placebo (5.63 ± 0.42 kg; 63.4% regain) during the second year ($P<.001$). Treatment with orlistat 120 mg for 2 years produced a 7.6% ± 0.9% weight loss from initial body weight. In contrast, subjects who received placebo for the full 2 years, or who had switched from orlistat 120 mg to placebo in year 2, lost 4.5% ± 0.9% and 4.2% ± 0.8% of initial body weight, respectively. Moreover, 34.1% of subjects who completed 2 full years of orlistat 120 mg treatment maintained a weight loss of more than 10% of initial body weight compared with only 17.5% of subjects who received placebo for 2 years ($P = .02$).

Obesity-Related Risk Factors

Blood Pressure and Waist Circumference. There was a small, though significantly greater, lowering of systolic blood pressure between randomization and week 52 of treatment in the orlistat 120 mg group vs placebo (119.4 ± 0.5 to 118.6 ± 0.6 mm Hg vs 118.6 ± 0.9 to 119.6 ± 1.3 mm Hg; $P = .002$). Diastolic

Table 1. Demographic Data From Start of Placebo Lead-in Period*

Characteristic	Intent-to-Treat Population (N = 880) Placebo (n = 223)	Orlistat (n = 657)
Sex		
Men, No.	26	113
Women, No.	197	544
Race, No. (%)		
White	177 (79.4)	534 (81.3)
Black	35 (15.7)	88 (13.4)
Hispanic	9 (4.0)	28 (4.3)
Age, mean ± SD, y	44.0 ± 0.7	43.3 ± 0.6
Weight, mean ± SD, kg	100.6 ± 0.9	100.7 ± 0.6
Body mass index, mean ± SD, kg/m²	36.5 ± 0.9	36.2 ± 0.1
Risk factors, No. (%)		
Abnormal oral glucose tolerance test results		
Impaired	13 (5.8)	40 (6.1)
Diabetic	10 (4.5)	26 (4.0)
Abnormal fasting insulin level	68 (30.5)	241 (36.7)
Abnormal low-density lipoprotein level	80 (35.9)	211 (32.1)
Abnormal high-density lipoprotein level	27 (12.1)	100 (15.2)
Abnormal triglycerides level	12 (5.4)	69 (10.5)
Diastolic blood pressure >90 mm Hg		
Untreated	16 (7.2)	36 (5.5)
Treated	4 (1.8)	18 (2.7)

*Body weight, blood pressure, and lipid levels were determined at the start of the 4-week placebo lead-in period. Glucose and insulin were determined at the end of the 4-week lead-in period before the start of double-blind treatment. The orlistat group received 120 mg, 3 times per day.

Table 2. Summary of Reasons for Study Withdrawal*

Withdrawal Reason	4-Week Lead-in (n = 1187)	Year 1 Placebo (n = 224)	Year 1 Orlistat (n = 668)	Year 2 Placebo (n = 133)	Year 2 Orlistat Then Placebo (n = 138)	Year 2 Orlistat† (n = 152)	Year 2 Orlistat (n = 153)
Lost to follow-up	43 (3.6)	21 (9.4)	59 (8.8)	15 (11.3)	15 (10.9)	22 (14.5)	17 (11.1)
Administrative	53 (4.5)	21 (9.4)	42 (6.3)	2 (1.5)	6 (4.3)	2 (1.3)	8 (5.2)
Adverse event	23 (1.9)	9 (4.0)	61 (9.1)	4 (3.0)	6 (4.3)	9 (5.9)	5 (3.3)
Uncooperative	64 (5.4)	16 (7.1)	26 (3.9)	5 (3.8)	4 (2.9)	6 (3.9)	6 (3.9)
Treatment failure	0 (0.0)	11 (4.9)	6 (0.9)	3 (2.3)	6 (4.3)	4 (2.6)	3 (2.0)
Protocol violation	12 (1.0)	5 (2.2)	13 (1.9)	3 (2.3)	6 (4.3)	5 (3.3)	3 (2.0)
Entry violation	98 (8.3)	1 (0.4)	3 (0.4)	0 (0)	0 (0)	0 (0)	0 (0)
Refused treatment	1 (0.1)	2 (0.9)	0 (0)	3 (2.3)	0 (0)	2 (1.3)	2 (1.3)
Total Withdrawn, %	24.8	38.3	31.3	26.5	31.0	32.8	28.8

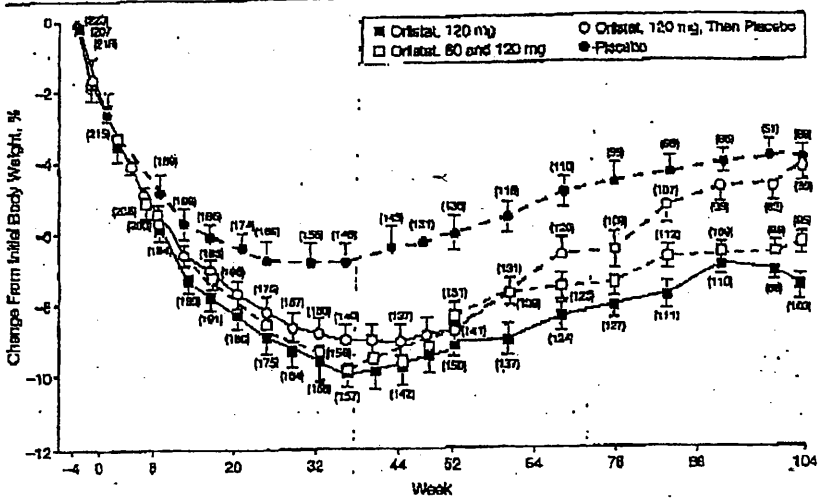
*Values are number (percentage). Subjects received 120 mg of orlistat, 3 times per day.
†Subjects received 120 mg or 60 mg of orlistat, 3 times per day.

blood pressure also decreased more in the orlistat 120 mg group compared with placebo (76.9 ± 0.4 to 75.9 ± 0.4 mm Hg vs 76.1 ± 0.6 to 77.4 ± 0.9 mm Hg; $P = .009$). In addition, after 2 years of treatment, the decrease in mean waist circumference was significantly greater in the orlistat-treated group compared with the placebo group (−4.52 ± 0.8 cm vs −2.38 ± 1.0 cm; $P < .05$).

Lipid Profile. The mean serum lipid levels are shown in TABLE 3. The initial reduction in serum lipid levels during the placebo lead-in period was similar in the 2 groups, approximately an 8% decrease in total cholesterol and LDL-C levels. After randomization, during year 1 total cholesterol levels continued to decline in the orlistat-treated subjects (FIGURE 3) but started to increase immediately in the placebo group even though the subjects were still losing weight. Although total cholesterol levels increased from randomization to the end of year 2, this increase was significantly smaller in the subjects who received orlistat 120 mg for 2 years, than in those who received placebo for 2 years (Table 3; $P < .001$). The LDL-C levels also declined further after randomization over year 1 in the orlistat group (Figure 3) but increased in the placebo group. Similarly, after 2 years of treatment with orlistat 120 mg, LDL-C values were reduced significantly below initial values compared with placebo ($P < .001$). The greater improvements in total and LDL-C were independent of the greater weight loss in the orlistat group, as evidenced by a significant treatment effect in the analysis of covariance using body weight loss as the covariate. The magnitude of the treatment effect over 2 years was roughly 0.28 mmol/L (11 mg/dL) and 0.22 mmol/L (8 mg/dL) for total cholesterol and LDL-C, respectively.

Glucose and Insulin. The group that received orlistat 120 mg for 2 years had less of an increase in fasting serum glucose levels from study day 1 (0.06 ± 0.03 mmol/L [1.1 ± 0.54 mg/dL]) than those who received placebo for 2 years (0.26 ± 0.04 mmol/L [4.68 ± 0.72 mg/dL]; $P = .001$) (TABLE 4). Fasting serum insulin levels decreased significantly over 2 years in the orlistat 120 mg group but remained unchanged in the placebo group (84.02 ± 3.46 to 66.52 ± 3.92 pmol/L vs 86.37 ± 4.71 to 86.32 ± 6.89 pmol/L, respectively; $P = .04$).

Figure 2. Mean Body Weight Change (± SEM) During 2 Years of Double-Blind Treatment*



*Numbers in parentheses are number of subjects at each time point.

Table 3. Results of Serum Lipid Studies

Serum Lipid or Ratio	Study Period	Placebo			Orlistat*			P Value†
		mmol/L	mg/dL	n	mmol/L	mg/dL	n	
Total cholesterol	Week −4	5.41 ± 0.07	209 ± 3	215	5.36 ± 0.07	207 ± 3	216	
	Day 1	4.96 ± 0.06	193 ± 2	222	4.93 ± 0.07	191 ± 3	219	<.001
	Week 104	5.19 ± 0.10	201 ± 4	89	5.04 ± 0.09	195 ± 4	106	
Low-density lipoprotein cholesterol	Week −4	3.44 ± 0.06	133 ± 2	213	3.39 ± 0.06	131 ± 2	216	
	Day 1	3.18 ± 0.05	123 ± 2	222	3.09 ± 0.06	119 ± 2	219	<.001
	Week 104	3.22 ± 0.09	25 ± 4	88	3.14 ± 0.08	121 ± 3	104	
High-density lipoprotein cholesterol	Week −4	1.33 ± 0.02	51 ± 1	215	1.29 ± 0.02	50 ± 1	216	
	Day 1	1.21 ± 0.02	47 ± 1	219	1.17 ± 0.02	45 ± 1	219	.11
	Week 104	1.36 ± 0.04	53 ± 2	89	1.28 ± 0.03	49 ± 1	106	
Ratio of low-density lipoprotein to high-density lipoprotein	Week −4	2.76 ± 0.07		213	2.79 ± 0.07		216	
	Day 1	2.77 ± 0.06		219	2.77 ± 0.06		219	.11
	Week 104	2.51 ± 0.09		88	2.50 ± 0.10		104	
Triglycerides	Week −4	1.53 ± 0.05	136 ± 4	215	1.63 ± 0.06	144 ± 5	216	
	Day 1	1.41 ± 0.04	125 ± 4	222	1.58 ± 0.06	140 ± 5	219	.64
	Week 104	1.55 ± 0.16	138 ± 14	89	1.51 ± 0.08	134 ± 7	106	

