UNITED STATES OF AMERICA
BEFORE 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**

COMPLAINT COUNSEL'S OPPOSITION TO SCHERING-PLOUGH CORPORATION'S MOTION TO LIMIT THE REBUTTAL EXPERT TESTIMONY OF DR. BERTRAM PITT REGARDING CONVERSATIONS WITH FDA OFFICIALS

Dr. Bertram Pitt is a professor of medicine and expert in cardiology. He is being offered to testify in rebuttal about his concerns with the safety, efficacy, and likelihood of FDA approval of Niacor-SR, a product for which Schering supposedly guaranteed payments of $60 million to Upsher.[1] To confirm his conclusion [redacted] Dr. Pitt spoke with officials with the FDA, the agency charged with approving new drug products.[2] Schering now moves to preclude Dr. Pitt's reliance upon and testimony about this conversation on the basis that Dr. Pitt

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[1] Pitt Rebuttal Report at 3 (Attachment A).

[2] *Id.* at 8.

is simply serving as a "mouthpiece" for the FDA.[3] Schering's motion should be denied for the following reasons:

- Dr. Pitt's opinion about the likelihood of FDA approval of Niacor-SR is based upon his substantial expertise and review of the relevant materials, and his conversation with FDA officials merely serves to corroborate that opinion;
- Dr. Pitt may reasonably rely on his FDA conversation as part of the basis for his opinion;
- Schering had every opportunity to conduct discovery about these conversations, from both Dr. Pitt and the FDA; and
- Schering's arguments go only to the weight of Dr. Pitt's testimony, not its admissibility.

I. Dr. Pitt's Opinion Niacor-SR .... Is Based on His Substantive Experience

Dr. Pitt is an expert in the area of cardiology. He has been a medical doctor for over 40 years and completed a fellowship in cardiology from Johns Hopkins University School of Medicine. He has been a professor of medicine at two universities, serving as the Director of the Division of Cardiology at the University of Michigan School of Medicine.[4]

Dr. Pitt has had extensive relevant experience in the area of clinical cardiology and clinical investigations. He has been involved in approximately twenty clinical trials, several of which were done as part of the FDA approval process,[5] and several of which involved statins, a class of drugs that, like nicotonic acid, is used to treat high cholesterol.[6]

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[3] Schering Mem. at 1.

[4] Pitt Rebuttal Report at 1.

[5] Pitt Dep. at 42-43 (Attachment B).

[6] *Id.* at 12.

Dr. Pitt also has served on the Cardiorenal Advisory Committee of the FDA, which reviews New Drug Applications ("NDA") submitted to the FDA's Cardiorenal division and provides recommendations as to their approval.[7] He is or has been a member of numerous professional societies relating to cardiology,[8] and has authored or co-authored over 600 publications, including works in numerous peer-reviewed journals in the field of cardiology.[9] Dr. Pitt reviewed materials relating to the clinical data for Niacor-SR that Upsher provided to Schering at the time Schering licensed the product, respondents' expert reports relating to the clinical issues of Niacor-SR, as well as the materials relied upon by some of these experts.[10]

As an expert in cardiology, Dr. Pitt will testify in rebuttal to two fundamental points: [redacted] [11] As part of his analysis and to confirm his opinions and conclusions, Dr. Pitt had a

[7] *Id.* at 45; Pitt Rebuttal Report at 2.

[8] Pitt Rebuttal Report at 2-3; *Curriculum Vitae* of Dr. Pitt at 3 (Attachment A).

[9] *Curriculum Vitae* of Dr. Pitt at 4-45.

[10] Pitt Rebuttal Report at 8.

[11] *Id.* at 7.

brief conversation with officials of the FDA.[12] The purpose of this conversation, according to Dr. Pitt, was to confirm whether FDA "shared" his concerns about the safety of Niacor-SR.[13]

Schering seeks to preclude Dr. Pitt from testifying about this conversation.[14] It argues that this testimony is inadmissible because Dr. Pitt is simply a "mouthpiece" for the FDA, improperly passing along the opinions of FDA officials. This argument suggests that Dr. Pitt either lacks the expertise, or failed to conduct the analysis, necessary to form his opinions, independent of his conversation with the FDA.[15] Yet, Schering does not challenge Dr. Pitt's credentials in the field of cardiology. Nor does it contest that Dr. Pitt has the qualifications and expertise to reach clinical opinions on the safety and efficacy of Niacor-SR and the likely problems this product would have faced in obtaining FDA approval. Nor does it assert that Dr. Pitt failed to review the information necessary to form the opinions about which he intends to

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[12] *Id.* at 8.

[13] Pitt Dep. at 22, 25.

[14] Schering Mem. at 1, 6.

