UNITED STATES OF AMERICA
BEFORE 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., d/b/a BASIC RESEARCH, L.L.C., OLD BASIC RESEARCH, L.L.C., BASIC RESEARCH, A.G. WATERHOUSE,	)	
BAN, L.L.C., d/b/a KLEIN-BECKER USA, NUTRA SPORT, and SOVAGE DERMALOGIC LABORATORIES,	)	**DOCKET NO. 9318**
DENNIS GAY,	)	
DANIEL B. MOWREY, d/b/a AMERICAN PHYTOTHERAPY RESEARCH LABORATORY, and	)	
MITCHELL K. FRIEDLANDER	)	
Respondents.	)	

RESPONDENTS' OPPOSITION TO COMPLAINT COUNSEL'S MOTION FOR PROTECTIVE ORDER

Respondents 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 Friedlander, file this Opposition to Complaint Counsel's Motion for Protective Order dated November 18, 2004 and state as follows:

I. INTRODUCTION

As part of its case in chief, Complaint Counsel will have to prove, *inter alia*, that Respondents' advertising contained certain fat and weight loss claims and that the level of substantiation possessed by Respondents somehow fell short of what was required. However, what level of substantiation the FTC believes was required is not clear. In fact, since filing the lawsuit, Complaint Counsel has consistently avoided disclosing that substantiation standard which the FTC used to evaluate the claims contained in Respondents' advertising. In opposing a Motion for More Definite Statement, for example, the FTC stated that discovery would provide any relevant information needed by Respondents as to the substantiation standard the FTC believed applicable. In response to discover requests, the FTC said expert testimony would provide the information sought by Respondents. Neither promise was kept.

Although the FTC has disclosed its Experts and produced Expert Reports purportedly clarifying the substantiation standard and addressing Respondents' evidence, these reports are unilluminating and continue to thwart Respondents' efforts to investigate the applicable standard.

Now, the FTC has moved for a Protective Order designed to further hobble Respondents' ability to meaningfully cross examine and rebut the testimony of those Experts by severely limiting Respondents' access to discovery. If granted, the FTC's Motion for Protective Order would essentially force the Respondents to merely accept the view of the FTC's experts as to what constitutes competent and reliable scientific evidence and, whether under that standard Respondents' substantiation sufficed. This concern is particularly relevant here. Respondents are aware that in at least one instance,

the FTC's Expert Witness Dr. Stephen Heymsfeld--who has opined that double blind placebo controlled tests represent the requirement for adequate testing--has nevertheless failed to hold himself to his purported standard.[1]

In sum, the relief Complaint Counsel seeks would undercut Respondents' ability to investigate those very inconsistencies between what Complaint Counsel's Experts now contend constitutes competent and reliable scientific evidence and what they contended by practice in the past. Such a result is fundamentally at odds with the requirement of liberal discovery, impartial hearings and the opportunity to fully develop claims and defenses during the administrative proceedings. *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 512 (2002) ("notice pleading relies on liberal discovery rules...to define disputed facts"); *Duffield v. Charleston Area Medical Center,* 503 F.2d 512 (4th Cir. 1974) (Due process requires impartial hearing). Because the adequacy of the Experts' conclusions as to what generically as well as specifically constitutes competent and reliable scientific evidence is central to the case and defense, this Court should deny Complaint Counsel's Motion for Protective Order.

II. THE FTC'S EXPERT WITNESSES

The FTC has asserted that it determines what constitutes competent and reliable scientific evidence to support an advertising claim on a case by case basis with reference to the relevant field of expertise. For all health and safety related claims, including each dietary supplement and weight-loss claim in this case, the FTC has adopted a high, but malleable, "competent and reliable scientific evidence" standard. *See* FTC's November

[1] As discussed further, *supra*, Dr. Heymsfeld was one of the principle investigators in a test of Orlistat, a weight loss product. Although Dr. Heymsfeld referred to the test as a double blind placebo controlled study, review of the published article demonstrates that his study failed that standard. Nevertheless, Dr. Heymsfeld considered his results valid and publishable.