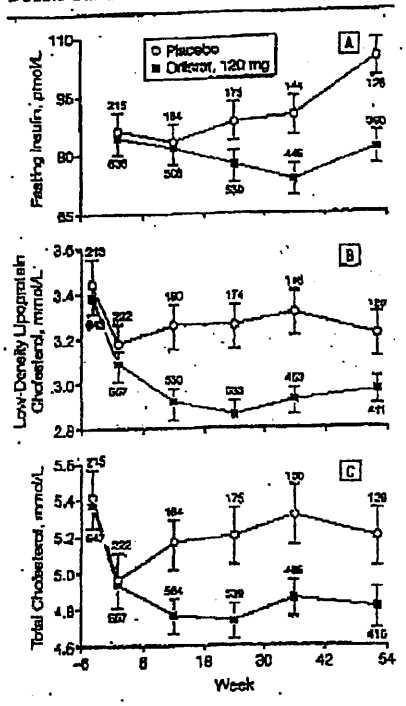
*Subjects received 120 mg, 3 times per day.
†Compared with placebo/placebo at week 104 based on least squares mean.

Adverse Events. The overall incidence of adverse events was similar in placebo and orlistat groups. However, there were more adverse GI events associated with orlistat. At least 1 GI event was experienced by 79% of subjects in the orlistat group compared with 59% of subjects in the placebo group. The majority of subjects treated with orlistat experienced 1 or 2 of these GI events, which typically occurred early during treatment, were mild to moderate in intensity, and generally resolved spontaneously. Seven types of GI events occurred with at least a 5% incidence rate and in twice as many subjects in the orlistat group: flatus with discharge (40.1%), oily spotting (32.7%), fecal urgency (29.7%), fatty/oily stool (19.8%), oily evacuation (14.3%), fecal incontinence (11.8%), and increased defecation (11.1%). Seven subjects in the orlistat group and 2 in the placebo group withdrew because of GI events. The adverse event rate was lower in year 2 than in year 1 and did not differ between groups.

Levels of fat-soluble vitamins and beta-carotene generally remained within the reference range in all treatment groups throughout the study. Vitamins D ($P = .001$) and E ($P = .003$) levels decreased significantly in the orlistat-treated group vs placebo at the end of year 1, but mean serum levels remained within the reference range. When corrected for LDL-C, vitamin E levels were unchanged in the orlistat-treated subjects. Supplementation was required in 14.1% of subjects treated with orlistat 120 mg for 2 years vs with 6.5% of placebo recipients. All subjects receiving supplementation attained normal serum vitamin levels by the end of the study and no subjects were withdrawn due to low values.

One (0.51%) of the 197 placebo-treated women and 3 (0.54%) of the 548 women treated with orlistat 120 mg were diagnosed as having breast cancer during the 2-year period following randomization. One of the orlistat-treated subjects had a 1-cm tumor identified 32 days after randomization. Two subjects, 1 taking orlistat and 1 taking placebo, had mammograms prior to starting the study that revealed preexisting breast malignancies.

Figure 3. Changes in Fasting Serum Insulin and Lipid Levels During 1 Year of Double-Blind Treatment Plus Hypocaloric Diet



A, Mean (±SEM) fasting serum insulin levels from randomization. $P = .11$ for placebo vs orlistat. B, Mean fasting serum low-density lipoprotein cholesterol levels from initial value. $P < .05$ for placebo vs orlistat. C, Mean (±SEM) total cholesterol levels from initial value. The numbers above the plot points are the number of subjects.

COMMENT

This randomized, multicenter, double-blind, placebo-controlled, 2-year study with the GI lipase inhibitor orlistat confirms the hypothesis that partial inhibition of dietary fat absorption combined with dietary intervention results in sustained negative energy balance and weight loss. The study also shows that modest reductions in body weight significantly improve obesity-related disease risk factors. This is the largest, to date, placebo-controlled, double-blind intervention in obese subjects designed to evaluate adjunctive pharmacotherapy for weight loss and prevention of weight regain over a 2-year period. Our findings support and extend the European orlistat trial reported by Sjöström and colleagues.[14]

Weight Loss Effects

Weight was lost and well maintained in the first year of the current study while subjects were taking orlistat plus maintaining a controlled-energy diet. In the second year, when the study design focused on preventing weight regain rather than inducing further weight loss, subjects treated with orlistat maintained about two thirds of their loss while those initially taking orlistat who were switched to placebo in year 2 regained most of the lost weight. As expected, there was some weight gain in the orlistat-treated group in year 2 when the diet was changed to weight maintenance energy intake. Additional factors may also have contrib-

Table 4. Results of Fasting Serum Glucose and Insulin Studies

		Placebo		Orlistat*		
Fasting Level	Study Period	Mean ± SD	No. of Subjects	Mean ± SD	No. of Subjects	*P* Value†
Serum glucose, mmol/L (mg/dL)	Day 1	5.60 ± 0.03 (101 ± 1)	223	5.62 ± 0.03 (101 ± 1)	218	.001
	Week 104	5.80 ± 0.06 (104 ± 1)	90	5.67 ± 0.05 (102 ± 1)	106	
Serum insulin, pmol/L	Day 1	86.37 ± 4.71	215	84.02 ± 3.46	209	.04
	Week 104	86.32 ± 6.89	88	66.52 ± 8.92	102	

*Subjects received 120 mg, 3 times per day.
†Compared with placebo/placebo at week 104 based on least squares mean.

uted to weight regain during year 2, including reduced energy requirements due to metabolically active tissue loss[15,16] and partial compensation for inhibition of dietary fat absorption with increased food intake. Nevertheless, the greater sustained weight loss in the orlistat-treated subjects contrasts to the gradual weight regain observed in subjects who received placebo in year 2.

The results of our orlistat study cannot easily be compared with trials of other antiobesity agents because there are no published reports of continuous double-blind treatment beyond 1 year with medications such as dexfenfluramine hydrochloride, sibutramine hydrochloride, and phentermine hydrochloride plus fenfluramine hydrochloride.[3,17-19] The inability of intensive lifestyle interventions alone to maintain weight loss in obese subjects is highlighted by the recent 2-year trial of diet, exercise, and diet plus exercise reported by Wing et al.[20] Despite the expertise of these investigators, all treatment groups except the diet plus exercise intervention relapsed to initial weight by the end of year 2. Moreover, the diet plus exercise group maintained only a small amount of weight loss (<2.5 kg) over 2 years. The placebo groups in the present study who also had a behavioral intervention similarly experienced weight regain and by treatment week 104 had a total weight loss of about 4.5 kg. Thus, these placebo-treated overweight subjects failed to maintain lost weight to the extent observed in the orlistat 120 mg group. Pharmacologic plus dietary intervention therefore appears to significantly improve the 2-year efficacy of weight management.

Risk Factor Reduction

During the 4-week placebo lead-in period, blood pressure and serum levels of several lipids improved with diet alone. This is consistent with the established independent impact of energy restriction on metabolic and cardiovascular measures, even before substantial weight loss.[21] After randomization, subjects treated with orlistat maintained the improvements in serum lipid levels. The improvements in LDL-C and total cholesterol levels were independent of the greater weight loss achieved in the orlistat-treated subjects, as indicated by analyses of covariance, and thus appear to reflect a pharmacologic lipid-lowering effect of orlistat. In contrast, total cholesterol levels in the placebo group increased progressively from randomization to treatment week 32 despite continued weight loss (Figure 3). Lipase inhibition by orlistat prevents the absorption of approximately 30% of dietary fat intake[22] and the prescribed diet of roughly 30% of energy from fat would thus become, in effect, a 20% to 24% fat diet when coupled with orlistat treatment. A reduction in effective absorbed fat intake of this magnitude, assuming much of it is saturated fat, could contribute to the improved LDL-C and total cholesterol levels.[23]

Fasting insulin levels declined throughout year 1 in the orlistat-treated subjects and this decrease was sustained for the full 2 years of the study. In contrast, in the placebo group, fasting insulin levels increased progressively from about treatment week 24 in the first year and at 52 weeks exceeded the randomization level. The sustained lowering of insulin levels in the orlistat group appeared related to the overall greater weight loss in these subjects rather than an independent drug effect. The significant and sustained lowering of insulin levels is clinically important because earlier studies link fasting serum insulin levels with ischemic heart disease risk,[24] insulin resistance, and obesity-related hypertension.[25] The sustained reduction in fasting serum insulin levels over 2 years of treatment thus suggests that orlistat effectively improves the constellation of metabolic risk factors, which comprise the insulin resistance syndrome.[26]

Adverse Effects

A concern with the long-term use of antiobesity agents is the potential for serious systemic adverse effects. As orlistat acts on GI lipases and is minimally absorbed, systemic adverse effects are negligible. This is confirmed in the present study by the similar systemic adverse event profiles in the placebo and orlistat treatment groups. However, as expected based on the pharmacologic action of orlistat, the incidence of GI effects, generally early during treatment, was higher in the orlistat group. It is likely that the majority of these effects occurred in subjects unable to maintain a moderate dietary fat intake. The GI symptoms diminished over time and study withdrawal due to adverse events was similar among all treatment groups in year 2.

Orlistat's mechanism of action may affect levels of fat-soluble vitamins. Although vitamin D and E levels decreased more in the orlistat group compared with placebo, the changes were small and all mean vitamin and beta-carotene values stayed within reference ranges. Subjects who required vitamin supplementation achieved normalized values by the end of the study.

