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

To: The Honorable D. Michael Chappell
Administrative Law Judge

COMPLAINT COUNSEL'S MOTION FOR OFFICIAL NOTICE

Complaint counsel respectfully requests that Your Honor take official notice of the facts set forth below. Rule 3.43(d) of the Commission's Rules of Practice provides that the Administrative Law Judge and the Commission may take official notice of material facts that do not appear in evidence of the record, so long as the other party is given the opportunity to disprove such noticed facts upon a timely motion. 16 C.F. R. § 3.43(d). The concept of official notice is akin to that of judicial notice, provided for under Rule 201 of the Federal Rules of Evidence, but courts consistently have recognized that administrative agencies' ability to take official notice is even broader than the courts' ability to take

judicial notice.[1]

Administrative Law Judges at the Federal Trade Commission, as well as the Commission itself, have frequently relieved the parties in administrative adjudication of the duty to present formal evidence of certain facts by taking official notice of those facts. For example Administrative Law Judges and the Commission haven taken official notice of, and relied upon, extra-record facts derived from government agency studies and publications,[2] government guidelines and regulations,[3] government records,[4] Congressional reports,[5] and dictionaries.[6] Official notice is particularly appropriate when notice is being

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[1]*See generally* Kenneth C. Davis and Richard J. Pierce, Jr., II *Administrative Law Treatise* (3d ed. 1994) §§ 10.5 & 10.6 (discussing cases and observing that administrative agencies operating under the Administrative Procedures Act enjoy broader discretion to take notice of contested material facts than do courts operating under the Federal Rules of Evidence).

[2]*Beauty-Style Modernizers, Inc.*, 83 F.T.C. 1761, 1779 (1974) (taking official notice of a Federal Reserve Board publication).

[3]*Skylark Originals, Inc.*, 80 F.T.C. 337, 350 (1972) (taking official notice of Federal Trade Commission guidelines); *Marcor, Inc.*, 90 F.T.C. 183, 185 (1977) (taking official notice of a change in a Federal Reserve Board regulation).

[4]*Avnet, Inc.*, 82 F.T.C. 391, 484 n.31 (1973) (taking official notice of U.S. census data).

[5]*Rueben H. Donnelley Corp.*, FTC Dkt. No. 9079, Order Admitting Congressional Report as an Exhibit, November 15, 1978 (ALJ Timony) (taking official notice of four findings taken from a report of the Committee on Government Operations of the United States House of Representatives on Airline Deregulation and Aviation Safety), *citing Stasiukevich v. Nicholls,* 168 F.2d 474, 479 (1st Cir. 1948) ("The official report of a legislative or congressional committee is admissible in evidence in a judicial proceeding, as an exception to the hearsay rule, where the report, within the scope of the subject matter delegated to the committee for investigation, contains findings of fact on a matter which is at issue in the judicial proceeding. Indeed, the court could properly take judicial notice of the report, without its formal introduction into evidence.")

[6]*See e.g., Thompson Medical Co., Inc.*, 104 F.T.C. 648, 809-10 (1984) (taking official notice of the definition of "aspirin" found in various dictionaries). *But see Bristol-Myers Co.*, 95 F.T.C. 279 (1980) (Commission order denying respondent's motion that the Commission take official notice of selected newspaper reports).

sought for so-called "legislative facts," that is, facts that do not concern the immediate parties "but are general facts that help the tribunal decide questions of law and policy and discretion."[7]

Complaint counsel seek to have Your Honor take official notice of excerpts from a number of government agency publications, studies, regulations, and guidelines akin to the type of documents from which the Commission has frequently taken official notice. These documents are:

1. Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998 ("CBO Study").

2. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, "CDER 2000 Report to the Nation: Improving Public Health Through Drugs," 2000 ("CDER Report").

3. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, "Fact Book 1997," 1997 ("CDER Fact Book").

4. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, "CDER Handbook," revised March 16, 1998 ("CDER Handbook").

5. Congress of the United States, Office of Technology Assessment, "Pharmaceutical R&D: Costs, Risks and Rewards," February 1993 ("OTA Study").

6. Health and Human Services, Food and Drug Administration, Proposed Rule for "180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications," 64 Fed. Reg. 42,873 (1999) (to be codified at 21 C.F.R. pt. 314) (proposed Aug. 6, 1999) ("FDA Proposed Rule").