[15] The cases upon which Schering relies stand for the limited and self-evident proposition that an individual cannot simply pass along as expert testimony the expert opinions of another where that individual lacks the expertise to form such an opinion on his own and/or where he or she has failed to conduct an independent evaluation of the relevant issue. *See, e.g., Hot Wax, Inc. v. Warsaw Chem. Co., Inc.*, 45 F. Supp. 2d 635, 638-640 (N.D.Ill. 1999) (striking testimony of expert whose opinion was solely a repetition of hearsay statements and in support of which he did no independent analysis); *Grant v. Chemrex, Inc.*, 1997 U.S. Dist. LEXIS 6058, at *21 (N.D.Ill. 1997) (striking report of expert who relied upon conclusions which he did not and could not have come to on his own and which were from another expert whose opinions he did not and could not have evaluated himself). Since Schering neither challenges Dr. Pitt's expertise to render his opinion, nor suggests that his review of the record was insufficient, its cases are not relevant.

testify. And Schering cannot show that Dr. Pitt did not form such opinions based on his own expertise and review of the relevant materials, independent of his conversation with the FDA.

In his testimony, Dr. Pitt explained that he reached an opinion that Niacor-SR [redacted]

- [redacted]
- [redacted][16]

He further testified that his opinion was based in part on the existence of Niaspan, a similar product with [redacted] or in [redacted] efficacy than Niacor-SR.[17]

> [redacted] [18]

Dr. Pitt went on to explain that he reached this opinion about Niacor-SR's safety and efficacy problems [redacted] his conversation with the FDA, and that this conversation only [redacted] his own concerns:

- [redacted]
- [redacted][19]

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[16] Pitt Dep. at 8.

[17] *Id.* at 19.

[18] *Id.*

[19] *Id.* at 23.

Dr. Pitt is not a "conduit" for the opinions of FDA officials, as Schering suggests. Instead, based on more than three decades of relevant medical experience in the cardiology field and his review of the pertinent clinical data and other materials, he offers his own opinions about the safety and efficacy concerns relating to Niacor-SR, concerns which were later [redacted] and [redacted] in his conversations with the FDA.[20]

II. Dr. Pitt May Reasonably Rely On His Conversation With The FDA As A Basis For His Opinion

In other parts of its memorandum, Schering appears to suggest that Dr. Pitt, a recognized expert in cardiology, cannot rely on a conversation with the FDA as a basis for his opinions [redacted][21] This position is inconsistent with basic evidence law. As Schering acknowledges,[22] an expert has wide latitude to rely on "all kinds" of information so long as that information is "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject."[23] In explaining Rule 703 of the Federal Rules of Evidence, the Court of Appeals for the Sixth Circuit emphasized that experts can even rely on normally inadmissible hearsay in forming and testifying as to their opinions:

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[20] *Id. See also id.* at 22 [redacted]

[21] Schering Mem. at 6.

[22] *Id.* at 3.

[23] Fed. R. Evid. 703.

> The purpose of Rule 703 is to make available to the expert all of the kinds of things that an expert would normally rely upon in forming an opinion without requiring that these be admissible in evidence. Under the Rule, the expert is free to give his opinion relying upon the types of data an expert would normally use in forming his opinion in his area of expertise. In short, through Rule 703, the law is catching up with the realities of professional life.[24]

It is not hard to see why an expert in the field of medicine, like Dr. Pitt, would consult the federal agency charged with evaluating and approving every new drug product application, to solicit its views on the safety and efficacy problems associated with a particular drug. That is precisely what Dr. Pitt has done here,[25] and it is entirely proper for him to rely on this FDA conversation as a basis for his opinion that Niacor-SR •• ••••••••••••• and to testify about this conversation at the hearing.[26]

III. Schering Had Every Opportunity To Conduct Its Own Discovery

Schering next suggests that Dr. Pitt's expected testimony should be excluded because Schering did not participate in Dr. Pitt's conversation with the FDA officials and has not had the opportunity to obtain similar information from the agency.[27] Schering is wrong on both counts.

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[24] *Mannino v. Int'l Manufac. Co.*, 650 F.2d 846, 851 (6th Cir. 1981). *See also Sphere Drake Insurance PLC v. Trisko*, 226 F.3d 951, 955 (8th Cir. 2000) ("[A]s an expert, Crowley was entitled to rely on otherwise inadmissible hearsay in forming the basis of his opinion, so long as the hearsay is of the type reasonably relied upon by experts in his field"); *International Adhesive Coating Co., v. Bolton Emerson Int'l, Inc.*, 851 F.2d 540, 544 (1st Cir. 1988) ("[A]n expert is entitled to rely on facts and/or data which have not been admitted into evidence if the expert's reliance on these or data is reasonable. . . . [R]easonableness is measured against the facts or data upon which experts in the particular field normally rely.")

[25] Pitt Dep. at 46-47.

[26] *Sphere Drake*, 226 F.3d at 955; *United States v. Affleck*, 776 F.2d 1451, 1457 (10th Cir. 1985) (holding hearsay statements admissible to explain how the expert had corroborated his opinions).

[27] Schering Mem. at 5-6.

First, Schering has no right to be involved in an informal discussion involving one of the our experts, just as we have no right to be included in a similar discussion involving respondents' experts. Second, contrary to Schering's assertion, it has had every opportunity to conduct discovery on the FDA. In his report, Dr. Pitt listed his conversation with the FDA, including the names of each FDA official who participated in the call.[28] At his deposition, respondents questioned Dr. Pitt about this conversation, and he provided his best recollection of it.[29] If Schering believed it needed additional information, Schering could have sought to compel testimony directly from the FDA. Schering's failure to do so should not be a basis for precluding Dr. Pitt's testimony on this subject.