Breast malignancies were identified in 3 women (0.54%) treated with orlistat 120 mg and 1 woman (0.51%) treated with placebo over the 2-year study. There was strong evidence for tumor preexistence in 3 of 4 cases (2 orlistat, 1 placebo) at the time of study randomization. In addition, animal genotoxicity and carcinogenicity studies do not indicate any carcinogenic potential of orlistat.[27] Orlistat's minimal (<1%) absorption[28] and lack of an estrogen-stimulating effect in women[27] support the conclusion that no biological association exists between orlistat and breast cancer.

Study Limitations

A major difficulty in conducting long-term weight management studies is the high dropout rate, especially in subjects receiving placebo, who therefore generally experience minimal weight loss.[29] The completion rate of subjects in several earlier behavioral-pharmacologic weight loss studies over 6 months to 2 years ranged from 30% to 63%.[2,14,26] The retention rates of 43% and 45% in the placebo and orlistat groups after 2 years of treatment, respectively, in the present study are therefore in accord with previous long-term weight loss studies.

A second concern is potential study bias may impact either favorably or negatively on the weight loss efficacy of orlistat. Subjects may have dropped out of the study because of lack of treatment efficacy in the placebo-treated group and because of GI adverse effects in the orlistat group. Although this study was double-blind, some subjects may have suspected

they were taking placebo or orlistat by the presence or absence of GI adverse events specific to orlistat. This unplanned unblinding could bias the study results. If patients in the placebo group who experienced lesser weight loss and fewer GI symptoms were more likely to drop out, then the comparison of subjects who completed the study could underestimate the true benefit of orlistat by yielding an unrepresentative cohort who were able to achieve sustained weight loss despite inactive treatment for comparison with orlistat-treated subjects. Another possible source of bias, operating in the opposite direction, is that dropouts from the orlistat group may have included noncompliant subjects who ingested large amounts of fat and who had minimal weight loss and experienced more GI adverse effects. Analysis of only subjects who completed 2 full years of treatment could thus overestimate actual treatment efficacy. However, there were no apparent systematic differences in weight loss among subjects who experienced several, 1, or no GI adverse effects.

Use of the data derived from the last recorded observation before the subjects withdrew from the study attempts to compensate for the bias inherent in using only completers' data. To evaluate the impact of the last observation carried-forward approach on potential bias, we compared weight loss at 12, 24, and 36 weeks of treatment in the subjects whose weight was measured at each of these time points and who subsequently dropped out with subjects who did not withdraw. At each time point, the subjects who subsequently dropped out lost less weight than those who remained in the study. Furthermore, the pattern of differences between the placebo- and orlistat-treated cohorts was similar in both dropouts and completers at each time point. Weight loss was approximately 40% greater on a consistent basis in the cohorts of dropouts and completers who received orlistat compared with placebo. Application of the last observation carried-forward approach to the intent-to-treat population would theoretically minimize the opposing sources of bias by carrying forward trends in the responses of subjects who dropped out as well as those who completed the study to the end result.[29,30]

This study demonstrates that partial inhibition of fat absorption in obese subjects can produce sustained weight loss. Subjects treated with orlistat plus a mildly controlled-energy diet lost significantly more weight than those treated with placebo plus diet even though all subjects received a high standard of care and similar dietary counseling. Moreover, orlistat treatment was associated with greater improvements in fasting serum lipid and insulin levels. These observations collectively suggest that orlistat may be a useful adjunct to dietary intervention in producing and maintaining weight loss over 2 years.

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Funding/Support: Supported by a research grant from Hoffmann-La Roche Inc, Nutley, NJ.

Previous Presentation: Presented in part at meetings of the Endocrine Society, Minneapolis, Minn, June 1997; American Diabetes Association, Boston, Mass, June 1997; the European Society of Cardiology, Stockholm, Sweden, August 1997; the American Heart Association, Orlando, Fla, November 1997; and the North American Association for the Study of Obesity, Cancun, Mexico, November 1997.

Acknowledgment: We wish to thank Mark N. Boldrin, MS, for his valuable assistance with the statistical analyses.

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EXHIBIT F

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Barrie Berman VanBrackle
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November 8, 2004

Client-Matter: 00001-001

VIA FIRST CLASS MAIL

C.S. Coffey
c/o Dept of Biostatistics
University of Alabama, Birmingham
Alabama Ryals Public Health Bldg. 327
1665 University Blvd.
Birmingham, AL 35294

Re: ***Basic Research LLC, et al., Docket No. 9318***

Dear Dr. Coffey:

Enclosed is a subpoena for production of documentary materials and tangible things in connection with the above-referenced matter. The subpoena contains instructions for compliance.

Please contact Christopher P. Demetriades at (305) 358-5001 if you have any questions regarding this subpoena.

Thank you for your cooperation.

Sincerely,

Barrie Berman VanBrackle

Barrie Berman VanBrackle

30172847.2

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO

C.S. Coffey
Department of Biostatistics
University of Alabama
Alabama Ryals Public Health Bldg. 327
1665 University Boulevard
Birmingham, AL 35294

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION

FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

4. MATERIAL WILL BE PRODUCED TO

Christopher P. Demetriades

5. DATE AND TIME OF PRODUCTION OR INSPECTION

November 23, 2004

6. SUBJECT OF PROCEEDING

In the Matter of Basic Research, LLC, et. al., Docket No. 9318

7. MATERIAL TO BE PRODUCED

See attached Exhibit A

8. ADMINISTRATIVE LAW JUDGE

The Honorable Stephen J. McGuire

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Christopher P. Demetriades
FeldmanGale, P.A.
201 S. Biscayne Blvd.
Miami, FL 33131

DATE ISSUED

Nov. 8, 2004

SECRETARY'S SIGNATURE

Richard C. Donohue, Acting Secretary

GENERAL INSTRUCTIONS

APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

MOTION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any motion to limit or quash this subpoena be filed within the earlier of 10 days after service or the time for compliance. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission, accompanied by an affidavit of service of the document upon counsel listed in Item 9, and upon all other parties prescribed by the Rules of Practice.

TRAVEL EXPENSES

The Commission's Rules of Practice require that fees and mileage be paid by the party that requested your appearance. You should present your claim to counsel listed in Item 9 for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from counsel listed in Item 9.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

EXHIBIT A

INSTRUCTIONS FOR COMPLIANCE BY DELIVERY OF DOCUMENTS

If documents are delivered by hand, overnight delivery service, mail, or electronic means, your response shall be accompanied by an affidavit, executed by you, that provides:

1. The names, addresses, positions, and organizations of all persons whose files were searched and all persons who participated in or supervised the collection of the documents, and a brief description of the nature of the work that each person performed in connection with collecting the documents;

2. A statement that the search was complete and that all responsive documents are being produced;

3. A statement as to whether the documents were made and kept in the course of your regularly conducted business, and whether it was your regular practice to make and keep such documents; and

4. A statement as to whether any document called for by the subpoena has been misplaced, lost, or destroyed. If any document has been misplaced, lost, or destroyed, identify: the type of document; the date (or approximate date) of the document; subject matter of the document; all persons to whom it was addressed, circulated, or shown; its date of destruction, or when it was lost or misplaced; the reason it was destroyed, lost, or misplaced; and the custodian of the document on the date of its destruction, loss or misplacement.

If the affidavit is incomplete, or additional information is necessary, you may be compelled to appear and testify.

Specifications

1. All records and documents of whatever kind reflecting side effects experienced by subjects in control or placebo groups during the study titled *A Randomized Double-Blind Placebo-Controlled Clinical Trial of a Product Containing Ephedrine, Caffeine, and Other Ingredients from Herbal Sources for Treatment of Overweight and Obesity in the Absence of Lifestyle Treatment* a copy of which is attached as Exhibit A. You may provide redacted records or documents redacting identifying information concerning the test subjects including but not limited to name, address, telephone number, social security number or similar.

2. All records and documents of whatever kind reflecting comments by subjects concerning or related to any side effects experienced by subjects in the control or placebo group during the study titled *A Randomized Double-Blind Placebo-Controlled Clinical Trial of a Product Containing Ephedrine, Caffeine, and Other Ingredients from Herbal Sources for Treatment of Overweight and Obesity in the Absence of Lifestyle Treatment*a copy of which is attached as Exhibit A. You may provide redacted records or documents redacting identifying information concerning the test subjects including but not limited to name, address, telephone number, social security number or similar.