Each of these documents is reliable on its face. The Congressional Budget Office study was conducted

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[7]Davis and Pierce, Jr., II *Administrative Law Treatise* at §§ 10.5 p. 141 (contrasting "legislative facts" with "adjudicative facts," which "usually answer the questions of who did what, where, when, how, why, with what motive or intent"). *See also United States v. Gould*, 536 F.2d 216, 220 (8th Cir. 1976) ("Legislative facts are established truths, facts or pronouncements that do not change from case to case but apply universally, while adjudicative facts are those developed in a particular case.").

at the request of the Chairman of the Senate Committee on the Budget. As set forth in the CBO Study's preface, the study relies upon data and information provided by the Food and Drug Administration, the Patent and Trademark Office, the Health Care Finance Administration, and a variety of industry experts, and the study was peer reviewed by outside economics professors from MIT, Stanford, and Harvard prior to its publication.

The CDER Report, CDER Fact Book, and CDER Handbook were issued by the Food and Drug Administration's Center for Drug Evaluation and Research ("CDER"). The CDER is the division within the Food and Drug Administration that evaluates new drugs for safety and effectiveness before they can be sold to the public, monitors the use of drugs for unexpected health risks, monitors drug information and advertising to ensure accurate and complete information is disseminated about approved drugs, sets the standards for drug quality and manufacturing processes, and conducts applied laboratory research and testing.

The OTA Study was prepared at the request of the United States Congress House Committee on Energy and Commerce and its Subcommittee on Health and the Environment, and it was endorsed by the Senate Committee on the Judiciary's Subcommittee on Antitrust, Monopolies, and Business Rights. The Office of Technology Assessment was assisted in preparing the study by an advisory panel of business, consumer, and academic leaders. The study presents an in-depth examination of the costs of pharmaceutical research and development ("R&D"), the economic rewards from that investment, and the impact of public policies on both the costs and returns of pharmaceutical R&D.

Finally, the Food and Drug Administration has proposed amendments to its regulations governing 180-day generic drug exclusivity under the Federal Food, Drug, and Cosmetic Act, which are found at 64 Fed. Reg. 42,873 (1999), to clarify existing eligibility requirements for abbreviated new

drug application (ANDA) sponsors. The proposed amendments include a discussion of the background and rationale for changing the current regulations governing 180-day generic drug exclusivity.

The facts that we ask Your Honor to take official notice of are not about the parties to this litigation (that is, they are not "adjudicative facts"), but concern broader facts touching upon policy and law that cannot seriously be contested in the adjudication of this matter. Further, we believe that taking official notice of these facts will assist Your Honor, in the first instance, and the Commission and possibly the court of appeals, in deciding issues relevant to the ultimate resolution of this matter. Accordingly, we respectfully request that Your Honor take official notice of the following facts:[8]

1. In 1996, 43 percent of the prescription drugs sold in the United States (as measured in total countable units, such as tablets and capsules) were generic. CBO Study at p. ix.

2. Generic drugs contain the same active ingredient as a brand-name drug (CBO Study at p. 1) and are judged by the Food and Drug Administration to be comparable in terms of such factors as strength, quality, and therapeutic effectiveness. CBO Study at p. 2.

3. Generic drugs cost less than their brand-name, or "innovator," counterparts. Thus, they have played an important role in holding down national spending on prescription drugs from what it would otherwise have been. Considering only sales through pharmacies, the Congressional Budget Office estimates that by substituting generic for brand-name drugs, purchasers saved roughly $8 billion to $10 billion in 1994 (at retail prices). CBO Study at p. ix.

4. Three factors are behind the dramatic rise in sales of generic drugs. First, the Drug Price Competition and Patent Term Restoration Act of 1984 -- commonly known as the Hatch-Waxman Act -- made it easier and less costly for manufacturers to enter the market for generic drugs. Second, by 1980, most states had passed drug-product substitution laws that allowed pharmacists to dispense a generic drug even when the prescription called for a brand-name drug. Third, some government health programs,

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[8]The text of the facts set forth below for the most part is taken verbatim from the respective studies, reports, and regulations that are cited. Some editing has been made to improve readability and to facilitate comprehension, including the omission of footnotes.

such as Medicaid, and many private health insurance plans have actively promoted such generic substitution. CBO Study at p. ix.

5. The Hatch-Waxman Act tried to balance two competing objectives: encouraging competition from generic drugs while maintaining the incentives to invest in developing innovative drugs. CBO Study at p. ix.

6. The Hatch-Waxman Act eliminated the duplicative tests that had been required for a generic drug to obtain approval from the Food and Drug Administration. Before 1984, manufacturers of generic drugs were required to independently prove the safety and efficacy of their products, and they were prohibited from using unpublished test results of the original innovator drug, which were considered trade secrets of its manufacturer. CBO Study at p. xii.

