UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of SCHERING-PLOUGH CORPORATION, a corporation, UPSHER-SMITH LABORATORIES, INC., a corporation, and AMERICAN HOME PRODUCTS CORPORATION, a corporation.	Docket No. 9297 **PUBLIC VERSION**

(1) MEMORANDUM IN OPPOSITION TO UPSHER'S MOTION TO STRIKE COMPLAINT COUNSEL'S REBUTTAL WITNESS DR. BERTRAM PITT
AND
(2) COMPLAINT COUNSEL'S CROSS MOTION IN LIMINE TO EXCLUDE EXPERT TESTIMONY ON FDA APPROVAL OF NIACOR-SR

Upsher seeks to prevent complaint counsel from offering all testimony by Dr. Bertram Pitt, a highly respected cardiologist with relevant experience and opinions concerning the safety and efficacy of Niacor-SR, a development project for which Schering claims it paid $60 million up-front. Upsher's motion should be denied for two reasons. First, the motion is overly broad in that it seeks to fully exclude Dr. Pitt's testimony, based on this Court's recent finding that Dr. Pitt's opinion on FDA approval of Niacor-SR was not fair rebuttal. Since this Court's recent decision was limited to Dr. Pitt's opinion on FDA approval, and did not find that his other opinions concerning the safety and efficacy of Niacor-SR were improper, Dr. Pitt's testimony on these issues should be permitted. Second, Upsher's motion fails because it suffers no prejudice from Dr. Pitt's testimony, particularly

since this Court already has granted respondents leave to offer an additional expert specifically to rebut Dr. Pitt's testimony to the extent it goes beyond "fair rebuttal."

Related to our response to Upsher's motion to strike, we submit (at Section III of this memorandum) a motion in limine seeking to exclude the testimony of certain Schering and Upsher experts concerning FDA approval of Niacor-SR. This Court's recent decision that Dr. Pitt's opinion on FDA approval was not fair rebuttal is premised on the finding that respondents' experts did not address this issue in their reports. Since, according to this Court, none of respondents' experts opined in their reports concerning FDA approval of Niacor SR, it follows that none of respondents' experts (other than Dr. Davidson) should be permitted to testify at the hearing concerning FDA approval of Niacor-SR. To allow such testimony at trial would be inconsistent with this Court's order and prejudicial to complaint counsel.

Background

The Commission's complaint charges that Schering paid Upsher $60 million to delay Upsher's launch of its low-cost generic of K-Dur 20. Respondents contend that this $60 million non-contingent payment was not for delayed entry, but rather a licensing fee for certain Upsher products, principally Niacor-SR. By analyzing the information available to Schering at the time of the agreement, complaint counsel's licensing expert, Dr. Levy, demonstrates that Schering's $60 million payment cannot reasonably be considered a licensing fee for Upsher's Niacor-SR product, as claimed by respondents. Dr. Levy's opinion is based on his comprehensive review of the unusual circumstances surrounding the Niacor-SR license, including, among other things, (1) the unprecedented nature of Schering's $60 million non-contingent payment; (2) Schering's failure to pursue the Niacor-SR opportunity after

[1] *See*

However, Dr. Pitt's report and his anticipated testimony at trial is broader than his opinion that Upsher's Niacor-SR was unlikely to be approved by the FDA. (Pitt Report at 7, attached at Tab A)). As noted by Upsher in its motion to strike (at 6), Dr. Pitt's report primarily "addresses the question of whether the clinical data for Niacor-SR that was presented to Schering at the time it licensed Niacor-SR from Upsher indicated that the drug was safe and efficacious." (Pitt Report at 3).

This Court's November 28 Order found that the "opinion rendered by Dr. Pitt as an 'FDA approval expert' is outside the scope of fair rebuttal" because Schering's experts had only addressed FDA approval "in passing." (Order at 2; attached at Tab B)). That Order did not find that Dr. Pitt's opinion on other issues – such as whether the data for Niacor-SR indicated that it was safe and efficacious – was outside fair rebuttal.

Schering's and Upsher's experts clearly discuss clinical data regarding Niacor-SR more than just "in passing." Schering's pharmaceutical licensing experts – Dr. Horovitz and Mr. McVey – both provided detailed analysis of the Niacor-SR clinical data. In addition, Upsher's two medical experts – Drs. Keenan and Knopp – analyze these issues in their reports. Therefore, since the issue opined on by Dr. Pitt concerning analysis of clinical data regarding Niacor-SR rebuts "matters set forth in Respondents expert reports" (Scheduling Order, at 2), his report cannot be struck and he should be allowed to testify to these issues.