IV. Schering's Arguments Go Only To The Weight of Dr. Pitt's Testimony, Not Its Admissibility

Schering's argument that Dr. Pitt's testimony about his FDA conversation will have "little probative value" clearly is not a basis for exclusion. The "rejection of expert testimony is the exception rather than the rule."[30] A court should exercise its "power to exclude evidence *in limine* only when evidence is clearly inadmissible on all potential grounds."[31] Schering's quibbles with the "probative value" of Dr. Pitt's testimony can be fully aired on cross-examination and need not be determined in a motion to exclude.[32]

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[28] Pitt Rebuttal Report at 8.

[29] *See, e.g.*, Pitt Dep. at 22-27, 29, 46-47, 114-121.

[30] Fed. R. Evid. 702, Advisory Committee Notes.

[31] *Hawthorne Partners v. AT&T Tech., Inc.*, 831 F. Supp. 1398, 1400 (N.D. Ill. 1993).

[32] *Butler v. Home Depot, Inc.*, 984 F. Supp. 1257 (N.D.Ca. 1997).

More fundamentally, Schering's complaints about Dr. Pitt's expected testimony are not grounded in the facts. For example, Schering suggests that the FDA officials who participated in the conversation with Dr. Pitt did not have the information necessary to render a reliable opinion.[33] As Dr. Pitt testified, however, he verbally provided to the FDA the relevant liver toxicity results concerning Niacor-SR.[34] Based on these liver toxicity numbers, the FDA officials, according to Dr. Pitt, were ********** the safety and efficacy of Niacor-SR and **********[35] Although Schering accepts Dr. Pitt's ability to rely on this liver toxicity information, it somehow calls into question FDA's ability to render a reliable opinion based on that same information.

Schering's next argument, that any opinion from the FDA officials who participated in the conversation must be irrelevant because none of them would have participated in FDA's actual review of Niacor-SR in 1997 and 1998, is just wrong. As Upsher's own documents make clear, the primary FDA official who participated in the call, Dr. Orloff,[36] ********** **********[37] Dr. Orloff's view that he **********[38] corroborates Dr. Pitt's opinion and is certainly relevant to whether

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[33] Schering Mem. at 6.

[34] Pitt Dep. at 25-26, 116, 119-120.

[35] *Id.* at 25.

[36] *Id.* at 23.

[37] CX 917, Upsher-Smith FTC 107426-107455 at 107433 (Attachment C).

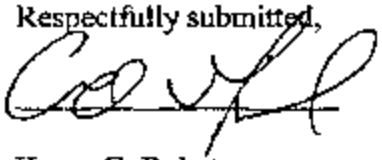
[38] Pitt Dep. at 25.

Schering's guaranteed $60 million in payments were truly for a drug, which based on the clinical data available at the time, faced significant regulatory approval obstacles.

V. Conclusion

Schering provides no basis to preclude relevant and reliable testimony from Dr. Pitt. Schering's motion should be denied in all respects.

Respectfully submitted,



Karen G. Bokat
Bradley S. Albert
Andrew S. Ginsburg

Counsel Supporting the Complaint

Dated: January 22, 2002

CERTIFICATE OF SERVICE

I hereby certify that this 22nd day of January, 2002, I caused a copy of the foregoing Public Version of Complaint Counsel's Opposition to Schering-Plough Corporation's Motion to Limit the Rebuttal Expert Testimony of Dr. Bertram Pitt Regarding Conversations With FDA Officials to be served upon the following person by hand delivery:

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

I caused one original and one copy to be served by hand delivery and one copy to be served by electronic mail upon the following person:

Office of the Secretary
Federal Trade Commission
Room H-159
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

I caused copies to be served upon the following persons by electronic mail and Federal Express:

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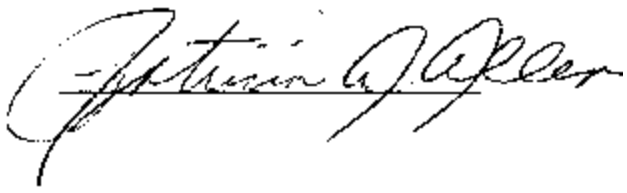

ATTACHMENT A

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

REBUTTAL REPORT OF DR. BERTRAM PITT

The remaining pages of the expert report have been redacted.

ATTACHMENT B

FEDERAL TRADE COMMISSION

IN THE MATTER OF:

SCHERING PLOUGH CORPORATION,
a corporation,

and

UPSHER-SMITH LABORATORIES,
a corporation

PAGE 1 TO 127 CONFIDENTIAL
SUBJECT TO PROTECTIVE ORDER

Ypsilanti, Michigan
Monday, December 3, 2001
Deposition of BERTRAM PITT,
being taken at 275 South Huron Street,
Ypsilanti, Michigan, commencing at 8:00 a.m.,
before Jill Beers, RPR, CM, CSR 3225.

The remaining pages of the transcript have been redacted.

ATTACHMENT C

This document has been redacted.