

### 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

#### MEMORANDUM IN OPPOSITION TO UPSHER-SMITH'S MOTION TO BAR COMPLAINT COUNSEL FROM ASSERTING THAT SCHERING-PLOUGH MADE "A \$60 MILLION NON-CONTINGENT PAYMENT"

Clinging to its argument that Schering's \$60 million payments were contingent on something other than Upsher allowing Schering to maintain its K-Dur 20 monopoly, but faced with overwhelming evidence to the contrary, Upsher, now tries to remove this damaging factual issue from the hearing. In its motion, Upsher seeks nothing less than a gag order preventing complaint counsel and its experts from uttering the words "\$60 million non-contingent payments." This extraordinary relief is premised on Upsher's claim that, based on the "record in this case" and as a "matter of fact," complaint counsel are wrong in our contention that Schering made \$60 million in non-contingent payments.

Upsher's motion is without merit and should be denied because:

- Whether Schering's payments totaled \$60 million and were non-contingent are factual issues in dispute and we are entitled to prove our position; and
- The evidence confirms that the payments totaled \$60 million and were noncontingent.

#### <u>ARGUMENT</u>

 Relevant Factual Evidence is Admissible and Cannot Be Excluded Simply Because Upsher Claims the Fact is Undisputed

Under Commission Rule 3.43(b), "[r]elevant, material, and reliable evidence shall be admitted." At trial complaint counsel intend to prove that Schering made \$60 million in payments to Upsher, and that these payments were guaranteed and not contingent on Upsher doing anything toward the development, FDA approval, or marketing of the Niacor-SR product for which Schering purportedly paid.

Upsher does not argue that evidence concerning the non-contingent nature of the \$60 million payments is irrelevant. How could it? The amount and structure of Schering's payments to Upsher are critical to assess whether the payments were for Niacor-SR, or to keep Upsher's generic K-Dur 20 product off the market. Nor does Upsher claim that such evidence is inadmissible on some other grounds.<sup>2</sup> Rather, Upsher argues that complaint counsel and its

FTC Rules of Practice for Adjudicatory Proceedings, 16 C.F.R. § 3.43(b) (2001).

<sup>&</sup>lt;sup>2</sup> A court should exercise its "power to exclude evidence in limine only when evidence is clearly inadmissible on all potential grounds." Hawthorne Partners v. AT&T Tech., Inc., 831 F. Supp. 1398, 1400 (N.D. III. 1993); accord National Union Fire Ins. Co. v. L.E. Meyers Grp., 937 F. Supp. 276, 287 (S.D.N.Y. 1996) (denying motion in limine to exclude extrinsic evidence as to contract terms); Koch v. Koch Indus. Inc., 2 F. Supp. 2d 1385, 1388-05 (D. Kan. 1998) (denying motion in limine where the "deposition testimony cited by the plaintiffs create[d] enough of a factual question" on the issue of an expert's damages calculation that the matter was "best

experts should be precluded from asserting that Schering made "\$60 million in non-contingent payments" because based on "the record in this case" and "as a matter of fact," we are wrong.

Simply put, Upsher is "arguing that the court should rule as a matter of law that no question of fact exists" on this matter. Since a factual dispute does exist as to this issue, a motion to exclude is simply improper, and Upsher's motion in limine should be denied.

#### IL The Evidence Confirms that the \$60 Million Payment was Non-Contingent

As a matter of law, Upsher's motion is ill conceived because it seeks to resolve in a motion in limine what is clearly a material factual dispute between the parties. More fundamentally, Upsher's motion ignores substantial evidence from the agreement itself, respondents' admissions, fact and expert witnesses, and documents; evidence which proves that Schering's payments for \$60 million to Upsher were guaranteed and were not contingent on Upsher doing anything to make Niacor-SR a product capable of being sold to consumers.

reserved for trial.").