30, 2000 denial of the Whitaker Rulemaking Petition, ("'Competent and reliable scientific evidence' is the standard the Commission requires for all claims relating to the safety or health benefits of a dietary supplement."); Proposed Order, Parts I-IV, XII, appended to the Commission's Complaint (for next twenty (20) years, Respondents shall possess and rely upon "competent and reliable scientific evidence" that substantiates any representation about product or service that "causes weight or fat loss," or the "health or weight loss benefits, performance, safety, or efficacy of such product or service"); Complaint Counsel's Response to Respondent's First Set of Interrogatories, Interrogatory No. 1e, (competent and reliable scientific evidence is "typically required by Commission jurisprudence to support claims relating to health and safety"); Complaint Counsel's Response to Basic Research LLC's First Request for Admission, RFA No. 36 ("'Competent and reliable scientific evidence' is the standard the Commission requires for all claims relating to the safety or health benefits of a dietary supplement."); Complaint Counsel's Response to Basic Research LLC's First Request for Admission, RFA No. 37 ("what constitutes competent and reliable scientific evidence may vary depending on a number of factors including the type of product, the type of claim being made, and the particular field of science based upon the claims and the product") Leaving aside that the regulatory scheme established by the FTC is unconstitutional, nevertheless the substantiation standard applied by the FTC is a critical issue at trial. The FTC, through its experts will attempt to show what the standard applied by experts in the field is. The FTC will then attempt to argue that the substantiation possessed by the Respondents somehow falls short. The FTC has acknowledged that part of their case in chief will be to establish the level of substantiation it believes Respondents should have

possessed. That level of substantiation, to be determined by reference to experts in the field, is the subject of the discovery to which the FTC now objects.

At issue in the FTC's Motion is discovery designed to prepare the Respondents to cross-examine and rebut the testimony of the FTC's experts Dr. Stephen Heymsfeld and Dr. Robert Eckels. Given that Dr. Heymsfeld and Eckels are the FTC's experts, not surprisingly, their reports opine that the substantiation possessed by the Respondents failed to constitute adequate substantiation for the claims contained in Respondents advertising. Respondents, however, maintain, and have maintained from the start of this litigation, that the standards which the FTC seeks to impose against them are vague, shifting and ill defined. The amorphous quality of the FTC's standards has formed one of Respondents' major defenses against the FTC in this case. Further, Respondents believe and intend to prove at the upcoming hearing that certain standards the FTC applies are inappropriate and do not constitute standards the relevant community of experts believe are applicable to the evaluation of the efficacy of fat and weight loss claims or dietary supplements.

III. DISCOVERY

Based on the plain language of Commission Rule of Practice §3.31 and under prevailing Commission and Federal authority, any discovery "reasonably related" to the allegations the FTC has made against Respondents or defenses to those allegations is permissible. See 16 C.F.R. § 3.31(c)(1) (emphasis added) ("[p]arties may obtain discovery to the extent that it may be reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, *or to the defenses of any respondent.*";) *In the Matter of North Texas Specialty Physicians*, 2004 WL 527340

(F.T.C. Jan. 20, 2004) ("Discovery sought in a proceeding before the Commission must be "reasonably expected to yield information relevant to the allegations of the complaint, to the proposal relief, or to the defense of any respondent."); *Federal Trade Commission v. Anderson*, 631 F.2d 741, 745 (D.C. Cir. 1979) (rejecting argument that discovery in adjudicative proceedings is limited to admissible evidence rather than reasonably relevant evidence pertaining to issues in the complaint); *In the Matter of MSC.Software* 2002 WL 31433978 (F.T.C. May 8, 2002) ("Parties may obtain discovery to the extent that it may be reasonably expected to yield information relevant to the allegations of the complaint, the proposed relief, or to the defenses of any respondent."); *Oregon Precision Industries, Inc. v. International Omni-Pac Corp.*, 160 F.R.D. 592, 594 (D. Ore. 1995) ("The scope of discovery is broad and encompasses any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case"). Indeed a party resisting relevant discovery carries a heavy burden in attempting to avoid discovery obligations. *In the Matter of MSC.Software, Id.* (Parties resisting discovery of relevant information carry a heavy burden of showing why discovery should be denied. citing *Schering Plough Corp.*, 2001 FTC LEXIS 105, *3 (July 6, 2001)); *Salter v. Upjohn Co., 593* F.2d 649, 651 (5th Cir. 1979) (party seeking to avoid discovery obligation carries heavy burden).