International Journal of Obesity (2004) 28, 1411–1419

0307-0565/04 $30.00
www.nature.com/ijo

PAPER

A randomized double-blind placebo-controlled clinical trial of a product containing ephedrine, caffeine, and other ingredients from herbal sources for treatment of overweight and obesity in the absence of lifestyle treatment

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OBJECTIVE: To evaluate the efficacy and side effects of an herbal formulation to promote weight loss, as compared to placebo.
DESIGN: 12-week multicenter double-blind, placebo-controlled, randomized parallel groups design. Study conducted at three clinical sites in New York State. Subjects were randomized to receive either the 'active' product or a 'placebo' supplement for 12 weeks. Minimal steps were taken to influence lifestyle changes with regard to diet or exercise.
SUBJECTS: 102 overweight/obese ($30 < BMI \leq 39.9$ kg/m^2) volunteers between the ages of 18 and 65 y.
MAIN OUTCOME MEASURES: Weight, percent body fat, fat mass, waist circumference, BMI, blood pressure, and pulse measured at 2 days, 1 week, 2 weeks, 4 weeks, 8 weeks, and 12 weeks postrandomization.
RESULTS: Subjects receiving the 'active' treatment experienced, on average, an additional 1.5 kg of weight loss compared with subjects receiving the placebo. In addition, subjects receiving the 'active' treatment experienced greater reductions in BMI and waist circumference over the 12-week period. No differences were observed with respect to percent body fat, fat mass, diastolic or systolic blood pressure, pulse, the occurrence of any adverse event, or the occurrence of any presumed treatment-related adverse event. Testing of the study product by two independent laboratories indicated that it had only approximately half of the intended amount of ephedrine alkaloids and caffeine.
CONCLUSIONS: Over the 12-week trial, subjects on the active treatment experienced significantly greater weight loss than subjects on placebo, without an increase in blood pressure, pulse, or the rate of adverse events. These benefits were achieved in the absence of any lifestyle treatment to change dietary or exercise behavior and with lower doses of ephedrine alkaloids and caffeine than those commonly utilized.
International Journal of Obesity (2004) 28, 1411–1419. doi:10.1038/sj.ijo.0802784
Published online 31 August 2004

Keywords: ephedra alkaloids; weight loss; BMI; safety; efficacy

Introduction

There is currently an increasing prevalence of obese and overweight individuals in this country. More than half of US adults are overweight and approximately one-third are obese.[1] Obesity is associated with a variety of adverse conditions such as cardiovascular disease and noninsulin-dependent diabetes mellitus (NIDDM)[2] and with decreased longevity.[3,4] Short-term weight loss is associated with improvements in health and reduced risk factors for morbidity and mortality.[5] Medium-term (4 y) weight loss is associated with markedly reduced risk of new onset NIDDM.[6] An emerging body of research suggests that, when analyses are confined to obese individuals who profess an intention to lose weight, subsequent weight loss is associated with no harmful effects and perhaps a very modest decrease

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Received 19 January 2004; revised 24 May 2004; accepted 15 June 2004; published online 31 August 2004

in mortality rate.[7,8] Nevertheless, weight loss is difficult to maintain, and only approximately one in five people who try to lose weight succeed in maintaining all weight initially lost or a clinically meaningful weight loss of 9–11 kg for 3–5 y.[9] Currently, only one FDA-approved OTC drug for weight loss exists (Benzocaine) and is not widely used, widely studied, or widely thought to be effective.[10] Several prescription drugs exist, but they are relatively expensive,[11] of modest efficacy,[12] and in some instances have raised safety concerns.[13] This has led many people to use dietary supplements for weight loss.[14] Perhaps, the best-known class of weight loss products are those which contain ephedra alkaloids from herbal sources.[15] However, the use of such products remains controversial (see addendum)[16] and it is therefore critical that as many data as possible be brought to bear on the safety and efficacy of such products. Thus, there is a great need to evaluate additional agents for weight loss and to conduct rigorous state-of-the-art clinical trials to evaluate the safety and efficacy of potential therapeutics. In addition, it has been shown that ephedrine and caffeine have synergistic effects on thermogenesis[17] and weight loss.[18] For reviews of the pharmacodynamics behind this synergy, see (Dulloo;[19] Greenway and Huber[20]). This study is intended to examine the efficacy and safety of a potential antiobesity product that is a combination of Ma huang (containing ephedrine), Kola nut (containing caffeine), White willow bark (containing salicin), and other herbal components.

Methods

Study design

The study was a multicenter placebo-controlled, randomized, parallel-group, 12-week, longitudinal trial designed to compare the weight loss efficacy and side-effects of an herbal formulation to that of a placebo. Subjects were randomly assigned to receive either the 'active' product or a placebo supplement (see Figure 1 for a study flow chart). Secondary outcomes were percent body fat, BMI, waist circumference, blood pressure, pulse, and serum lipid concentrations.

Subjects

Overweight/obese persons between the ages of 18 and 65 y with body mass index (BMI; kg/m^2) between 30.0 and 39.9 were enrolled in this trial (men: $n=14$ and women: $n=88$). Exclusion criteria were: a maintained weight loss >10 kg in the preceding 3 months; meals not eaten at regular intervals; participation in another investigational study within the past 30 days; a history of alcohol or drug abuse within the past year; females pregnant, lactating, or fertile and unwilling to use a method of birth control acceptable to the investigator; a significant history or current presence of diabetes mellitus or hypertension (systolic BP >140 and/or diastolic BP >90); clinically significant endocrine, hepatic, renal, or cardiovascular disease; a history of sleep disorders, clinical depression or other psychiatric conditions; abnormal

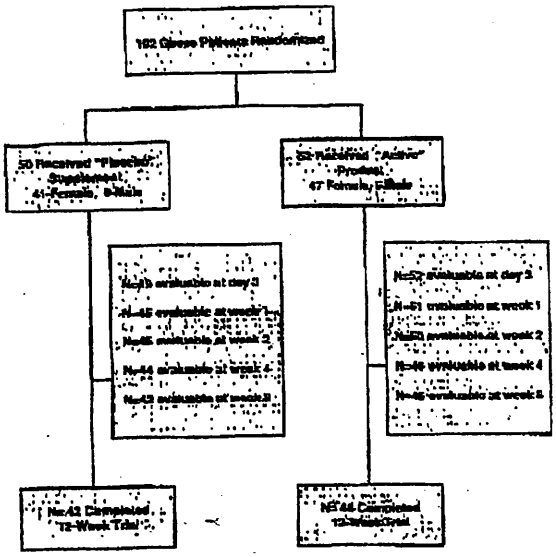

Figure 1 Study flow chart. Three patients (one in the placebo group, two in the active group) discontinued the study but returned for a final evaluation during a time window which provided a valid week 12 measurement.

ECG or laboratory values; the presence of any medical condition or the use of any medication that could have interfered with the conduct of the study or placed the prospective subject at risk; or known allergy or sensitivity to any of the 'active' or 'placebo' product ingredients. (Protocol violations occurred when two subjects were enrolled and randomized to the active group in error. Both subjects answered 'No' to the question 'Female subject is not currently receiving or planning to receive any assisted reproductive technologies capable of producing pregnancy (whether in a same-sex relationship, single or abstinent, or subfertile/infertile)'. Since complete data was collected for both subjects and no major differences in conclusions were observed when these subjects were or were not included in the analyses, they are included in all analyses reported here.) The study was approved by a legally constituted IRB located at RTI, Inc. in Great Neck, New York on May 2, 2001, and all subjects signed informed consent forms. Prospective subjects were determined to be in good general health and appropriate for study participation based on the results of medical history, physical examination, 12-lead electrocardiogram, and laboratory testing, all interpreted by the study physician.

Treatment conditions

The 'active' study product was a potential antiobesity product that contained Ma huang (containing ephedrine),

Kola nut (containing caffeine), White willow bark (containing salicin), and other herbal components. The proposed per-caplet formula for the three primary ingredients was 125 mg Ma huang (10 mg ephedra at 8%), 250 mg Kola not (60 mg caffeine at 25%), and 100 mg White willow bark (15 mg salicin at 15%). However, tests of the pill at two independent labs revealed that they contained approximately half that amount. We will return to this point in the discussion section. To place this dose of caffeine in perspective, even at the intended dose, one tablet contains approximately the same dose of one Exedrine tablet or a 12 oz. can of Mountain Dew soda, approximately two-thirds the dose of an ordinary 8 oz. cup of coffee (http://www.cspinet.org/new/cafchart.htm, accessed 01/13/04), and only 1/10th of the upper end of the dose range that the US Army considers safe and effective for enhancing performance in their personnel.[21]

The study design was intended to emulate 'real-life' conditions under which the study product is administered. Hence, minimal steps were taken to influence other lifestyle changes. At the time of randomization, subjects were given pamphlets that described lifestyle modifications that would achieve a healthier lifestyle. However, no additional counseling with regard to modifications of dietary or exercise behaviors was provided during the course of the study. Thus, this study assessed the efficacy of the study product in a group of patients given the freedom to eat whatever they desired and not encouraged to make other modifications beyond taking the tablets in the appropriate manner (two caplets taken three times daily).

Measures

Study subjects returned to the clinics at 2 days, 1, 2, 4, 8, and 12 weeks postrandomization. At each visit, compliance assessments were performed and subjects were given a sufficient supply of the appropriate study product to permit dosing until the time of the next scheduled visit.

Height measurements were obtained at the randomization visit. At randomization and each subsequent visit, brief physical assessments were repeated on all subjects, including measurements of weight, vital signs, and girth at the waist. From the height and weight measurements, BMIs were calculated. At the randomization visit and 12 week follow-up visit, electrocardiograms (ECGs) were performed, and blood and urine samples were collected for routine laboratory analyses. In addition, serum lipid levels were obtained at baseline and study conclusion.

Height was measured within 0.1 in, using a unit attached to the scale, and then converted to cm. Body weight was measured within 0.1 kg using a standardized calibrated scale. Body fat determinations were performed using a Health Management System 1000 (Bioanalogics; Beaverton, OR, USA) bioimpedance analyzer (See: http://www.bioanalogics.com/validity.htm for validity information). All anthropometric measurements were taken using the Gullick 2 Anthropometric Tape Measure Model 67020, manufactured by Country Technology, Inc. Waist measurements were completed as per NHANES III Protocol. Blood pressure was measured after at least 5 min of rest using a standard mercury sphygmomanometer and appropriately sized cuffs, according to the guidelines of the American Heart Association.

Adverse events (AEs) were assessed by the investigator. For each AE encountered, the study physician classified the relationship between the AE and the study product as None, Possible, Probable, or Definite. Any AE classified by the study physician to have at least a possible relationship to treatment was presumed to be a treatment-related adverse event.

Statistical analysis

The principal aim of the analysis was to compare the effects of the 'active' product and placebo over time on the primary and secondary outcomes. Because dropouts were observed over the course of the study, the primary analysis consisted of an intent-to-treat (ITT) repeated measures mixed model[22,23] examining weight loss over the course of the study. As opposed to traditional repeated measures techniques, mixed models permit the inclusion of subjects with missing values for some visits. These mixed models examined linear and quadratic trends over time separately for group assignment (control or active), the main independent variable of interest. Baseline weight (at visit 2) entered the model as a covariate. In order to reduce the problem of multicollinearity, often present in polynomial models, we subtracted the integer value closest to the mean values of time and baseline weight from each individual value.