<sup>&</sup>lt;sup>3</sup> Upsher-Smith's Memorandum in Support of its Motion to Bar Complaint Counsel from Asserting that Schering Made a "\$60 Million Noncontingent Payment," at 1 & 5.

<sup>&</sup>lt;sup>4</sup> Unitroyal Goodrich Tire Co. v. Mutual Trading Corp., 1992 U.S. Dist. LEXIS 19170 at \* 4 (N.D. III. Dec. 15, 1992).

<sup>5</sup> Id.

<sup>&</sup>lt;sup>6</sup> Koch, 2 F. Supp. 2d at 1388 ("The movant has the burden of demonstrating that the evidence is inadmissible on any relevant ground.").

<sup>&</sup>lt;sup>7</sup> CX 787 at SP1200194 (Attachment A).

conditions let alone the development or sales of Niacor-SR or any other "licensed" products.
Schering's duty to pay the \$60 million was even exempt from the agreement's force majure
clause, which states that the
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This means that Schering's obligation to pay the \$60 million was absolutely required, and was
not contingent even upon
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It is difficult to imagine a contractual duty less contingent than Schering's obligation to pay the \$60 million to Upsher.

Party admissions. In response to complaint counsel's pretrial request for admissions, Schering concedes that the "\$60 million in Up-Front payments" it made to Upsher "were not contingent on Upsher taking any actions or satisfying any conditions concerning the development of Niacor-SR," regardless of whether "Upsher abandoned the development of Niacor-SR;" and

<sup>8</sup> CX 787 at SP1200192-SP1200199.

<sup>9</sup> CX 787 at SP1200199.

<sup>&</sup>lt;sup>10</sup> CX 787 at SP1200199.

<sup>&</sup>lt;sup>11</sup> Respondent Schering-Plough Corporation's Objections and Responses to Complaint Counsel's Revised Second Request for Admissions, Answer to Request No. 70 (Attachment B).

even if Upsher "did not inform Schering" that it had done so.<sup>12</sup> In fact, Schering admits that it continued to pay installments on the \$60 million despite making virtually no sales of the underlying products<sup>13</sup> and even after Upsher had ceased to seek FDA approval for Niacor-SR as a new drug.<sup>14</sup>

<sup>12</sup> Schering, Answer to Request No. 72.

<sup>&</sup>lt;sup>13</sup> See Schering, Answer to Request No. 75 (admitting that "Schering made a payment of \$12 million to Upsher approximately two years" after the original agreement), Answers to Request No. 84-87 (admitting that Schering has made no sales of Niacor-SR and less than \$1 million in sales of Prevalite since June, 1997 and has no current plans to sell any of the products).

Schering, Answer to Request No. 429.

<sup>15</sup> CX 340 at SP0700003 (Attachment C).

<sup>16</sup> CX 338 at SP1200270 (Attachment D).

<sup>&</sup>lt;sup>17</sup> Morley dep. at 58-59 (Attachment E).

Morley dep. at 59.

During his testimony, Schering's chairman and chief
executive officer, Richard Kogan, made it perfectly clear that the \$60 million in payments were
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Expert Witness Testimony. Each of the five licensing expert witnesses in this case conclude that the payments totaled \$60 million and were non-contingent. Not even Upsher's own experts deny these obvious facts. One of Upsher's licensing experts testified that the payments were and that described that the payments were upsher's other experts concur. Both of Schering's licensing experts also agree with our position, one of whom testified that it described that

Morley dep. at 59-60. Another member of Schering's board of directors understood that the guaranteed payments added up to \$60 million, that Schering had \* it would pay the \$60 million, and that Schering was obligated to pay the \$60 million without regard to the success of Niacor-SR. Patricia Russo dep. at 30-31 (Attachment F).

<sup>26</sup> Kogan dep. at 35 (Attachment G).

<sup>&</sup>lt;sup>21</sup> Dr. Nelson Levy (complaint counsel), Richard DiCicco (Upsher), Walter Bratic (Upsher), Dr. Zola Horovitz (Schering), and Kenneth McVey (Schering).