The broad right to discovery encompasses materials relevant to cross-examination and rebuttal. See e.g. *U.S. v Meyer,* 398 F.2d 66, 72 (9th Cir. 1968) ("Pretrial discovery is particularly important to effective preparation for effective cross-examination..."). Accordingly, discovery designed to prepare for cross-examination and rebuttal of expert witness testimony is proper and should be allowed.

IV. Documents Sought from Testifying Experts

Specifications 8[2], 9[3], 10[4] and 11[5] [6] all seek discovery related to one of the central issues of this lawsuit, i.e. the substantiation needed to make claims regarding fat loss, weight loss, obesity and dietary supplements. Complaint Counsel argues that Respondents are improperly seeking discovery beyond the scope of the "specific efficacy and establishment claims" and the "specific products" at issue in this litigation. But under the FTC's regulatory scheme, experts in relevant fields determine what level of support constitutes substantiation for categories of claims. Thus, while Drs. Heymsfeld and Eckels may testify as to the particular products and claims at issue here, their role in these proceedings is also more general. In their testimony, they are also the FTC's

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[2] Specification 8 provides: 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."

[3] Specification 9 provides: 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."

[4] Specification 10 provides: 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."

[5] Specification 11 provides: 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 investor or patent owner or assignee of any invention relating to: a) obesity; b) weight loss; c) fat loss; d) dietary supplements."

[6] Specification number 12 seeks legal documents related to lawsuits in which the Experts have been named as parties. As discussed in the body of this Opposition, discovery relevant cross-examination and rebuttal is proper. Specification 12 is designed to elicit discovery related to those aspects of the trial. The Specification is reasonably calculated to lead to the discovery of admissible evidence useful for cross-examination by allowing Respondents to discover whether Experts have adopted other positions in different lawsuits, exposing potential biases and discovering whether Experts have committed any impeachable offenses. It should therefore be allowed.

witnesses to establish generally what level of substantiation experts in the relevant field deem adequate.

To prepare for cross-examination and rebuttal of the FTC's experts concerning those general conclusions, Respondents promulgated the discovery requested in Specifications 8, 9, 10 and 11. The requests seek information that relates to what the relevant scientific community considers adequate with respect to weight loss, fat loss, obesity and dietary supplements. Dr. Heymsfeld's Orlistat study is illustrative. Dr. Heymsfeld was one of the principle investigators in a test of this weight loss product wherein he referred to the test as a double blind placebo controlled study. A careful review of the published article, however, demonstrates that his study failed that standard. Yet, he considered his results valid and publishable. In his current Expert Report, Dr. Heymsfeld, yet again, alleges that double blind placebo controlled testing is the standard. Respondents are entitled to probe this inconsistency and to seek others.

Respondents are also seeking other inconsistent positions maintained by the FTC's experts that will allow Respondents to show, *inter alia*, (1) that the substantiation standard against which the FTC judged Respondents advertisements is *not,* in fact, the standard applied by relevant experts in the field; (2) that application of the regulatory mechanism violates the Constitution; and (3) that substantiation disregarded by the FTC in actuality would have been considered adequate under the standards of the relevant scientific community. All of those issues are relevant to the Respondents' defenses and therefore discoverable.

