BEFORE THE FEDERAL TRADE COMMISSION
WASHINGTON, D.C.

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

UPSHER-SMITH'S OPPOSITION
TO MOTION TO ADD REBUTTAL WITNESSES

Complaint Counsel now propose a ***tenth*** rebuttal witness, a certain William Groth of Walgreens, whose name has never appeared on any of Complaint Counsel's witness lists. One needs a scorecard to keep track of Complaint Counsel's growing list of rebuttal witnesses.[1]

Complaint Counsel assert that they have good cause for adding Mr. Groth at this late date due to supposed "unexpected and misleading testimony" from certain of Respondents' witnesses. In reality, there was nothing unexpected or misleading about the testimony in question. As demonstrated below, Complaint Counsel has no good cause to add Mr. Groth as a rebuttal witness, and allowing his testimony would be grossly unfair to the Respondents.

[1] The ten proposed "rebuttal" witnesses are as follows. **Fact Witnesses**: Bell and Patel from KOS; Egan from Searle; Valazza from IPC; and now Groth from Walgreens. **Expert Witnesses**: Bresnahan and Levy (returnees); Bazerman (to bolster Bresnahan); Adelman (patent) and Banakar (patent).

ARGUMENT

The rule regarding proper rebuttal is clear and simple: "Rebuttal evidence is appropriate only if it is offered in response to ***evidence first presented to the court during the defendant's case***." *Heatherly v. Zimmerman*, 15 F.3d 1159, 1993 WL 523995, *2 (D.C. Cir. April 8, 1994) (emphasis added). This rule precludes the addition of new witnesses on topics that Complaint Counsel raised in its case in chief and this motion. The rule is discussed in greater detail in Upsher-Smith's pending Motion to Exclude Improper Rebuttal Witnesses of March 8, 2002.[2]

Complaint Counsel feign surprise that certain of Respondents' witnesses, including principally Phillip Dritsas (Upsher-Smith's Vice President of Sales and Marketing), would testify about how pharmacists sometimes substitute non-AB-rated potassium chloride supplements for K-Dur 20 as a result of Upsher-Smith's marketing efforts. In fact, Complaint Counsel first raised the issue of generic substitution. They elicited testimony from their own witnesses on the issue in their case in chief and they introduced documentary evidence on the issue as well. Moreover, Upsher-Smith's witness lists indicated that Mr. Dritsas would testify on the issue and Complaint Counsel actually examined Mr. Dritsas on the issue during his deposition. In short, there is no surprise and no justification for "rebuttal" testimony on this issue by Mr Groth or any witness.[3]

A. The Issue of Generic Substitution Was Featured Throughout Complaint Counsel's Case In Chief

Complaint Counsel presented evidence through various sources in their case in chief regarding generic substitution, mandatory state substitution laws and the limitations on "how

---

[2] *Rodriguez v. Olin Corp*, 780 F.2d 491 (5th Cir. 1986), the only case cited by Complaint Counsel in their motion, confirms the authorities cited in Upsher-Smith's Motion to Exclude Improper Rebuttal Witnesses and is inapplicable to Complaint Counsel's instant motion where Complaint Counsel did in fact raise in their case in chief exactly the issues they now seek to rehash with Mr. Groth.

[3] Complaint Counsel inform the Court that Mr. Groth is an employee of Walgreens. Complaint Counsel neglect to note that Walgreens has filed a copy-cat lawsuit against Schering-Plough, Upsher-Smith and AHP seeking millions of dollars in damages. Complaint Counsel have been coordinating closely with such private plaintiffs.

pharmacies can and do substitute" generic products for brand product. Consistent with *Heatherly*, rebuttal testimony on this topic by Mr. Groth ? or any witness ? is improper and should not be permitted.

Complaint Counsel's Trial Brief prominently featured both the issue of generic substitution generally as well as the issue of state mandatory substitution laws. Section II of Complaint Counsel's Trial Brief is captioned "The Commercial Realities of Generic Drug Competition in the Pharmaceutical Marketplace." Trial Br. 9. Therein Complaint Counsel invoke the policies of "government officials" and "private purchasers" to "encourage or require pharmacists to substitute a generic drug for it branded equivalent." *Id.* at 10. Another section of the brief, captioned "State Substitution Laws," discusses generally the fact that some states require generic substitution. *Id.* at 12. ("States have encouraged competition by generic drugs through laws that allow pharmacists to automatically substitute a generic drugs for its branded equivalent unless a physician directs otherwise.").[4] Complaint Counsel also addressed the issue in opening statement. Tr. at 15 ("[I]n several states, laws permit the pharmacist to dispense a generic in place of the branded product without having to call the physician for authorization. . . .").