<sup>22</sup> Bratic dep. at 108 (Attachment H).

to make the \$60 million payments non-contingent and that

In sum, this extensive evidence demonstrates that Schering's payments totaled \$60 million and were not contingent on the success of Niacor-SR or any other licensed products. At

<sup>&</sup>lt;sup>24</sup> McVey dep. at 99 (Attachment J); see also Horovitz dep. at 77 \*(Attachment K).

<sup>&</sup>lt;sup>25</sup> CX 753 at FTC0020505 (Attachment L). Contrary to respondents argument (Upsher Mem. at 4-5), Dr. Levy's opinion is not offered as a legal construction of the agreement, but rather is based on his extensive industry experience and a detailed review of the record. CX 753 at FTC0020527

Thus, the accuracy of Dr. Levy's testimony is a "matter of weight and not admissibility." Liquid Air Corp. v. Rogers, 834 F.2d 1297, 1308 (7th Cir. 1987). See also Complaint Counsel's Opposition to Respondents' Joint Motion to Exclude the Expert Testimony of Dr. Neison L. Levy.

<sup>&</sup>lt;sup>26</sup> Troup Investigational Hearing at 143 (Attachment M).

Upsher-Smith's Motion to Bar Complaint Counsel from Asserting that Schering-Plough Made a "\$60 Million Noncontingent Payment," at 5 n.2.

a minimum, it shows that there is a material dispute of fact as to these issues, which "cannot be determined on a motion in limine." 28

#### III. Upsher's Factual Arguments are Unpersuasive

Upsher throws out various explanations for why the payments did not total \$60 million or were contingent. These explanations are either irrelevant or unpersuasive. First, Upsher disputes what it perceives is our characterization of a single \$60 million payment, on the basis that Schering actually made the payments in three installments. Upsher misses the point. Whether Schering made three payments or one, the point is that Schering's \$60 million in payments were not contingent on anything relating to Upsher's Niacor-SR product, but only on Upsher's agreement to delay marketing its generic K-Dur 20 product until September, 2001.

Next, Upsher asserts that the \$60 million in payments was contingent upon the approval of Schering's board of directors. This unremarkable insight, however, does nothing to further Upsher's argument. It goes without saying that Schering's payments first required Schering's agreement to make the payments. Without board approval, there would have been no agreement, no \$60 million in payments, and no delay of generic K Dur-20 entry. Therefore, the Schering board's approval did not make the payments "contingent," it simply authorized Schering to make them.

Finally, Upsher disputes complaint counsel's reference to the payments as totaling \$60 million, because their present value was closer to \$54 million. Again, Upsher seizes upon a meaningless distinction. Complaint counsel do not dispute that the present value of the payments

<sup>28</sup> Uniroyal, 1992 U.S. Dist. LEXIS 19170 at \*4.

was less than \$60 million. But, whether the payments were \$60 million or \$54 million, we will prove that these payments far exceeded the value of the licenses obtained by Schering and that Schering's payments were for a delay in Upsher's expected generic K-Dur 20 entry.

#### CONCLUSION

For the foregoing reasons, complaint counsel respectfully request that Your Honor deny Upsher's motion in limine to bar complaint counsel and its expert witnesses from asserting that Schering-Plough made a "\$60 million non-contingent payment."

Respectfully submitted,

Karen G. Bokat

Bradley S. Albert

David Dudley

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 Memorandum in Opposition to Upsher-Smith's Motion to Bar Complaint Counsel from Asserting that Schering-Plough Made "A \$60 Million Non-Contingent Payment" 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:

Laura S. Shores Howrey Simon Amold & White 1299 Pennsylvania Avenue, N.W. Washington, D.C. 20004

Christopher Curran White & Case LLP 601 13th St., N.W. Washington, D.C. 20005

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### ATTACHMENT A

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## ATTACHMENT B

#### UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
Schering-Plough Corporation,	)	
a corporation,	.)	
	)	
Upsher-Smith Laboratories,	) Do-	cket No. 9297
a corporation,	)	
_	)	
and	)	
	)	
American Home Products Corporation,	)	
a corporation.		