In its effort to prevent Respondents' discovery, Complaint Counsel grossly overstates the holding in *Dura Lube Corp.*, 9292, 1999 F.T.C. Lexis 254 (Dec. 15, 1999). Fundamentally, *Dura Lube* stands for the proposition that expert discovery is an important tool in preparing a case for trial. In support of this proposition, the ALJ clarified that, as a matter of fundamental fairness, respondents were entitled to inquire into instances where experts adopted inconsistent positions. See also *Thomson Medical* 101 F.T.C. 385, 387 (1983) (noting the propriety of seeking expert discovery for purposes of preparing for cross examination and rebuttal). Further, the ALJ in *Dura Lube* stated that respondents were allowed to seek production of reports and transcribed testimony reflecting those inconsistent positions. Contrary to Complaint Counsel's assertion, Specifications 8 and 11 specifically address documents authored by the Experts or, as in the case of the Patents, documents the experts played a significant role in drafting. Those are precisely the sort of documents that should be produced under *Dura Lube* because they will show when the experts have adopted positions that--in theory or in practice--are at odds with those they now espouse.

Complaint Counsel's assertion that discovery of the documents requested in Specification 9 and 10 is barred by the holding of *Dura Lube* is also misplaced. What appears to have been at issue in *Dura Lube*, although not clear, were underlying source documents on which the testifying experts based specific factual conclusions as to certain challenged fuel additives. The ALJ did allow production of those documents if they were relied upon or reviewed for the case at hand. *Dura Lube* does not control Specifications 9 and 10, however, because those specifications seek material related to the general issue on which Experts will testify, namely, the level of substantiation the relevant community

of experts considers adequate. Other documents wherein the Experts have espoused different viewpoints as to what constitutes adequate substantiation or different instances where they have applied or sanctioned other standards are all related to one of the main issues on which they will testify, what substantiation Respondents should have possessed and whether Respondents did. The Court should thus allow Respondents' discovery request so that they will be able to adequately prepare those issues for trial.

Finally, Complaint Counsel's unsupported assertion that Specifications 8, 9, 10 and 11 are unduly burdensome is insufficient as a matter of law. When a party asserts that a discovery request is unduly burdensome, that party is obliged to produce affidavits or other evidence demonstrating specifically how the request is unduly burdensome. In other words, a party may not avoid its discovery obligations by simply maintaining that the requests are unduly burdensome. Rather, the party opposing discovery must produce evidence showing how the request is burdensome. *Compagnie Francaise d'Assurance Pour le Commerce Exterieur v. Phillips Petroleum Co.* 105 F.R.D. 16, 42 (D.C.N.Y. 1984) (a party opposing discovery must specifically show by affidavit or other evidence how the discovery request is burdensome). In this case, Complaint Counsel has produced no evidence in support of its burdensome objection, but has relied on nothing more than its own bald assertion. Complaint Counsel have not demonstrated, for example, that producing the requested discovery is anything more difficult than producing already assembled files for copying or that the experts do not have ready access to their published materials or research files.

Complaint Counsel's objections to Specifications 13-19[7] are similarly based on their misapprehension as to the scope of discovery because Complaint Counsel fails to appreciate that in judging the challenged products and advertisements, the FTC is invoking a generalized standard that it believes and must prove exists. As discussed above, Drs. Heymsfeld and Eckels have opined and are expected to testify as to the level of substantiation the FTC maintains advertisers should possess for advertising claims. Thus their testimony will of necessity go beyond the specific products challenged and attempt to establish the consensus of opinion for this field as a whole as to what constitutes competent and reliable scientific evidence for the types of claims made in the ads.

Specifications 13-19 are all relevant to that inquiry. They relate to whether what the Experts contend is sufficient for competent and reliable scientific evidence is in fact the standard the field accepts and whether it is a standard they themselves have consistently maintained. For example, the Experts have opined as to what constitutes an adequate scientific test. Certainly it is relevant for cross-examination to confront those

[7] Specifications 13-19 provide: 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." 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."

witnesses with evidence of studies they themselves have designed and claimed to be adequate that failed to meet the standard they now propose. These Specifications elicit that information.

More specifically, Specifications 16-19 directly relate to another defense theory, that the FTC in essence holds sellers of dietary supplements improperly to the same level of substantiation applicable to pharmaceutical testing. Thus Respondents believe and intend to raise at trial that the FTC's experts are applying standards of substantiation which are perhaps proper for the regulation of pharmaceuticals by the Food and Drug Administration but in fact do not constitute to the level of substantiation that the relevant community of experts in the area dietary supplements and weight and fat loss apply.