II. This Motion to Strike Must Be Denied Since Upsher Has Suffered No Prejudice.

A party moving to strike a witness must demonstrate prejudice. For example, Administrative Law Judge Timony has twice denied motions to strike where the movant failed to demonstrate the

should not now complaint that we retained five additional experts to respond to the range of issues introduced by respondents.

III. Cross-Motion in Limine to Exclude Expert Testimony on FDA Approval on Niacor-SR.

Upsher's present motion seeks to strike the report of Dr. Pitt, and to eliminate Schering's expert Dr. Davidson. As noted above, Upsher premises its present motion on this Court's November 28 Order concluding that Dr. Pitt's opinion on FDA approval is not fair rebuttal. However, in the November 28 Order, this Court found that Dr. Pitt's report was not "fair rebuttal" based on a finding that Schering "did not submit an 'FDA approval expert' opinion." Thus, according to this Court, Schering's experts have not offered an opinion on this issue. 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. Presumably, had Upsher's experts offered such an opinion, Dr. Pitt's opinion on FDA approval would have been fair rebuttal, because it would have been a "matter[] set forth in Respondents' expert reports."

Since, according to the November 28 Order, the matter of FDA approval was not a "matter[] set forth in Respondents' experts reports," it follows that respondents' experts should not be permitted to testify on this issue at the hearing. *See* Fed. R. Civ. P. 26(a)(2)(B) (expert must provide a written report containing "a complete statement of all opinions to be expressed"); Fed. R. Civ. P. 37(c)(1) (party who "without substantial justification fails to disclose information required by Rule 26(a). . . shall not, unless such failure is harmless, be permitted to use as evidence at a trial. . . any. . . information not

so disclosed"). *Mary Joe Ferriso v. Conway Org.* 1995 U.S. Dist. LEXIS 14328 (S.D.N.Y. 1995) (upholding magistrate's order which confined expert trial testimony to the opinions expressed in her report); *Saroeung Nguon v. T.E.X. Assoc.*, 1992 U.S. Dist. LEXIS 16346, at *2 (E.D. Pa. 1992) ("Of course, at trial the Expert's testimony will be confined to the matters covered by his report"). Accordingly, we seek an order from the Court excluding expert testimony from respondents' experts regarding whether Niacor-SR would have been approved by the FDA. (So long as Dr. Pitt is permitted to offer his opinion about FDA approval, the order we seek would not apply to Dr. Davidson who was granted leave to file a report in response to Dr. Pitt's opinion.).

Based on recent deposition testimony, it appears that several of respondents' experts intend to offer testimony on whether Niacor-SR would have been approved by FDA. For example, Dr. Horovitz stated at his deposition that "

" (Horovitz Dep. at).[2] **[REDACTED]** Similarly, Dr. Knopp, one of Upsher's two medical experts, opined at his deposition that one dose of Niacor-SR may have been approved, while he "doubt[ed]" that another higher dose would have been approved because it had a "higher incidence of [liver] elevations, [and] more symptomatic side effects." (Knopp Deposition at

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[2] *See also* McVey Expert Report. Mr. McVey

. Mr. McVey "

." (McVey Report at). **[REDACTED]**

[3] Upsher's medical experts also discuss FDA approval in more than just a "passing' manner in their reports. In his report, Dr. Knopp discussed several of the safety hazards of time-released niacin use, including liver damage possibly leading to death. (Knopp Report at 7). Dr. Knopp concluded his report by stating his opinion on whether "Niacor-SR falls within the range of acceptability for medical safety and efficacy in treating lipid disorders." (*Id*. at 10). Dr. Keenan also offers his opinion on whether Niacor-SR "satisfied general safety and efficacy criteria for the treatment of lipid disorders." (Keenan Report at 11). Dr. Keenan stated his belief on whether "Niacor-SR could have been a successful niacin drug." (*Id*.). While neither Dr. Knopp nor Dr. Keenan use the magic word "approval"

Conclusion

For these reasons, we request that the Court deny Upsher's motion to strike and grant our motion in limine seeking to exclude respondents' expert testimony on FDA approval of Niacor-SR.

Respectfully submitted,

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Karen G. Bokat
Seth C. Silber
Karan R. Singh

Complaint Counsel

Dated: December 10, 2001