Furthermore, an examination of the raw data suggested that measurements observed over time within a patient were correlated and that the variation in measurements increased over time. In order to account for this, random intercepts and slopes were fit for each patient. The use of a random coefficient for each patient allows for the variation to differ between subjects and accounts for the fact that measurements observed over time within a patient are correlated. This standard random coefficients model can also be thought of as utilizing a random intercept for each subject. The addition of a random slope as well accounts for the fact that the variation in measurements within a subject tends to increase linearly over time. We considered more complex covariance structures that allowed the variation in measurements within a subject to increase in a quadratic or cubic fashion over time. Although these models provided a slightly improved fit over the model that allowed variation to increase linearly with time, the overall conclusions were not affected. Hence, we report the results from the model with a random intercept and slope for parsimony.

By utilizing mixed models with random intercepts and slopes for each patient, we were then able to simultaneously address the following questions in the final model:

Was there a difference in immediate 2-day weight loss, 1-week weight loss, and 12-week weight loss among subjects

receiving the active product *vs* subjects receiving the placebo?

Was there a difference in the trend of weight loss over the entire course of the study among subjects receiving the active product *vs* subjects receiving the placebo, that is, was there a time by treatment interaction?

Hence, this mixed model time by treatment interaction analysis allowed us to examine not only the amount of weight loss at the end of the study, but also how that weight loss came to be (ie was the weight loss rapid and then maintained? slow but consistent from week to week? etc).

Secondary efficacy analyses to compare 2-day, 1-week, and 12-week changes in percent body fat, fat mass, body mass index, and waist circumference were performed in a similar manner. Finally, the percentage of patients in the two groups achieving reductions of >1 and >5% from baseline weight at the conclusion of the 12-week study period were compared using the Pearson χ^2-test. In addition, we conducted a last observation carried forward (LOCF) analysis to examine the impact of the 11 subjects who dropped out before the conclusion of the study. The conclusions from this LOCF analysis were identical to the completers only analysis reported above, hence we report only the latter analysis here.

The 12-week changes in serum lipid values were examined using the nonparametric Wilcoxon test. For one subject, a member of the investigative team determined that the initial lipid baseline values should be repeated since these initial laboratory values were nonfasting. Hence, the repeated laboratory values were used as baseline values for analytic purposes.

With respect to side effects, we also examined changes in systolic blood pressure, diastolic blood pressure, and pulse using mixed model techniques in the same manner as with the efficacy analysis. We also used logistic regression methods to compare both the percentage of subjects having any adverse event (AE) and the percentage of subjects having any putatively treatment-related adverse events (PTRAE) in the two groups. All significance tests were conducted at the two-tailed 0.05 alpha level.

Results

Descriptive statistics

Baseline characteristics of subjects enrolled in the trial are shown in Table 1. As expected due to the randomization scheme, subjects in both groups had similar characteristics upon entering the study. Possible exceptions included a slightly higher (though not statistically significant) percentage of subjects in the active group with high BMI (≥35) at baseline, past gastrointestinal and endocrine conditions, and abnormal skin condition during the baseline medical exam. In all, 81% of subjects were White Non-Hispanic, 6% were Hispanic, 11% were Black Non-Hispanic, and 2% were other or unknown. Compliance for an individual subject was determined by taking the ratio of the cumulative number of tablets actually taken to the cumulative number of tablets that should have been taken over the course of the study and was expressed as a percentage. Mean group compliance was above 95% for both groups.

Table 1 Baseline subject characteristics (mean and s.d. = standard deviation)[a]

Characteristic	Placebo group N	Placebo group Mean (s.d.)	Active group N	Active group Mean (s.d.)
Age, y	50	42.1 (10.9)	52	44.9 (9.1)
Weight, kg	49	92.0 (12.5)	52	93.5 (11.4)
Body mass index (BMI: kg/m^2)	49	34.0 (2.9)	52	35.1 (2.9)
Fat mass, kg	49	14.2 (3.3)	51	15.2 (3.3)
Total body fat mass %	49	34.2 (6.3)	51	36.2 (5.6)
Waist circumference, cm	49	106.1 (10.5)	52	106.4 (8.9)
Total cholesterol, mg/dl	50	195.6 (31.7)	52	213.4 (32.8)
LDL cholesterol, mg/dl	49	117.6 (27.3)	52	127.5 (28.1)
HDL cholesterol, mg/dl	50	51.3 (13.6)	52	52.6 (9.4)
Diastolic blood pressure, mmHg	50	75.2 (7.8)	52	77.0 (6.5)
Systolic blood pressure, mmHg	50	119.1 (10.4)	52	121.6 (9.7)
Triglycerides, mg/dl	50	138.5 (72.9)	52	165.2 (86.9)
Hips, cm	49	116.1 (8.4)	52	118.4 (8.2)
Pulse, beats/min	50	75.2 (9.6)	52	76.2 (8.2)
Thigh circumference, cm	49	59.2 (4.2)	52	60.7 (5.1)

[a]Ns differ because some measures were missing and because two ineligible participants were randomized to the active group.

A total of eight patients in each group (16 total) discontinued the study. In the control group, three subjects discontinued due to an adverse event (Emesis, Elevated Blood Pressure, and Hypothyroidism), three subjects withdrew consent, and two subjects were lost to follow-up. In the active group, two subjects discontinued due to an adverse event (Compression Fracture of L1 and Elevated Blood Pressure), one subject was unable to meet protocol criteria ('Subject was unable to return to study site for Visit 8'), one subject was withdrawn for a protocol violation or noncompliance ('Subject missed visit 7 and has been off product since 11/30/01'), two subjects withdrew consent, and two subjects were lost to follow-up. However, it should be noted that three of these subjects who discontinued returned for a final evaluation during a time window which provided a valid week 12 measurement.

Efficacy analyses

Table 2 summarizes each of the efficacy outcome variables between baseline and 2 days, 1 week, and the conclusion of the study (12 weeks), respectively, for subjects in the active and control groups. For each variable, the table displays unadjusted mean decreases and standard deviations as well as model adjusted mean decreases, standard errors, and the *P*-values for comparing the two groups. The model adjusted means correspond to the final mixed model incorporating linear and quadratic effects to measure the effect over time for both groups, random intercepts and slopes for each subject to account for correlations over time and increasing

Table 2 Mean decreases for efficacy outcome variables by group

Variable	Unadjusted		Adjusted		P-value
	Control (n=50)	Active (n=52)	Control (n=50)	Active (n=52)	
Weight loss (kg)					0.007
After 2 days	0.24 (0.71)	0.39 (0.81)	0.39 (0.12)	0.47 (0.12)	0.64
After 1 week	0.39 (0.84)	0.69 (0.95)	0.40 (0.12)	0.61 (0.11)	0.19
After 12 weeks	0.53 (2.73)	2.18 (2.31)	0.46 (0.37)	2.10 (0.35)	0.002
Percent body fat					0.62
After 2 days	0.80 (2.54)	−0.39 (1.66)	0.72 (0.31)	−0.12 (0.30)	0.05
After 1 week	0.66 (2.58)	0.26 (1.69)	0.76 (0.29)	−0.02 (0.28)	0.06
After 12 weeks	1.38 (3.48)	1.41 (2.15)	1.59 (0.41)	1.13 (0.40)	0.42
Fat mass					0.15
After 2 days	0.83 (2.34)	−0.26 (1.54)	0.83 (0.29)	0.09 (0.28)	0.07
After 1 week	0.79 (2.49)	0.48 (1.51)	0.87 (0.27)	0.24 (0.26)	0.1
After 12 weeks	1.40 (3.70)	2.04 (2.31)	1.61 (0.45)	1.80 (0.43)	0.76
BMI					0.006
After 2 days	0.08 (0.27)	0.17 (0.34)	0.14 (0.05)	0.19 (0.05)	0.49
After 1 week	0.14 (0.33)	0.25 (0.45)	0.14 (0.05)	0.24 (0.05)	0.14
After 12 weeks	0.21 (1.03)	0.87 (0.88)	0.18 (0.14)	0.82 (0.13)	0.001
Waist circumference (cm)					0.01
After 2 days	0.07 (1.60)	0.32 (1.74)	0.24 (0.24)	0.47 (0.23)	0.49
After 1 week	0.62 (1.93)	0.90 (1.70)	0.41 (0.23)	0.65 (0.22)	0.45
After 12 weeks	0.86 (2.78)	2.55 (3.13)	0.91 (0.43)	2.57 (0.42)	0.006

Values shown are unadjusted means and standard deviations and model adjusted means and standard errors. The model adjusted means correspond to the final mixed model incorporating linear and quadratic effects to measure effect over time for both groups, random intercepts and slopes for each patient to account for correlations over time and increasing variation from visit to visit within a patient, and adjusts for baseline measurements. The first P-value for each outcome represents the test for a time by treatment interaction, that is, that the effect differs in the active and control groups over time. Positive values correspond to decreases from baseline. Negative values correspond to increases from baseline.

variation from visit to visit within a subject, and adjusts for baseline measurements. The table also presents the P-values for the test of a time by treatment interaction from the mixed model, that is, a test of differences in the trend for changes from baseline over time for the two groups. Note that positive numbers indicate decreases from baseline while negative numbers indicate increases from baseline.

