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

In the Matter of) OCT 2 0 2005
BASIC RESEARCH, L.L.C.,	OCT 2 D 2005
A.G. WATERHOUSE, L.L.C.,	SECRETARY SECRETARY
KLEIN-BECKER USA, L.L.C.,	
NUTRASPORT, L.L.C.,)
SOVAGE DERMALOGIC) Docket No. 9318
LABORATORIES, L.L.C.,)
BAN, L.L.C.,)
DENNIS GAY,) PUBLIC DOCUMENT
DANIEL B. MOWREY, and)
MITCHELL K. FRIEDLANDER,)
)
Respondents.)
)

COMPLAINT COUNSEL'S OPPOSITION TO RESPONDENTS' PETITION FOR LEAVE TO FILE REPLY

Complaint Counsel oppose Respondents' Petition to File Reply to Complaint Counsel's Opposition to Respondents' Motion to Add an Expert Witness and Reopen Discovery.

Respondents' proffered Reply misrepresents Dr. Heysmfield's deposition testimony and presents unfounded accusations and inaccurate information in the guise of "correct[ing] two false misrepresentations of material facts." Petition at 1. Respondents also fail to show how any of the issues raised in their Petition are material. Far from assisting the Court, Respondents' Reply confuses the record and is even inconsistent with their own factual statements. The Court should deny Respondents' Motion.

As Complaint Counsel has pointed out in response to Respondents' numerous proffers of Replies, the RULES OF PRACTICE state that "[t]he moving party shall have no right to reply, except as permitted by the Administrative Law Judge or the Commission." RULE OF PRACTICE

3.22(c). "Reply papers should be the exception and not the rule." See United States v. Int'l Bus. Machines Corp., 66 F.R.D. 383, 384 (S.D.N.Y. 1975). The Southern District of New York observed that "[c]learly, nothing but delay, unnecessary work, and unwarranted expense can result from the routine filing of reply and, inevitably, surreply papers which do nothing more than restate in a different form or with additional detail material set forth in the moving and opposing papers." Id. The Court recognized that reply papers may be warranted where an opposition raises "raises new material issues" but this is "the exceptional though rare case." Id.

Respondents' proffered *Reply* contains no discussion of why the issues presented are material and, in their effort to make corrections, Respondents themselves misrepresent Complaint Counsel's statements in its *Opposition*, Dr. Heymsfield's testimony and the Darsee papers. Respondents summarily argue that Complaint Counsel misrepresented Dr. Heymsfield's involvement in the research that Respondents discussed in their opening *Motion*. Citing Complaint Counsel's Opposition at page 6, Respondents' assert that Complaint Counsel contended that "Dr. Heymsfield had no involvement with Darsee in obtaining the data used in the six fraudulent studies." Reply at 2. Complaint Counsel's actual statements were that "Dr. Heymsfield participated in some research with Mr. Darsee at Emory. Dr. Heymsfield was not, however, privy to all of the research data." *Opposition* at pp. 5-6. Complaint Counsel based this statement upon Dr. Heymsfield's deposition testimony:

Q. So did you share any responsibility in the fraudulent data being supplied by Darsee?

A. You mean, are you asking me if I was involved in the fraud?

Q. I'm asking you what your involvement was in the study?

A. I was a colleague and I participated in the research with him. I saw some of the patients that were in the study and I helped him prepare the manuscript, manuscripts, several.

Q. So you were privy to all the data?

A. No. "All of the data," no. I rarely see all the data in any study, except in studies which I'm the primary author of the paper.

Deposition at 455 attached as Exhibit D to *Opposition*. Complaint Counsel's statement is consistent with this testimony and even mirrors the very language used by Respondents in their questioning.