Furthermore, two of Complaint Counsel's experts and two of their fact witnesses testified regarding generic substitution. In defending his single-product product-market definition, Professor Bresnahan testified at length regarding the relative "switching cost" of switching AB-

[4] There is no "surprise" here given that Complaint Counsel injected the issue of generic substitution and "switching costs" into the case as early as August 15, 2001, through Dr. Bresnahan's report:

> A generic K-Dur 20 has advantages as a substitute for branded K-Dur 20 compared to other forms of potassium chloride because switching costs to a bioequivalent generic are lower. The switch from a branded pharmaceutical can be made at the pharmacy, and many states' mandatory substitution laws and many managed care health plans require this if there is a bioequivalent generic. In contrast, the switch to anything else requires approval of the physician, a switching cost.

Bresnahan Rep. At 25-26. As described below, Dr. Bresnahan also testified on these same issues.

rated generic for K-Dur 20 versus a non-AB-rated generic. Tr. 432:24–433:9, 490:20–494:24. He asserted that the "automatic" substitution for AB generic gave it an advantage over non-AB-generics which he posited would have higher "switching costs" in the form of the pharmacists having to call for physician approval. *Id*. In the course of this testimony Dr. Bresnahan cited to several documents Complaint Counsel moved in evidence in their case in chief that purportedly support his conclusions regarding "switching costs." *Id.* (citing CX 747, CX 18, CX 22). And in fact, as a lead into the discussion of switching costs, ***Professor Bresnahan quotes from Mr. Dritsas's deposition*** and projected it onto the courtroom monitors. Tr. at 486:17–487:15. Similarly, Complaint Counsel's case in chief expert Joel Hoffman testified regarding AB generics and the fact that a pharmacist is in some states "free," and in others "required," to substitute such generics for brand products. Tr. 2278:6-16.

The two fact witnesses in Complaint Counsel's case in chief who testified regarding generic substitution were Dean Goldberg of United Healthcare and Russell Teagarden of Merck-Medco. Before the trial began, Complaint Counsel had designated Mr. Goldberg to testify "generally about United's prescription drug coverage program, contracting, and cost-containment strategies, and, in particular, United's selection of potassium chloride supplements for its formulary," and about "the impact of generic competition." Fin. Wit. List at 2. Similarly, Complaint Counsel designated Mr. Teagarden to "testify generally about Merck-Medco's prescription drug program, contracting, and cost-containment strategies, and, in particular, Merck-Medco's selection of potassium chloride supplements for its formulary." *Id.* At trial, during his direct examination, Mr. Goldberg testified at length about UHC's policy of promoting generic substitution, the fate of branded drugs on UHC's formulary once there is a generic alternative, and the effect of generic alternatives on branded prices and the marketplace

generally. *See* Tr. 117:9–121:8. Likewise, during his direct testimony — in direct response to Complaint Counsel's questions — Mr. Teagarden pointedly addressed generic substitution and the effect of "local laws and regulations" on substitutability, including the effect of AB-rated generics on how pharmacies fill prescriptions and the effect of a physician's DAW indication on a prescription. *See* Tr. 196:22–199:6. Mr. Teagarden even explained exactly what an AB rating entails and its affects branded drugs on Merck-Medco's formulary. *Id.* at 197:17-198:18.

There can be no question that the issue for which Complaint Counsel propose to designate Mr. Groth as a "rebuttal" witness — pharmacy substitution of generic products for brand products — was covered in their case in chief such that he is not a proper rebuttal witness.

B. Complaint Counsel Did Not Object To Scope Of Testimony And Cross-Examined Respondents' Witnesses

Complaint Counsel had the opportunity to object to scope of the testimony of Mr. Dritsas, Ms. Freese or Dr. Addanki. Indeed, with respect to another Upsher-Smith witness, Robert Clark, Complaint Counsel did exactly that and limited his testimony. Complaint Counsel, however, made no such objections with regard to these three witnesses.