Weight loss. Figure 2 displays the mean decrease in weight from baseline for both groups over the course of the six study visits. The points connected by dashed lines represent the observed decreases over the course of the study. The points connected by solid lines represent predicted values from the final mixed model. Measurements for the active and control groups are represented by green and red lines, respectively. There was a significant initial weight loss at 2 days in both the control (0.39 kg±0.12, $P=0.002$) and active groups (0.47 kg±0.12, $P=0.0001$), but there was no statistically significant difference in the amount of initial weight loss between the two groups ($P=0.64$). No additional weight loss over time was observed in the control group ($P=0.79$); hence, the initial weight loss observed in the control group appears to be due to a placebo effect. On the contrary, there was a highly significant effect of time on weight loss in the active group with the amount of weight loss increasing linearly over the course of the study ($P=0.0001$). As a consequence, there is a highly significant time by treatment interaction observed with respect to weight loss ($P=0.007$)

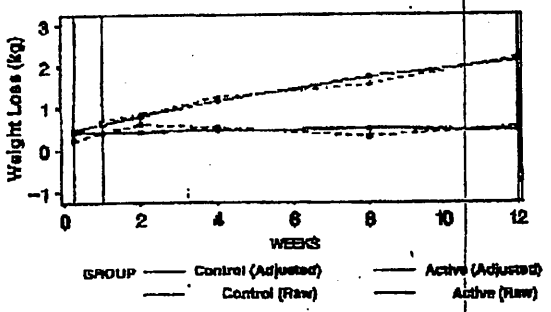

Figure 2 Mean weight loss from baseline in kilograms (positive numbers indicate weight loss). The plotted points connected by dashed and solid lines represent the observed decreases and model adjusted predicted values, respectively. The green lines represent the active group and the red lines indicate the control group.

and a highly significant difference in the amount of weight loss observed in the two groups at the conclusion of the study (2.10 kg ± 0.35 for the active group vs 0.46 kg±0.37 for the control group, $P=0.002$). Furthermore, as is to be expected since the height of the patients remains unchanged during this trial, we obtained similar results when we conducted the analysis using BMI as the outcome.

Percent body fat. There was a significant initial reduction in percent body fat at 2 days in the control group (0.72%±0.31,

$P=0.02$) but not the active group (−0.12%±0.30, $P=0.69$). Reductions in percent body fat continued in a linear manner over time for both groups, although the rate of reduction seemed slightly higher in the active group ($P=0.002$) than in the control group ($P=0.09$). As a consequence, no statistically significant difference in reduction of percent body fat in the two groups was observed at the conclusion of the study (1.13%±0.40 for the active group *vs* 1.59%±0.41 for the control group, $P=0.42$).

Fat mass. The results for the analyses with fat mass serving as the outcome of interest mirror the results obtained when using percent body fat as the outcome. Most notably, there was no statistically significant difference in reduction of fat mass in the two groups at the conclusion of the study (1.61 kg±0. 45 for the active group *vs* 1.80 kg±0.43 for the control group, $P=0.76$).

Waist circumference. There was a significant initial reduction in waist circumference at 2 days for the active (0.47 cm±0.23, $P=0.04$) but not the control group (0.24 cm±0.24, $P=0.32$), although there was no statistically significant difference in the amount of initial reduction in waist circumference between the two groups ($P=0.49$). There was a highly significant effect of time on reduction of waist circumference in both the active ($P<0.001$) and control ($P=0.002$) groups, with the reduction in waist circumference increasing over the course of the study. However, a significant time by treatment interaction was observed ($P=0.01$) due to the fact that the rate of reduction in waist circumference was linear in the active group, but quadratic in the control group (ie linear at first, then leveling off). This was evidenced by the fact that little additional reductions in waist circumference were observed in the control group after the first week, while the reductions in waist circumference continued throughout the 12-week study period for the active group. As a consequence, there was no difference in the reduction of waist circumference observed in the two groups 1 week into the study (0.65±0.22 for the active group *vs* 0.41±0.23 for the control group, $P=0.45$) but a highly significant difference was observed at the conclusion of the study (2.57 cm±0.42 for the active group *vs* 0.91 cm±0.43 for the control group, $P=0.006$).

Responder rates. Table 3 summarizes the percentage of baseline weight lost at the end of the 12-week period in the two groups. At the conclusion of the study, there was a statistically significant increase in the percentage of patients who lost greater than 1% of their initial body weight in the active group as opposed to the control group (69 *vs* 45%, $P=0.02$). However, there was no statistically significant difference between the two groups in the percentage of patients who lost greater than 5% of their initial body weight (15 *vs* 12%, $P=0.62$). This implies that while there was a greater response with regards to weight loss in the active group, the observed weight loss was relatively small when considered as a percentage of initial weight.

Table 3 Percentage of baseline weight lost by group

Group	1% or less	>1–5%	>5–10%	>10%	n
Control	24 (56%)	14 (33%)	5 (12%)	0 (0%)	43
Active	14 (30%)	25 (54%)	6 (13%)	1 (2%)	46

Serum lipid analyses

There were 'marginally significant' (defined as $0.05<P<0.10$) larger decreases in total cholesterol and triglycerides in the active group as compared to the control group. All other serum lipids showed no significant differences between the two groups.

Safety-related results

Systolic blood pressure, diastolic blood pressure, and pulse. Table 4 summarizes the change in systolic BP, diastolic BP, and pulse between baseline and 2 days, 1 week, and 12 weeks, respectively, for subjects in the active and control groups. As with the efficacy variables, the table displays unadjusted means and standard deviations as well as adjusted means, standard errors, and the *P*-values obtained from the final mixed model for comparing the two groups. However, it should be noted that this table presents changes from baseline in these variables rather than decreases. Hence, in this table, positive numbers indicate increases from baseline while negative numbers correspond to decreases from baseline. No significant time by treatment interaction was observed for systolic BP ($P=0.76$) and diastolic BP ($P=0.49$). Although the time by treatment interaction was not statistically significant ($P=0.09$), there was a marginally significant difference in change in pulse rates observed in the two groups at the conclusion of the study. However, this was primarily due to an observed decrease in pulse rates for the control group at 12 weeks (0.78 bpm±1.15 for active group *vs* −2.32 bpm±1.19 for control group, $P=0.06$).

Adverse events. Table 5 displays the distribution of the number of adverse events and treatment-related adverse events per person in the study sample for each treatment group. Of the 102 patients in the study, 78 (76%) suffered at least one AE and 30 (29%) suffered at least one PTRAE over the course of the study. There was no difference in the occurrence of any adverse event between the two groups (77% for active *vs* 76% for control, $P=0.91$). Similarly, there was no difference in the occurrence of any PTRAE between the two groups (33% for active *vs* 26% for control, $P=0.46$).

Of the 78 subjects who experienced adverse events, 56 had multiple adverse events. Hence, a total of 196 adverse events observed over the course of this study. Of these, five 'serious' adverse events occurred in two subjects. One subject in the

Table 4 Changes for safety outcome variables by group

	Unadjusted		Adjusted		
Variable	Control (n=50)	Active (n=52)	Control (n=50)	Active (n=52)	P-value
Systolic blood pressure					0.76
After 2 days	1.55 (10.20)	−0.71 (10.90)	1.03 (1.14)	0.27 (1.10)	0.63
After 1 week	1.16 (9.40)	−1.72 (9.37)	0.33 (1.05)	−0.22 (1.01)	0.71
After 12 weeks	1.56 (10.11)	−1.39 (10.55)	1.56 (1.41)	0.36 (1.36)	0.54
Diastolic blood pressure					0.49
After 2 days	−0.57 (8.40)	−0.56 (7.80)	−0.70 (0.78)	0.48 (0.75)	0.28
After 1 week	−0.31 (7.89)	−0.04 (6.29)	−0.63 (0.69)	0.28 (0.67)	0.35
After 12 weeks	0.56 (8.39)	0.30 (7.28)	0.75 (0.98)	0.57 (0.95)	0.9
Pulse					0.09
After 2 days	0.24 (10.37)	0.88 (10.57)	−0.39 (1.00)	1.31 (0.97)	0.22
After 1 week	−0.89 (9.48)	1.06 (9.13)	0.24 (0.90)	1.38 (0.87)	0.36
After 12 weeks	−3.63 (11.65)	−0.35 (9.12)	−2.32 (1.19)	0.78 (1.15)	0.06

Values shown are unadjusted means and standard deviations and model adjusted means and standard errors. The model adjusted means correspond to the final mixed model incorporating linear and quadratic effects to measure effect over time for both groups, random intercepts and slopes for each patient to account for correlations over time and increasing variation from visit to visit within a patient, and adjusts for baseline measurements. The first P-value for each outcome represents the test for a time by treatment interaction, that is, that the effect differs in the active and control groups over time. Positive values correspond to increases from baseline. Negative values correspond to decreases from baseline.

Table 5 Distribution of the number of adverse events per person in the study sample

No. of adverse events	0	1	2	3	4	≥5
Control	11	11	10	9	5	3
Active	12	11	18	4	3	4
No. of PTRAEs	*0*	*1*	*2*	*3*	*4*	*≥5*
Control	36	7	3	3	0	0
Active	35	9	5	1	2	0

control group had three adverse events classified as serious: 'Exacerbated Depression', 'Atrial Fibrillation', and 'Exacerbation of Asthma'. However, none of these adverse events kept the subject from completing the study. One subject in the active group had two adverse events classified as serious: 'Low Back Pain' and 'Compression Fracture of L1', which forced this patient to discontinue the study.

Discussion

This 12-week weight loss trial comparing an active treatment to placebo indicated that the active treatment was associated with greater weight loss as well as greater reductions in other related health variables. There were no significant differences between the two groups in changes in percent body fat, diastolic blood pressure, systolic blood pressure, pulse, the occurrence of any adverse event, or the occurrence of any putatively treatment-related adverse event.

The results of this study seem quite clear and quite consistent with a growing body of literature on the effects of ephedra-containing products for weight loss.[14,24] Specifically, this study shows that a product containing ephedra, caffeine, and salicylic acid from herbal sources is effective in producing weight loss and does not produce commonly significant short-term adverse effects. Although one patient in the active treatment group withdrew due to elevated blood pressure, so too did one subject in the control group.