In a similar vein, Respondents' "correction" of the record regarding the retraction of the Darsee studies is misplaced. Once more Respondents attempt to shore up their accusations with summary citations. Respondents assert that Complaint Counsel stated that all six studies involving Darsee were retracted. Reply at 2 citing Opp. at pp. 1,6. However, on page one, Complaint Counsel summarized Respondents' arguments:

Respondents own assertions on this topic are contradictory. In their opening motion they stated that five of the six studies "were rescinded by the publications." Respondents' Motion for Leave to Add an Expert Witness and Reopen Discovery at 3 and footnote 1. In their second motion, Respondents' proffered Reply, they assert that not one but "two" studies were not retracted. Yet their Reply contradicts their latest statement on the topic. In their third submission, Respondents point to certain "facts" as "revealed" during Dr. Heymsfield's August 30, 2005 deposition: "[t]he six Darsee studies were withdrawn from publication. . ." See Respondents' Motion to Exclude A Witness and for Sanctions at 10-11. In their efforts to "correct" the record, Respondents can not even present consistent facts.

Respondents assert the right to call a new expert and reopen discovery not on the parties' claims and defenses, but on the supposed ethical or professional ramifications of the fabrication of data by a colleague of one of Complaint Counsel's expert witnesses, in papers that were retracted and withdrawn from publication, over twenty years ago.

Opp. at 1 [emphasis added]. On page six Complaint Counsel referenced Dr. Heymsfield's deposition testimony. Dr. Heymsfield testified that he believed that all the papers in which he, among other medical doctors were listed as co-authors with Dr. Darsee, were withdrawn:

Q Now, you've listed or you've mentioned a number of Darsee studies that were published. How many Darsee studies were published in which you were a co-author?

A. I don't remember the exact number because this is not really what I've prepared for today, but nevertheless, I would say it could have been anywhere between five and eight papers.

Q. And how many of those five to eight papers were withdrawn?

A. I think everything Darsee did was withdrawn as a blanket, including all of the work he did at Harvard, Emory and Notre Dame. All of those papers were clouded by suspicion and, therefore, mainly withdrawn. Certainly the major ones were withdrawn.

Dep. at 646 attached as Exhibit D to Opposition.

It appears that Dr. Heymsfield was mistaken in his belief that all the papers were withdrawn. Respondents' printout from Pubmed indicates that one study at item 3 of the printout, *Hemodynamics of LeVeen shunt pulmonary edema*, Ann. Surgery 1981, was not

retracted.² However, Respondents also mistakenly assert that this printout establishes that another study, *Hypertrophic cardiomyopathy* was also not retracted. *Reply* at 2. It appears that entries 1, 6 and 7 all relate to a single study and that entry 1 is the retraction of that study from publication. *See Reply* at Exhibit 1.

Respondents' *Reply* resorts to mischaracterizations and inconsistent statements in an effort to muddy the factual record, attack the integrity of Complaint Counsel, and create unnecessary work in unraveling Respondents' selectively presented "corrections." We respectfully request the Court deny Respondents' *Petition*.

Respectfully submitted,

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

COMPLAINT COUNSEL

October 20, 2005

² Dr. Heymsfield himself provided guidance to Respondents. In response to questioning on where Respondent Friedlander might find those papers, Dr. Heymsfield advised him to "go on to Pubmed and more than likely you will be able to find if you type in Darsee, D-A-R-S-E-E-, you should be able to pull up those papers." *Id.* at 454. Respondents apparently did just that.

CERTIFICATION OF REVIEWING OFFICIAL

I certify that I have reviewed the attached public filing prior to its filing to ensure the proper use and redaction of materials subject to the *Protective Order* in this matter and protect against any violation of that *Order* or applicable RULE OF PRACTICE.

ames A. Kohm

Associate Director, Division of Enforcement

Bureau of Consumer Protection

CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of October 2005, I caused Complaint Counsel's Opposition to Respondents' Petition for Leave to File Reply to be served:

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

Donald S. Clark, SecretaryFederal Trade Commission
600 Penn. Ave., N.W., Room H-135
Washington, D.C. 20580

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

 The Honorable Stephen J. McGuire
 Administrative Law Judge
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- one (1) electronic copy via email and one (1) paper copy by first class mail to the following persons:

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