Finally, as above, Complaint Counsel has substituted mere assertion of burden for evidence of burden. See *Compagnie Francais*, supra. Complaint Counsel has failed to demonstrate that compliance with Specification 16-19 in this case would impose any real, significant burden. Accordingly, this Court should disregard Complaint Counsel's unsubstantiated assertions.

Complaint Counsel's objections to Specification 23 and 24[8] of the Subpoena to Dr. Heymsfeld once again ask this Court and Respondents to ignore the fundamental role

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[8] Specifications 23 and 24 provide: 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 . . ."

the FTC asks Dr. Heymsfeld to play in establishing what constitutes competent and reliable evidence in the context of the Respondents advertisements. It bears repeating though, as part of their case the FTC will have to establish that fact in order to argue that the Respondents substantiation somehow fell short. Thus Respondents must be allowed to prepare their cross-examination and rebuttal of that testimony. That Complaint Counsel misses this fundamental point is apparent by their position that the information related to "side effects" of Orlistat is only relevant to safety concerns. In the case of Dr. Heymsfeld's Orlistat study those side effects had a further effect directly relevant to the issues in this case. Although Dr. Heymsfeld designed the study as a double blind placebo controlled test, the "side effects" had the effect of unblinding the study. Yet Dr. Heymsfeld still considered the results valid, publishable and significant. It is precisely that sort of inconsistency in the testimony of Experts that discovery is designed to elicit and that Respondents are entitled to explore in their defense.

Somewhat puzzlingly, Complaint Counsel cites to the case of *U.S v. Boykoff* 67 Fed.Apprx. 15 (2nd Cir. 2003) for the proposition that the evidence sought by Respondents would be inadmissible. As a starting matter, the opinion in *Boykoff* expressly states that it shall not be used as precedential or binding authority in any other court. *Id.* at 16. Second, it is entirely unclear as to what portion of the opinion Complaint Counsel is citing. The opinion appears to cite Rule Fed.R.Evid. 608(b) for the proposition that a trial court may deny admission of extrinsic evidence to impeach the credibility of a witness. Based on that provision, Complaint Counsel argues that Respondents should not be allowed to pursue this discovery. What is clear, however, is that what Dr Heymsfeld has considered appropriate substantiation in the past is relevant

to whether what he opines to in this matter is in fact accurate. Whether the specific materials are admitted into evidence subsequently is irrelevant. See Fed.R.Civ.Proc. 26(b)(1) ("Relevant information need not be admissible at trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence"). Because discovery of this material will permit Respondents to effectively cross-examine the experts thereby eliciting evidence regarding the level of substantiation the field considers adequate, the discovery is proper.

V. THIRD PARTY SUBPOENAS

Complaint Counsel raises essentially two objections to the Third Party Subpoenas Respondents served in this matter. The first is that the Subpoenas were not timely served pursuant to the Trial Court's Scheduling Order. The Scheduling Order required that all written discovery including Subpoenas Duces Tecum be served by November 8, 2004. Commission Rule of Practice expressly provides that Subpoenas may be served by mail although it is questionable whether service by email of a Third Party is adequate. Commission Rule of Practice §4.4. Since the Subpoenas were directed to Third Parties, the provisions of the Scheduling Order governing service by email of pleadings between Counsel by 5:00 PM does not govern. Rather as Counsel for the FTC notes the Certificates of Service of the Subpoenas reflect a service mail date of November 8, 2004. Therefore, the Subpoenas were timely served per Commission Rule and Trial Court Scheduling Order. Commission Rule of Practice §4.4(3) (providing for an effective service date as the date a document is mailed)

