

December 20, 2001

VIA HAND DELIVERY

Donald S. Clark
Secretary
Federal Trade Commission - Office of the Secretary
6th and Pennsylvania Avenue, NW
Room 172
Washington, D.C. 20580

*Re: Schering-Plough Corp., Upsher-Smith Laboratories, Inc.,
American Home Products Corporation, Docket No. 9297*

Dear Secretary Clark:

Enclosed please find an original and one copy of the public version of Upsher-Smith's Opposition To Complaint Counsel's Cross-Motion To Limit Expert Testimony On FDA Approval Of Niacor SR. This motion will be filed in public version only.

If you have any questions, please do not hesitate to contact me at (202) 626-3705.

Sincerely,

Paul F. Stone

Enclosures

cc: Karen G. Bokat, Esq.
Laura S. Shores, Esq.

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

In the Matter of)	
)	
Schering-Plough Corporation,)	
a corporation,)	
)	
Upsher-Smith Laboratories, Inc.,)	Docket No. 9297
a corporation,)	PUBLIC VERSION
)	
and)	
)	
American Home Products Corporation,)	
a corporation.)	
)	

**UPSHER-SMITH’S OPPOSITION TO
COMPLAINT COUNSEL’S CROSS-MOTION
TO LIMIT EXPERT TESTIMONY ON FDA APPROVAL OF NIACOR SR**

This Court’s November 28 Order did *not* state that Upsher-Smith’s experts did not address FDA approvability. Indeed, Complaint Counsel admits as much. Cross-Motion at 6 (“We also assume — although not expressly stated by the Court in its November 28 Order — that the Court found that Upsher’s two medical experts (Drs. Knopp and Keenan) did not offer an opinion on FDA approval of Niacor-SR.”). In fact, Upsher-Smith’s experts expressly addressed FDA approval in response to Complaint Counsel’s case-in-chief expert Nelson Levy. Thus, there is no basis upon which to preclude Upsher-Smith’s experts from testifying at trial on this issue.

Complaint Counsel assert that their rebuttal witness Dr. Pitt would not have been improper rebuttal on FDA approvability, as this Court found in the November 28 Order, if Upsher-Smith’s experts previously addressed the issue. Complaint Counsel is mistaken. As far as Upsher-Smith is concerned, Dr. Pitt’s opinion on FDA approvability is improper rebuttal

because it merely buttressed Complaint Counsel's case-in-chief witness Dr. Levy. Upsher-Smith's motion to exclude Dr. Pitt is clear on this point.

Complaint Counsel's attempt to limit Upsher-Smith's experts is purely strategic. This case indisputably does not involve a naked payment for delay of entry of a generic drug. Rather, this case involves the novel accusation by Complaint Counsel that an arms-length licensing transaction, in which Upsher-Smith licensed several pharmaceutical products to Schering-Plough, was actually a sham transaction at the time that it was entered into (June 1997). The only supporting "evidence" that the products were worthless is provided by Plaintiffs expert Dr. Levy, who opines that Niacor SR the most promising drug licensed to Schering, was neither safe nor efficacious. In response, Upsher-Smith proffers extensive factual evidence and expert testimony of Drs. Knopp and Keenan and former FDA – official Robert Pollock. Complaint Counsel seek to exclude testimony of these experts, timely disclosed to Complaint Counsel, that responds to the heart of the FTC's case.

The Cross-motion erroneously assumes that Your Honor's Order of November 28 "found that Upsher's two medical experts (Drs. Knopp and Keenan) did not offer an opinion on FDA approval of Niacor SR." Cross-mot. at 6. In fact, the Order allowing Dr. Davidson as a rebuttal witness on the issue of FDA approvability was based on the limited (and accurate) express holding that "when Schering submitted its expert reports to Complaint Counsel, it did not submit an 'FDA approval expert.'" Order at 2. Thus, the Court's ruling to permit Dr. Davidson as an FDA approval expert follows naturally from the Court's conclusion that the opinion rendered by Dr. Pitt was as "an FDA approval expert." *Id.* The Order simply permitted Schering to answer in kind Complaint Counsel's new "FDA approval expert."

Upsher-Smith's experts in its defense case in chief had simply answered in kind Complaint-Counsel's case-in-chief witness, Dr. Levy. As Complaint Counsel admits, Dr. Levy put the safety, efficacy and approvability of Niacor SR into issue. *See* Opp. to Schering Mot. For

Leave to Submit One Additional Expert Rep. at 4. As Complaint Counsel also admits, Upsher-Smith's experts, Drs. Knopp and Keenan and Mr. Pollock, all responded in kind. *See* Cross-mot. at 7-8; Opp. to Mot. To Add Schering's One Additional Expert at 7-8; Opp. to Mot. To Strike Bertram Pitt at 4. Accordingly, the Cross-motion should be denied.

Finally, both of the cases cited by Complaint Counsel are inapposite. In *Ferriso v. Conway Org.*, No. 93 Civ. 7962, 1995 U.S. Dist. LEXIS 14328, *4 (S.D.N.Y. Oct. 3, 1995) the district court upheld the magistrate judge's limitation of an expert's testimony because the magistrate judge had construed the expert's "report to suggest that [the expert] would testify primarily as an expert on corporate sexual harassment policy, not as an expert on the typical psychology of subjects of sexual harassment." Such testimony by a single expert testifying about a totally different areas of expertise in *Ferriso* contrasts starkly with the Upsher-Smith's expert reports. Likewise, *Nguon v. T.E.X. Assocs. Inc.*, No. CA 91-7625, 1992 U.S. Dist. LEXIS 16346 (E.D. Pa. Oct. 22, 1992) is similarly unhelpful to them. In *Nguon* the court was not ruling on the sufficiency or scope of an expert report, but rather on the effect of vague and untimely interrogatory responses regarding an expert's expected testimony and the complete absence of an expert report. *Id.* at *2.

CONCLUSION

For all the reasons stated above, Complaint Counsel's Cross-Motion In Limine To Limit Expert Testimony On FDA Approval On Niacor SR should be denied.

Dated: December 20, 2001

Respectfully submitted,

WHITE & CASE LLP

By: _____

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Attorneys for Upsher-Smith Laboratories, Inc.

Certificate of Service

I hereby certify that this 20th day of December 2002, I caused an original, one paper copy and an electronic copy of Upsher-Smith's Opposition To Complaint Counsel's Cross-Motion To Limit Expert Testimony On FDA Approval On Niacor SR to be filed with the Secretary of the Commission, and that two paper copies were served by hand upon:

Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

and one paper copy was hand delivered upon:

Karen Bokat
Federal Trade Commission
Room 3410
601 Pennsylvania Ave, N.W.
Washington, D.C. 20580

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Washington, D.C. 20004

Sanjiv S. Kala

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

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Upsher-Smith Laboratories,)	Docket No. 9297
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**ORDER DENYING COMPLAINT COUNSEL’S CROSS-MOTION
TO LIMIT EXPERT TESTIMONY ON FDA APPROVAL OF NIACOR SR**

IT IS HEREBY ORDERED that Complaint Counsel’s Cross-Motion To Limit Expert
Testimony On FDA Approval Of Niacor SR is hereby DENIED

D. Michael Chappell
Administrative Law Judge

Date: _____