### RESPONDENT SCHERING-PLOUGH CORPORATION'S OBJECTIONS AND RESPONSES TO COMPLAINT COUNSEL'S REVISED SECOND REQUEST FOR ADMISSIONS

Pursuant to Federal Trade Commission ("FTC") Rule of Practice Section 3.32, respondent Schering-Plough Corporation ("Schering") submits these objections and responses to Complaint Counsel's <u>Revised</u> Second Request for Admissions.

#### GENERAL OBJECTIONS AND STATEMENT

Schering objects to Complaint Counsel's <u>Revised</u> Second Requests for Admissions to the extent that they seek to impose on Schering burdens or duties inconsistent with or in addition to those requested under the FTC's Rules of Practice.

Schering further objections to the "Definitions" and "Instructions" provided with these requests to the extent that they are vague or ambiguous and to the extent that they impose requirements beyond those imposed by the FTC's Rules of Practice.

Request No. 70: Under the Schering/Upsher Agreement, if Upsher abandoned the development of Niacor-SR, Upsher would still receive the full \$60 million in Up-Front Payments.

Answer: Admitted, but only so long as Upsher complied with its

obligation to make clinical trial data and intellectual property available to Schering.

Request No. 72: Under the Schering/Upsher Agreement, if Upsher abandoned the development of Niacor-SR, and did not inform Schering that it, Upsher, had abandoned the development of Niacor-SR, Upsher would still receive the full \$60 million in Up-Front Payments.

Answer: Schering admits this request, excepting that the payments to

Upsher were conditional upon Upsher's obligations of good faith and fair dealing.

Request No. 73: Schering made a payment of \$28 million to Upsher within 48 hours of the date on which the Schering/Upsher Agreement was approved by Schering's Board of Directors.

Answer: Admitted.

Request No. 74: Schering made a payment of \$20 million to Upsher approximately one year from the date on which the Schering/Upsher Agreement was approved by Schering's Board of Directors.

Answer: Admitted.

Request No. 75: Schering made a payment of \$12 million to Upsher approximately two years from the date on which the Schering/Upsher Agreement was approved by Schering's Board of Directors.

Answer: Admitted.

Request No. 80: Since June 1997, Schering has made no sales of Pentoxifylline pursuant to the license obtained in the Schering/Upsher Agreement.

Answer: Admitted.

Request No. 81: Schering had no intention, as of September 2001, to sell Pentoxifylline pursuant to the license obtained in the Schering/Upsher Agreement.

Answer: Schering admits that, by September 2001, it no longer had plans to sell Pentoxifyiline.

Request No. 82: Since June 1997, Schering has made no sales of KLOR CON products pursuant to the license obtained in the Schering/Upsher Agreement.

Answer: Admitted.

Request No. 83: Schering had no intention, as of September 2001, to sell the KLOR CON products pursuant to the license obtained in the Schering/Upsher Agreement.

Answer: Schering admits that, by September 2001, it no longer had plans to sell Klor-Con products.

Request No. 84: Since June 1997, Schering has made no sales of Niacor-SR pursuant to the license obtained in the Schering/Upsher Agreement.

Answer: Admitted.

Request No. 85: Schering had no intention, as of September 2001, to sell Niacor-SR pursuant to the license obtained in the Schering/Upsher Agreement.

Answer: Schering admits that, by September 2001, it no longer had plans to sell Niacor-SR.

Request No. 86: Since June 1997, Schering sales of Prevalite, pursuant to the license obtained in the Schering/Upsher Agreement, have totaled less than \$1 million.

Answer: Admitted.

Request No. 87: Schering had no intention, as of September 2001, to make any additional sales of Prevalite pursuant to the license obtained in the Schering/Upsher Agreement.