Complaint Counsel's second argument is more substantive but also misses the point. The Subpoenas are relevant to the issue of what experts in the field of weight loss consider competent and reliable evidence. As discussed above, despite Dr. Heymsfeld's design and intention, the Orlistat study was unblinded by side effects associated with subjects taking Orlistat. In fact, it appears side effects made virtually any double blind study of Orlistat impossible. Whether studies of certain dietary supplements including some of the challenged products can ever be double blinded for the same reasons is an issue the Respondents have raised in defense. The Subpoenas seek evidence to further clarify what happened during the study and whether in fact the study which Dr. Heymsfeld contended was a competent study comported with the standards which the FTC has imposed against Respondents. Accordingly, the discovery sought by the Subpoenas while ostensibly focusing on other products nevertheless relate to a central issue here, what relevant experts deem competent and reliable scientific evidence.

VI. DERMTECH SUBPOENAS

Complaint Counsel has also sought to limit the scope of the depositions of four other witnesses, Dermtech International, Edward G. Fey, Ken Shirley and Paul Lehman on the basis that Respondents are seeking improper expert testimony. Those individuals were involved in conducting tests as to the efficacy of aminophylline gels. Complaint Counsel states that it has no objection to the deposing listed witnesses as to their factual knowledge but argues that in deposing these witnesses Respondents are seeking improper expert testimony as to the "results" of the studies and "conclusions" of the study.

As a preliminary matter, the general rule is that a party to litigation lacks standing to object to a third party subpoena. See *Oliver B. Cannon and Son, Inc. v. Fidelity and Casualty Company of New York*, 519 F.Supp. 668, 680 (D.C. Del. 1981) and cases cited therein (citing the general rule that a party lacks standing to object to a subpoena served on a third party). In this case the Witnesses at issue have raised no objection to the subpoena and accordingly, the depositions should be allowed to continue as noticed. Aside from that, however, Complaint Counsel fundamentally misunderstands the distinction between expert opinion testimony and fact testimony in raising its specific objections. Generally, an expert witness is a person retained specially to provide testimony concerning issues in litigation or employed by a party who regularly provides expert testimony. Fed.R.Civ.Proc. 26(2)(B); *F.D.S. Marine v. Brix Maritime,* 211 F.R.D. 396 (D. Or. 2001) (striking as an "expert" an employee who was neither retained specially to provide evidence in a matter nor provided expert testimony in the regular course of employment). Simply calling a witness possessing "expert knowledge" does not transform the witness in to an "Expert Witness" for purposes of civil procedure and discovery. See Advisory Committee Notes to Fed.R.Civ.Proc. 26(B)(4) (clarifying that an expert who was not retained for litigation but has expert knowledge as a result of being an "actor" or "observer" should be treated as an "ordinary witness"). Thus when a physician treats a patient and is called to testify, the physician is not an expert witness but rather a fact witness. See *Davoll v. Webb,* 194 F.3d 1116, 1138 (10th Cir. 1999) (treating physician deemed not to be an expert witness). In the course of testifying, a treating physician is allowed to testify as to expert facts and opinion where helpful and based upon what the witness observed during the course of treatment. *Id.*

Similarly, these Witnesses should be allowed to testify as to the results and conclusions of their studies. They were not retained specially for this litigation and their knowledge as to the conclusions and results of their studies stems from being actors and observers in the studies not retained or employed experts. Accordingly, there was no requirement to list them as Expert Witnesses. And, further, any evidence they may give will not constitute Expert Witness testimony but rather fact evidence. The results of their studies as to the efficacy of aminophylline gels do not constitute expert testimony in this context because they merely report the results and conclusions reached.

Furthermore, the relief requested by Complaint Counsel, i.e. precluding inquiry into the results of the studies serves no purpose at this point. The more sensible course of action is to allow the depositions to go forward without limitation as to scope. In the unlikely event that Complaint Counsel can establish that the testimony elicited by the witnesses qualifies as Expert Testimony and should therefore be excluded, this Court can always address the issue at trial as a question of admissibility.