Further, Complaint Counsel cross-examined Mr. Dritsas on exactly the issues about which they now complain. Indeed, they cite to that testimony in footnote 3 of their motion. Likewise, Ms. Freese and Dr. Addanki were subjected to full cross-examination on their testimony. That Complaint Counsel with hindsight may be unhappy now with their cross-examination is not a grounds for adding rebuttal witnesses.

C. There Is Nothing Surprising About Mr. Dritsas's Testimony And It Directly Addresses Bresnahan And Other Complaint Counsel Witnesses

Complaint Counsel's claim of "surprise" is also based upon their selective quotation from the pretrial description of Mr. Dritsas's proposed testimony. In fact, Upsher-Smith gave ample notice that their Vice President of Sales and Marketing would respond on those issues.

First, both Upsher-Smith's Revised Witness List of September 20, 2001, and its Final Witness List of December 14, 2001, clearly articulated that Mr. Dritsas would testify broadly as to the potassium chloride market and Upsher-Smith's marketing efforts to compete against K-Dur with Klor Con M ***and*** Klor Con products:

> Mr. Dritsas is Vice President of Sales and Marketing for Upsher-Smith. ***Among other things, Mr. Dritsas will testify about the potassium chloride market in general*** and the large number of competitors and products in that market. ***Mr. Dritsas will testify as to Upsher-Smith's efforts to market the Klor Con products and to compete with Schering's K-Dur 20 before and after the patent settlement***. He will also testify about the launch of Klor Con M and the value of the drugs licensed to Schering, including facts relevant to Kos and the niacin advisory panel.

Upsher-Smith Wit. Lists at 3 (emphasis added).

Second, Complaint Counsel's "surprise" at Mr. Dritsas' testimony regarding generic substitution is incredible given that ***he was deposed at length on the topic***. During the deposition, Complaint Counsel specifically asked: "***[D]o you know what substitution is permitted among potassium chloride products without getting authorization from a physician?***" Dep. at 54:9-11 (emphasis added). The ensuing deposition colloquy on substitution and the interchangeability of different forms (tablets, effervescents, and powders) as well as dosages (5, 10, and 20) of potassium chloride supplements spans four pages. Strikingly, ***Complaint Counsel have even designated this exact deposition testimony in their case in chief***. *See* Complaint Counsel's First Set Of Dep. Designations at 19 (designating Dritsas Depo. "54:6 to 55:18"). Plainly, there is no "surprise" here.

Third, it was only in response to Dr. Bresnahan's direct testimony on "switching costs" that Mr. Dritsas testified that the term "switching costs" is not used in his industry, that he understood it referred to pharmacists having to call physicians before they could substitute a non-AB-generic for a brand, and that this imposed no "switching costs" on the consumer. Tr.

4651:22-4654:4. He testified squarely within the scope of the broad designation when he stated that: (1) Upsher-Smith was marketing to pharmacists to make them aware that they could substitute two Klor Con 10 wax matrix tablets for one K-Dur 20; (2) he was aware that doctors often authorize members of their staff to respond to pharmacist's calls regarding substitutions such that it is not a great burden; and (3) certain chain pharmacies were particularly receptive to the campaign when K-Dur 20 was in short supply in August of 2001. *Id.* 4652:6-4653:5, 4682:1–4683:21.[5]

Fourth, Complaint Counsel's claim of surprise is also belied by ***Complaint Counsel's own revised and final witness lists.*** In reserving the right to call Mr. Dritsas as their own witness, they indicated that they expected that, he would "***testify generally about*** Upsher-Smith's efforts to launch its generic 20 mEq product and ***the potassium chloride market.***" Final Wit. List at 10; Rev. Wit. List at 8 (emphasis added).[6]

D. Mr. Dritsas's Testimony Was Accurate, Not "Misleading"

Complaint Counsel dispute the accuracy of Mr. Dritsas's testimony on Walgreen's response to the shortage of K-Dur 20 in the summer of 2001. Complaint Counsel had ample opportunity to expose this supposed inaccuracy on cross-examination. They could not do so, and for good reason. Mr. Dritsas's testimony is demonstrably accurate. As the attached chart shows, Upsher-Smith's sales of Klor-Con 10 toWalgreens spiked dramatically at the precise time when

[5] Likewise, the very limited excerpt of Ms. Freese's testimony cited in the motion directly addresses Complaint Counsel's testimony in the case in chief regarding generic substitution and "switching costs" at pharmacies. She simply testified that calling doctors to obtain approval for generic substitution is a regular part of a pharmacist's responsibilities and that it involves no cost to the consumer. Tr. 4955:25-4959:20 ("That is one of the major responsibilities that a pharmacist has, and so throughout the course of a day a pharmacist spends — is continuously calling doctor's offices.")