Answer: Schering admits that, by September 2001, it no longer had plans for additional sales of Prevalite as of September 2001.

Request No. 92: The Schering/Upsher Agreement placed no obligation on Schering to carry out any activities concerning the marketing of Niacor-SR in Europe.

Answer: Denied. The Schering/Upsher license contemplated a "detailed agreement," and drafts of that agreement placed an obligation on Schering to carry out activities concerning the marketing of Niacor-SR in Europe.

Request No. 420: Schering decided not to enter into a license agreement with Kos for Niaspan in part because of the size of the potential sales of Niaspan.

Answer: Denied. Schering never sought to enter into a license agreement with Kos for Niaspan. However, Schering did consider a proposal to enter into a co-marketing/detailing agreement with Kos for Niaspan.

Request No. 428: Prior to January 1, 2000, Schering was never informed by Upsher that Upsher intended to seek or considered seeking FDA approval of an ANDA for Kos' Niaspan product.

Answer: After reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit or deny whether it was informed by Upsher that Upsher intended to seek or considered seeking FDA approval of an ANDA for Kos' Niaspan product prior to January 1, 2000.

Request No. 429: In September 1998, Schering was informed by Upsher that Upsher had ceased its activities directed at submitting to the FDA an NDA for Niacor-SR.

Answer: Admitted.

Request No. 430: Prior to September 1998, Schering had not been informed by Upsher that Upsher had ceased its activities directed at submitting to the FDA an NDA for Niacor-SR.

Answer: After reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit or deny if Schering had been informed by Upsher that Upsher had ceased its activities directed at submitting an NDA prior to September 1998.

Request No. 431: Prior to September 1998, Schering had no discussions with Upsher about whether Upsher had reduced its level of efforts or activity directed at submitting an NDA for Niacor-SR to the FDA.

Answer: After reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit or deny whether

Request No. 418: Schering decided not to enter into a license agreement with Kos for Niaspan in part because of clinical data demonstrating a flushing side effect resulting from taking Niaspan.

Answer: Denied. Schering never sought to enter into a license agreement with Kos for Niaspan. However, Schering did consider a proposal to enter into a co-marketing/detailing agreement with Kos for Niaspan.

Request No. 420: Schering decided not to enter into a license agreement with Kos for Niaspan in part because of the size of the potential sales of Niaspan.

Answer: Denied. Schering never sought to enter into a license agreement with Kos for Niaspan. However, Schering did consider a proposal to enter into a co-marketing/detailing agreement with Kos for Niaspan.

Request No. 428: Prior to January 1, 2000, Schering was never informed by Upsher that Upsher intended to seek or considered seeking FDA approval of an ANDA for Kos' Niaspan product.

Answer: After reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit or deny whether it was informed by Upsher that Upsher intended to seek or considered seeking FDA approval of an ANDA for Kos' Niaspan product prior to January 1, 2000.

Request No. 429: In September 1998, Schering was informed by Upsher that Upsher had ceased its activities directed at submitting to the FDA an NDA for Niacor-SR.

Answer: Admitted.

Request No. 430: Prior to September 1998, Schering had not been informed by Upsher that Upsher had ceased its activities directed at submitting to the FDA an NDA for Niacor-SR.

Answer: After reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit or deny if Schering had

# ATTACHMENT C

This document has been redacted.

## ATTACHMENT D

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### ATTACHMENT E

### In The Matter Of:

SCHERING-PLOUGH CORP., UPSHER-SMITH
LABORATORIES AND AMERICAN HOME PRODUCTS COR

H. BARCLAY MORLEY August 23, 2001

For The Record, Inc.