Moreover, this study demonstrates that the study product was effective in a group of subjects who were not encouraged to make lifestyle modifications other than taking the study product as directed. These results suggest that subjects do not have to be jointly involved in a structured program to modify lifestyle in order to achieve the weight-loss benefits of the study product. Of course, combining the study product with a healthy diet and exercise program would be expected to increase the amount of weight loss.

With respect to clinical benefit, clearly longer term studies would be valuable. Results from the Diabetes Prevention Program (DPP) suggest that even moderate weight losses that are not fully sustained can confer marked health benefits.[5] Whether such benefits can be produced via long-term treatment with ephedrine-containing products remains to be demonstrated.

With respect to safety, our results are consistent with past research in showing no serious, deleterious consequences with the use of such products in controlled weight loss studies. Although this is an encouraging outcome, several points should be kept in mind. First, because our study was only 12 weeks in duration, it offers no direct evidence about any potential positive or negative effects associated with long-term usage. Second, our exclusion criteria and the nature of the study process are such that our sample cannot be presumed to be representative of the general population. Therefore, one can speculate that different results might be

obtained in the general population. Third, our study included only 102 subjects which means we had insufficient statistical power to detect adverse effects in very rare events. Fourth, our results only apply to the conditions of our study and do not offer any information about what might occur if, for example, people took markedly higher doses.

A number of safety concerns have been raised about the use of ephedrine-containing products.[16] At the same time, there are also data to suggest that the closely related compound pseudoephedrine can be used widely with apparent safety.[25] There are also interesting data that, among Fisher 344 female rats, long-term ingestion of ephedrine results in lower body weight and greater longevity.[26] These data suggest the possibility of important clinical benefits to use of ephedrine-containing products among obese persons.

An important limitation of this study concerns the quality control of the product. As stated above, although the product was supposed to have 10 mg of ephedra alkaloids and 60 mg of caffeine per unit, testing of the product by two independent laboratories indicated that it only had roughly half that amount (4.15 mg ephedrine alkaloids; 25.3 mg caffeine) (Pinnacle Inc, personal communication, 2003). This is not entirely surprising given the results of Gurley *et al*.[27] It is noteworthy that the dose of ephedrine alkaloids that we used (~30 mg/day) is quite modest compared to doses of ephedrine previously used. The most common preparation used, based on Astrup's research, contains 20 mg ephedrine plus 200 mg caffeine three times a day. This is actually a reduction by 50% compared to the earlier Elsinore pill (40 mg ephedrine + 100 mg caffeine), which was available in Denmark for a number of years.[20,28] On the one hand, it can be taken as encouraging that we so clearly demonstrated efficacy even with such reduced doses of ephedrine alkaloids and caffeine. On the other hand, it is challenging to conduct the most rigorous of studies when manufacturing standards are not at a higher level. It also implies that our safety-related results can only be definitively taken to apply to the dose given and not to higher doses. Clearly, this suggests that greater standards for manufacturing control of such herbal products would be beneficial to ensure that the stated doses of the 'active' ingredients are correct. It also suggests the need for federal or other nonindustry funding of such studies so that protocols, including thorough checking the composition of the test product, can be run with a greater degree of rigor. In this regard, it should be noted, as one reviewer did, that it is not unheard of for herbal products to be adulterated or 'laced' with unlabeled ingredients (eg, Ku *et al*[29]). We operated under the assumption that the manufacturer's statements about active ingredients were accurate. However, in future research, it would be wise to test for this via an independent laboratory as was done here for the ephedrine and caffeine content.

In conclusion, we believe our results demonstrate the efficacy of the product tested and provide some reassurance with respect to its safety. These benefits were achieved in the absence of any enjoinder to lifestyle treatment to change dietary or exercise behavior and with lower doses of ephedrine alkaloids and caffeine than those commonly utilized. Our results are consistent with a body of literature but are also limited by being short-term, based on a modest number of subjects, and with a product containing a lower dose than expected. We believe that the latter points underscore the need for larger, longer term studies of pharmaceutical grade ephedrine for the treatment of obesity.

Addendum

As we completed writing this manuscript, the US Food & Drug Administration announced that 'The Food and Drug Administration (FDA) is alerting the public to its forthcoming determination that dietary supplements containing ephedra present an unreasonable risk of illness or injury, and should not be consumed. The agency has notified firms manufacturing and marketing these products that it intends to issue a final rule prohibiting their sale, which will become effective 60 days after its publication.'[30] Although products marketed as dietary supplements containing ephedra like the one tested herein will presumably not be available in the US in the near future, our results should still be of use to those in other parts of the world where such supplements may still be in use, to investigators considering designing studies of other dietary supplements for weight loss, to litigators working on cases involving alleged effects of ephedra-containing products, and to designers of new potential antiobesity products who wish to consider the effects of related products.

Acknowledgements

Supported by Pinnacle, Inc., the manufacturer of the product tested.

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EXHIBIT G

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

In the Matter of	:	
BASIC RESEARCH, L.L.C., A.G. WATERHOUSE, L.L.C., KLEIN-BECKER USA, L.L.C., NUTRASPORT, L.L.C., SOVAGE DERMALOGIC LABORATORIES, L.L.C., BAN, L.L.C., DENNIS GAY, DANIEL B. MOWREY, and MITCHELL K. FRIEDLANDER,	:	Docket No. 9318
Respondents.	:	

NOTICE OF VIDEOTAPE RULE 30(b)(6) DEPOSITION OF DERMTECH INTERNATIONAL

PLEASE TAKE NOTICE that Respondent Dennis Gay will take the following Rule 30(b)(6) deposition upon the following dates and times:

DermTech International	December 9, 2004	9:00 a.m.

Said deposition will be taken at the San Diego Marriott Hotel & Marina, 333 West Harbor Drive, San Diego, California (619-234-1500), before a certified court reporter and videographer and will continue thereafter until completed.

Notice is given to DermTech International that examination is requested on those particular matters described below. Further, DermTech International is required to designate one

or more officers, directors, managing agents, or other persons to testify on its behalf and set forth the matter on which each person identified will testify.

DEFINITIONS

A. "Person" means any natural person or any corporation, partnership, association, joint venture, firm, or other business enterprise or legal entity and means both the singular and plural.

B. "Document" is intended to be comprehensive and to include, without limitation, any statements, contracts, work papers, letters, written communications, reports, memoranda, records, schedules, studies, notices, recordings, photographs, papers, charts, analyses, graphs, indices, data sheets, notes, notebooks, diaries, diagrams, forms, manuals, brochures, lists, publications, drafts, minutes, credits, debits, claim sheets, accounting records, and accounting work sheets, including copies of any of the above that differ in any respect from the original, such as copies containing marginal notations or other variations, and all other records or writings, however produced or reproduced.

C. The term "identify" or "identity":

1. When used in reference to an individual, means to state the individual's full name his or her present business and home addresses (or if unknown, the last known business and home addresses), and his or her business affiliations, positions and business addresses at all times relevant to the interrogatory or request in question.

2. When used in reference to a person other than an individual means to state its full name and the address of its principal place of business, to specify the kind of entity that it is and to identify the principal persons involved with said entity at all times relevant to the interrogatory or request in question.

3. When used in reference to a document means: (a) to state the date the document bears or, if undated, the date it was prepared, (b) to identify each person who prepared the document or participated in its preparation, (c) to identify each person who received a copy of the document, (d) to describe the document, as, for instance, "letter," "memorandum," (e) to set forth its title or caption and subject, (f) to state its present location or custodian, and (g) if any document is not presently in your possession or subject to your control, to state the disposition that was made of it, the reason for such disposition, and the date thereof.

4. When used in reference to an oral communication means: (a) to identify the person or persons who spoke and all persons overhearing the communication, (b) to state the substance of what each person said, and (c) to state the date on which and place where such communication took place.

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LIST OF AREAS OF INQUIRY

1. The circumstances under which DermPharm or Derm Tech International conducted the study known as "Evaluation of the Percutaneous Absorption of Aminophylline, *In Vitro*, Using the Human Cadaver Skin Model," Study No. DP01-645, dated December 6, 2001 (hereinafter the "First Study").

2. The circumstances under which DermPharm or Derm Tech International conducted the study known as "Determination of the Percutaneous Absorption of Aminophylline, *In Vitro*, Using the Human Cadaver Skin Model," Study No. DP02-618, dated September 1, 2002 (hereinafter the "Second Study").

3. The circumstances under which DermPharm or Derm Tech International conducted the study known as "Evaluation of the Percutaneous Absorption of Aminophylline, *In Vitro*, Using the Human Cadaver Skin Model," Study No. DP03-620, dated June 11, 2003 (hereinafter the "Third Study").

4. The identities and qualifications of the individuals conducting the First Study, the Second Study and the Third Study.

5. The relationship between DermPharm, Derm Tech International and any of the persons involved in the First Study, Second Study or Third Study, on the one hand, and Basic Research, L.L.C., A.G. Waterhouse, L.L.C., Klein-Becker USA, L.L.C., Nutrasport, L.L.C., Sovage Dermalogic Laboratories, L.L.C., Ban, L.L.C., Dennis Gay, Daniel B. Mowrey, The American Vital Therapy Research Laboratory, or Mitchell K. Friedlander, on the other hand.

6. The test protocols used in the First Study, the Second Study and the Third Study.

7. The objectives of the First Study, the Second Study and the Third Study.

8. The details of the test articles used in the First Study, the Second Study and the Third Study.

9. The methods and procedures used in the First Study, the Second Study and the Third Study.

10. The results of the First Study, the Second Study and the Third Study.

11. The conclusions of the First Study, the Second Study and the Third Study.

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DATED this 10th day of November, 2004.