[6] Similarly, Dr. Addanki's testimony raised no new issues not first raised in Complaint Counsel's case in chief. The *de minimus* portion of Dr. Addanki's testimony cited is his contrast of how buying detergent is different from buying pharmaceuticals because of "mandatory substitution and the A-B rated generic." Tr. 5748:18-4749:23. This directly responds to Complaint Counsel's trial brief and case-in-chief witnesses regarding these issues.

the K-Dur 20 shortage occurred. (USX 1627, attached as Ex. A.) In August 2001, when the K-Dur 20 shortage was particularly acute, Walgreens purchased approximately three times their normal volume of Klor-Con 10. Walgreens thereafter purchased elevated volumes for the remainder of 2001.

Providing misleading quotations from Mr. Dritsas's trial testimony, Complaint Counsel suggest that Mr. Dritsas accused Walgreens pharmacists of making ***unauthorized*** substitutions of Klor-Con 10 for K-Dur 20. Mot. at 2. In fact, Mr. Dritsas was careful to disclaim knowledge of whether Walgreens pharmacists obtained physician authorization for the substitutions: "I can't say whether or not each pharmacist called the doctor." Tr. 4683:18-19. Likewise, Mr. Groth necessarily cannot know whether or not each pharmacist called a doctor to get authorization for each switch. He can only know what Walgreens's corporate policy required, which is beside the point.

E. Allowing Surprise "Rebuttal" Witness Testimony Would Prejudice Respondents

Allowing Mr. Groth to testify on rebuttal would prejudice Upsher-Smith and Schering-Plough. Mr. Groth's name has never surfaced before in this case. His name did not appear on Complaint Counsel's initial witness list dated June 14, 2001, their revised witness list dated September 20, 2001 or their final witness list dated December 14, 2001. Respondents made their decisions regarding which witnesses to call — and what to ask them — based on the evidence Complaint Counsel presented in its case in chief. Allowing Complaint Counsel to call this witness now would deprive Respondents of the opportunity to respond to his testimony.

Upsher-Smith and Schering-Plough never took any discovery relating to Mr. Groth, and a simple deposition on a few days notice would be insufficient. For discovery to be meaningful, Upsher-Smith and Schering-Plough would need to serve a document request upon Walgreens, and get the results in advance of the deposition. Upsher-Smith and Schering-Plough may also

need to depose other Walgreens employees, and in particular pharmacists or managers directly responsible for supervising pharmacists' dispensing activities. Based on his title (Development Manager for Pharmaceutical Purchasing), Mr. Groth would appear to be responsible for purchasing rather than the dispensing activities of Walgreen's pharmacists.

CONCLUSION

For the foregoing reasons, Complaint Counsel's Motion For Leave To Call William Groth As A Rebuttal Witness should be denied.

Dated: March 12, 2002

Respectfully submitted,

WHITE & CASE LLP

By: _____

Robert D. Paul
J. Mark Gidley
Christopher M. Curran
Peter J. Carney
601 Thirteenth Street, N.W.
Washington, D.C. 20005-3807
Telephone: (202) 626-3600
Facsimile: (202) 639-9355

Attorneys for Upsher-Smith Laboratories, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on March 12, 2002, I caused a paper original and one copy as well as an electronic version of the foregoing Opposition to be filed with the Secretary of the Commission and two paper copies to be provided by hand delivery to:

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
601 Pennsylvania Ave, N.W.
Washington, D.C. 20580

and one paper copy to be served upon the following counsel by hand delivery:

David R. Pender
Assistant Director of Health Care Products Division
Federal Trade Commission, 3115
601 Pennsylvania Avenue, N.W.
Washington, DC 20580

Karen G. Bokat
Federal Trade Commission, 3115
601 Pennsylvania Avenue, N.W.
Washington, DC 20580

Laura S. Shores
Howrey Simon Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, DC 20004

_____