Court Reporting and Litigation Support
603 Post Office Road
Suite 309
Waldorf, MD USA 20602
(301) 870-8025 FAX: (301) 870-8333

Original File 10823HOBASC, 84 Pages Min-U-Script® File ID: 1094911690

Word Index included with this Min-U-Script®

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### ATTACHMENT F

#### In The Matter Of:

### SCHERING-PLOUGH CORP., UPSHER-SMITH LABORATORIES AND AMERICAN HOME PRODUCTS COR

PATRICIA A. RUSSO August 21, 2001

For The Record, Inc.

Court Reporting and Litigation Support

603 Post Office Road

Suite 309

Waldorf, MD USA 20602

(301) 870-8025 FAX: (301) 870-8333

Original File 10821RUSASC, 61 Pages Min-U-Script® File ID: 0873477176

Word Index included with this Min-U-Scripts

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# ATTACHMENT G

### In The Matter Of:

### SCHERING-PLOUGH & UPSHER-SMITH MATTER NO. 9910256

RICHARD KOGAN October 23, 2000

For The Record, Inc.

Court Reporting and Litigation Support
603 Post Office Road
Suite 309

Waldorf, MD USA 20602
(301) 870-8025 FAX: (301) 870-8333

Original File 11102KOGASC, 52 Pages Min-U-Script® File ID: 0719176492

Word Index included with this Min-U-Script®

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### ATTACHMENT H

#### In The Matter Of:

### SCHERING-PLOUGH & UPSHER-SMITH MATTER NO. D09297

WALTER BRATIC December 4, 2001

For The Record, Inc.

Court Reporting and Litigation Support

603 Post Office Road

Suite 309

Waldorf, MD USA 20602

(301) 870-8025 FAX: (301) 870-8333

Original File 11204BRA.ASC, 325 Pages Min-U-Script® File ID: 0166756193

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The remaining pages of the transcript have been redacted.

### ATTACHMENT I

#### In The Matter Of:

SCHERING-PLOUGH CORP. & UPSHER-SMITH LABS

MATTER NO. D09297

RICHARD L. DiCICCO November 27, 2001

CONFIDENTIAL

For The Record, Inc.
Court Reporting and Litigation Support
603 Post Office Road
Suite 309
Waldorf, MD USA 20602
(301) 870-8025 FAX: (301) 870-8333

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# ATTACHMENT J

#### In The Matter Of:

### SCHERING-PLOUGH & UPSHER-SMITH MATTER NO. 9910256

KENNETH MCVEY November 16, 2001

## CONFIDENTIAL

For The Record, Inc.

Court Reporting and Litigation Support
603 Post Office Road
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Waldorf, MD USA 20602
(301) 870-8025 FAX: (301) 870-8333

Original File 11116MCVASC, 288 Pages Min-U-Script® File ID: 4242\*46994

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# ATTACHMENT K

### In The Matter Of:

SCHERING-PLOUGH CORP. & UPSHER-SMITH LABS

MATTER NO. D09297

ZOLA P. HOROVITZ November 14, 2001

CONFIDENTIAL

For The Record, Inc.

Court Reporting and Litigation Support
603 Post Office Road
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Waldorf, MD USA 20602
(301) 870-8025 FAX: (301) 870-8333

Original File 11114HOR, ASC, 237 Pages Min-U-Script® File ID: 2050114380

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## ATTACHMENT L

### United States of America Federal Trade Commission

In the matter of Schering-Plough Corporation Upsher-Smith Laboratories, Inc. and American Home Products Corporation

Docket No. 9297

## **Expert Report**

by

Nelson L. Levy, Ph.D., M.D.

August 13, 2001

The remaining pages of the expert report have been redacted.

# ATTACHMENT M

### In The Matter Of:

### SCHERING-PLOUGH & UPSHER-SMITH MATTER NO. 9910256

IAN TROUP May 25, 2000

For The Record, Inc.

Court Reporting and Litigation Support
603 Post Office Road
Suite 309

Waldorf, MD USA 20602
(301) 870-8025 FAX: (301) 870-8333

Original File 00525TRO ASC, 166 Pages Min-U-Script® File ID: 0500934891

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