Respectfully submitted,

Richard D. Burbidge
Burbidge & Mitchell
215 South State, Suite 920
Salt Lake City, Utah 84111
Tel: (801) 355-6677
Fax: (801) 355-2341

Counsel for Respondent Dennis Gay

Dated: November 10, 2004

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of November, 2004, I caused the foregoing **NOTICE OF VIDEOTAPE RULE 30(b)(6) DEPOSITION OF DERMTECH INTERNATIONAL** to be filed and served as follows:

(1) one paper copy by Federal Express and one electronic copy in PDF format by electronic mail to:

Laureen Kapin
Walter C. Gross
Joshua S. Millard
Robin F. Richardson
Laura Schneider
Federal Trade Commission
600 Pennsylvania Ave, NW, Suite NJ-2122
Washington, D.C. 20580
Email: lkapin@ftc.gov

(2) one paper copy by Federal Express to:

Elaine D. Kolish
Associate Director, Enforcement
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, D.C. 20580

(3) one paper copy in United States mails to:

Jeffrey D. Feldman
Gregory L. Hillyer
Christopher P. Demetriades
FELDMANGALE, P.A.
201 S. Biscayne Boulevard
Miami, FL 33131

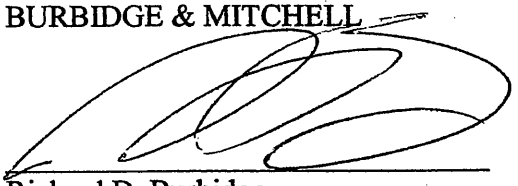
Ronald F. Price
PETERS SCOFIELD PRICE
111 E. Broadway Center #1100
Salt Lake City, Utah 84111

Mitchell K. Friedlander
c/o Compliance Department
5742 West Harold Gatty Drive
Salt Lake City, Utah 84116

I further certify that the electronic copies sent to the Secretary of the Commission are true and correct copies of the paper originals, and that paper copies with original signature are being filed with the Secretary of the Commission on the same day by other means.

DATED this 10th day of November, 2004.

BURBIDGE & MITCHELL



Richard D. Burbidge
Attorneys for Respondent Dennis Gay

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

In the Matter of	:	
BASIC RESEARCH, L.L.C., A.G. WATERHOUSE, L.L.C., KLEIN-BECKER USA, L.L.C., NUTRASPORT, L.L.C., SOVAGE DERMALOGIC LABORATORIES, L.L.C., BAN, L.L.C., DENNIS GAY, DANIEL B. MOWREY, and MITCHELL K. FRIEDLANDER, Respondents.	:	Docket No. 9318

NOTICE OF VIDEOTAPE DEPOSITION OF EDWARD G. FEY

PLEASE TAKE NOTICE that Respondent Dennis Gay will take the following deposition upon the following dates and times:

Edward G. Fey	December 7, 2004	9:00 a.m.

Said deposition will be taken at the Boston Marriottt Long Wharf, 296 State Street, Boston, Massachusetts (617-227-0800), before a certified court reporter and videographer and will continue thereafter until completed.

DATED this 10th day of November, 2004.

Respectfully submitted,

Richard D. Burbidge
Burbidge & Mitchell
215 South State, Suite 920
Salt Lake City, Utah 84111
Tel: (801) 355-6677
Fax: (801) 355-2341

Counsel for Respondent Dennis Gay

Dated: November 10, 2004

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of November, 2004, I caused the foregoing **NOTICE OF VIDEOTAPE DEPOSITION OF EDWARD G. FEY** to be filed and served as follows:

(1) one paper copy by Federal Express and one electronic copy in PDF format by electronic mail to:

Laureen Kapin
Walter C. Gross
Joshua S. Millard
Robin F. Richardson
Laura Schneider
Federal Trade Commission
600 Pennsylvania Ave, NW, Suite NJ-2122
Washington, D.C. 20580
Email: lkapin@ftc.gov

(2) one paper copy by Federal Express to:

Elaine D. Kolish
Associate Director, Enforcement
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, D.C. 20580

(3) one paper copy in United States mails to:

Jeffrey D. Feldman
Gregory L. Hillyer
Christopher P. Demetriades
FELDMANGALE, P.A.
201 S. Biscayne Boulevard
Miami, FL 33131

Ronald F. Price
PETERS SCOFIELD PRICE
111 E. Broadway Center #1100
Salt Lake City, Utah 84111

Mitchell K. Friedlander
c/o Compliance Department
5742 West Harold Gatty Drive

Salt Lake City, Utah 84116

I further certify that the electronic copies sent to the Secretary of the Commission are true and correct copies of the paper originals, and that paper copies with original signature are being filed with the Secretary of the Commission on the same day by other means.

DATED this 10th day of November, 2004.

BURBIDGE & MITCHELL

Richard D. Burbidge
Attorneys for Respondent Dennis Gay

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

In the Matter of	:	
BASIC RESEARCH, L.L.C., A.G. WATERHOUSE, L.L.C., KLEIN-BECKER USA, L.L.C., NUTRASPORT, L.L.C., SOVAGE DERMALOGIC LABORATORIES, L.L.C., BAN, L.L.C., DENNIS GAY, DANIEL B. MOWREY, and MITCHELL K. FRIEDLANDER,	:	Docket No. 9318
Respondents.	:	

NOTICE OF VIDEOTAPE DEPOSITION OF PAUL LEHMAN

PLEASE TAKE NOTICE that Respondent Dennis Gay will take the following deposition upon the following dates and times:

Paul Lehman	December 8, 2004	9:00 a.m.

Said deposition will be taken at the San Diego Marriott Hotel & Marina, 333 West Harbor Drive, San Diego, California (619-234-1500), before a certified court reporter and videographer and will continue thereafter until completed.

DATED this 10th day of November, 2004.

Respectfully submitted,

Richard D. Burbidge
Burbidge & Mitchell
215 South State, Suite 920
Salt Lake City, Utah 84111
Tel: (801) 355-6677
Fax: (801) 355-2341

Counsel for Respondent Dennis Gay

Dated: November 10, 2004

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of November, 2004, I caused the foregoing **NOTICE OF VIDEOTAPE DEPOSITION OF PAUL LEHMAN** to be filed and served as follows:

(1) one paper copy by Federal Express and one electronic copy in PDF format by electronic mail to:

Laureen Kapin
Walter C. Gross
Joshua S. Millard
Robin F. Richardson
Laura Schneider
Federal Trade Commission
600 Pennsylvania Ave, NW, Suite NJ-2122
Washington, D.C. 20580
Email: lkapin@ftc.gov

(2) one paper copy by Federal Express to:

Elaine D. Kolish
Associate Director, Enforcement
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, D.C. 20580

(3) one paper copy in United States mails to:

Jeffrey D. Feldman
Gregory L. Hillyer
Christopher P. Demetriades
FELDMANGALE, P.A.
201 S. Biscayne Boulevard
Miami, FL 33131

Ronald F. Price
PETERS SCOFIELD PRICE
111 E. Broadway Center #1100
Salt Lake City, Utah 84111

Mitchell K. Friedlander
c/o Compliance Department
5742 West Harold Gatty Drive
Salt Lake City, Utah 84116

I further certify that the electronic copies sent to the Secretary of the Commission are true and correct copies of the paper originals, and that paper copies with original signature are being filed with the Secretary of the Commission on the same day by other means.

DATED this 10th day of November, 2004.

BURBIDGE & MITCHELL

Richard D. Burbidge
Attorneys for Respondent Dennis Gay

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

In the Matter of	
BASIC RESEARCH, L.L.C., A.G. WATERHOUSE, L.L.C., KLEIN-BECKER USA, L.L.C., NUTRASPORT, L.L.C., SOVAGE DERMALOGIC LABORATORIES, L.L.C., BAN, L.L.C., DENNIS GAY, DANIEL B. MOWREY, and MITCHELL K. FRIEDLANDER, Respondents.	Docket No. 9318

NOTICE OF VIDEOTAPE DEPOSITION OF KEN SHIRLEY

PLEASE TAKE NOTICE that Respondent Dennis Gay will take the following deposition upon the following dates and times:

Ken Shirley	December 13, 2004	9:00 a.m.

Said deposition will be taken at the offices of BPI, 97 South Red Willow Road, Evanston, Wyoming (800-426-2457), before a certified court reporter and videographer and will continue thereafter until completed.

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of November, 2004, I caused the foregoing **NOTICE OF VIDEOTAPE DEPOSITION OF KEN SHIRLEY** to be filed and served as follows:

(1) one paper copy by Federal Express and one electronic copy in PDF format by electronic mail to:

Laureen Kapin
Walter C. Gross
Joshua S. Millard
Robin F. Richardson
Laura Schneider
Federal Trade Commission
600 Pennsylvania Ave, NW, Suite NJ-2122
Washington, D.C. 20580
Email: lkapin@ftc.gov

(2) one paper copy by Federal Express to:

Elaine D. Kolish
Associate Director, Enforcement
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, D.C. 20580

(3) one paper copy in United States mails to:

Jeffrey D. Feldman
Gregory L. Hillyer
Christopher P. Demetriades
FELDMANGALE, P.A.
201 S. Biscayne Boulevard
Miami, FL 33131

Ronald F. Price
PETERS SCOFIELD PRICE
111 E. Broadway Center #1100
Salt Lake City, Utah 84111

Mitchell K. Friedlander
c/o Compliance Department
5742 West Harold Gatty Drive
Salt Lake City, Utah 84116

DATED this 10th day of November, 2004.

Respectfully submitted,

Richard D. Burbidge
Burbidge & Mitchell
215 South State, Suite 920
Salt Lake City, Utah 84111
Tel: (801) 355-6677
Fax: (801) 355-2341

Counsel for Respondent Dennis Gay

Dated: November 10, 2004

I further certify that the electronic copies sent to the Secretary of the Commission are true and correct copies of the paper originals, and that paper copies with original signature are being filed with the Secretary of the Commission on the same day by other means.

DATED this 10th day of November, 2004.

BURBIDGE & MITCHELL

Richard D. Burbidge
Attorneys for Respondent Dennis Gay