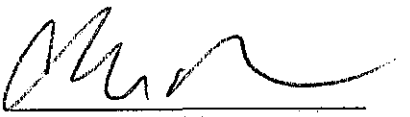
Complaint Counsel has raised a further unfounded objection pertinent to only deponents Lehman and Shirley. Complaint Counsel contends that because these individuals were not listed on the Preliminary Witness List, Respondents should not be allowed to depose them. The Preliminary Witness List, however, was merely a good faith listing. That Respondents did not list the specific identities of the Witnesses at that time does not violate their obligations. Final Proposed Witness Lists are not due until February 8, 2005. If Complaint Counsel believes that Shirley and Lehman should be excluded from testifying because Respondents did not list them on their Preliminary Witness List, they should raise those objections at that time. Further, as discussed above,

the testimony sought from these witnesses is not Expert Testimony but rather Fact Testimony. Because the discovery sought from these witnesses is both admissible and reasonably calculated to lead to the discovery of admissible evidence, the depositions should be permitted to go forward.

VII. CONCLUSION

For the forgoing reasons, Complaint Counsel's Motion for Protective Order should be denied. The discovery Respondents have sought is proper and focuses on issues central to this litigation.

Respectfully submitted,



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DATED this 2nd day of December, 2004.

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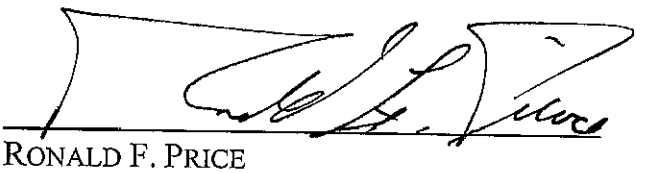

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was provided to the following parties this 2nd day of December, 2004 as follows:

(1) One (1) original and two (2) copies by Federal Express to Donald S. Clark, Secretary, Federal Trade Commission, Room H-159, 600 Pennsylvania Avenue, N.W., Washington, D.C., 20580;

(2) One (1) electronic copy via e-mail attachment in Adobe® ".pdf" format to the Secretary of the FTC at Secretary@ftc.gov;

(3) Two (2) copies by Federal Express to Administrative Law Judge Stephen J. McGuire, Federal Trade Commission, Room H-104, 600 Pennsylvania Avenue N.W., Washington, D.C. 20580;

(4) One (1) copy via e-mail attachment in Adobe® ".pdf" format to Commission Complaint Counsel, Laureen Kapin, Joshua S. Millard, and Laura Schneider, all care of lkapin@ftc.gov, jmillard@ftc.gov; rrichardson@ftc.gov; lschneider@ftc.gov with one (1) paper courtesy copy via U. S. Postal Service to Laureen Kapin, Bureau of Consumer Protection, Federal Trade Commission, Suite NJ-2122, 600 Pennsylvania Avenue, N.W., Washington, D.C., 20580;

(5) One (1) copy via U. S. Postal Service to Elaine Kolish, Associate Director in the Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580

(6) One (1) copy via United States Postal Service to Stephen Nagin, Esq., Nagin Gallop & Figueredo, 3225 Aviation Avenue, Suite 301, Miami, Florida 33131.

(7) One (1) copy via United States Postal Service to Richard Burbidge, Esq., Jefferson W. Gross, Esq. and Andrew J. Dymek, Esq., Burbidge & Mitchell, 215 South State Street, Suite 920, Salt Lake City, Utah 84111, Counsel for Dennis Gay.

(8) One (1) copy via United States Postal Service to Ronald F. Price, Esq., Peters Scofield Price, A Professional Corporation, 340 Broadway Centre, 111 East Broadway, Salt Lake City, Utah 84111, Counsel for Daniel B. Mowrey.

(9) One (1) copy via United States Postal Service to Mitchell K. Friedlander, 5742 West Harold Gatty Drive, Salt Lake City, Utah 84111, *Pro Se.*

CERTIFICATION FOR ELECTRONIC FILING

I HEREBY CERTIFY that the electronic version of the foregoing is a true and correct copy of the original document being filed this same day of December 2, 2004 via Federal Express with the Office of the Secretary, Room H-159, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

CHRISTOPHER P. DEMETRIADES

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