7. The Hatch-Waxman Act streamlined the process for approving generic drugs by requiring only that manufacturers demonstrate "bioequivalence" to an already-approved innovator drug. (Bioequivalence means that the active ingredient is absorbed at the same rate and to the same extent for the generic drug as for the innovator drug.) The tests necessary to prove bioequivalence are much less costly than those required to prove safety and efficacy. CBO Study at p. xii.

8. By accelerating the approval process for a generic drug and also allowing its producer to begin clinical tests before the patent on the innovator drug has expired, the Hatch-Waxman Act has reduced the average delay between patent expiration and generic entry from more than three years to less than three months for top-selling drugs. Even more important, the Act increases the proportion of brand-name drugs that face generic competition once their patents expire. CBO Study at p. xii.

9. After an innovator drug's patent expires, generic copies quickly gain a large share of its market. The Congressional Budget Office examined 21 brand-name prescription drugs in its retail pharmacy data set that first saw generic competition between 1991 and 1993. Within their first full calendar year after patent expiration, those drugs lost an average of 44 percent of their market (as measured by the quantity of prescription drugs sold through pharmacies) to generic drugs. And the generic versions cost an average of 25 percent less than the original brand-name drugs at retail prices. CBO Study at p. xiii.

10. Manufacturers of brand-name drugs invest an average of about $200 million (in 1990 dollars) to bring a new drug to market, when the cost of capital and the cost of failures (that is, investments in drugs that never make it to the market) are included. CBO Study at p. xiii.

11. The dramatic rise in generic sales since 1984 has held down average prices for drugs that are no longer protected by a patent. Those lower prices, however, tend not to result from reductions in price of the original brand-name drugs when it begins facing competition from generic drugs. Rather, average prices fall primarily because consumers switch from the higher-priced innovator drug to the lower-priced generics. CBO Study at p. 13.

12. Since generic prices tend to fall as the number of producers rises, generic manufacturers are most profitable when they are one of the first to enter a market. CBO Study at p. 32.

13. Manufacturers of generic drugs who sell nearly identical versions of the same product compete more intensely on the basis of price than do manufacturers of innovator drugs, who compete more on the basis of quality and other differences between products. CBO Study at p. 35.

14. A schematic diagram of the payment system for prescription drugs, including how pharmaceutical benefit management companies ("PBMs") fit into this payment system, is set forth in the CBO Study, figure 1, at page 8. (Attached to this motion at Tab 1).

15. A schematic diagram of the distribution channels for prescription drugs is set forth in the CBO Study, figure 2, at page 14. (Attached to this motion at Tab 2).

16. A table showing the changes in patent protection for U.S. pharmaceuticals, comparing times before and after the enactment of the Hatch-Waxman Act, is set forth in the CBO Study, table 7, at page 39. (Attached to this motion at Tab 3).

17. The Food and Drug Administration's median total time for approval of new drugs acted on in 2000 was 11.2 months. Approval time represents the total review time at the FDA, plus the time for the innovator drug companies' response to the FDA's requests for additional information. CDER Report at FTC 0022379

18. The Food and Drug Administration's median approval time for generic drugs in 2000 was 18.2 months. CDER Report at FTC 0022387.

19. A schematic diagram of the development process for new drugs, including the average amount of time it takes to complete each phase of new drug development, is set forth in the CDER Fact Book at page 16. (Attached to this motion at Tab 4).

20. The steps necessary to complete the generic drug review process, including a schematic diagram of that process and a description of each step, is set forth in the CDER Handbook at pages 29-34. (Attached to this motion at Tab 5).

21. Pharmaceutical research and development is a costly and risky business, but in recent years the financial rewards from R&D have more than offset its costs and risks. OTA Study at p.1.

22. Pharmaceutical R&D is an investment. The principal characteristic of an investment is that money is spent today in the hope that even more money will be returned to the investors sometime in the future. If investors (or the corporate R&D managers who act on their behalf) believe that the potential profits from R&D are worth the investment's cost and risks, then they will invest in it. Otherwise, they will not. OTA Study at p. 3.

23. The long-run persistence in the pharmaceutical industry of dollar returns higher than the amount needed to justify the cost and risk of R&D is evidence of unnecessary pricing power for pharmaceuticals. OTA Study at p. 3.

24. Despite the fact that many pharmaceutical compounds, though protected from generic competition by patents or other market exclusivity provisions, compete for market share with similar compounds, that competition tends to focus on product characteristics, such as ease of use, favorable side-effects profiles, or therapeutic effects, and not on price. Pharmaceutical companies spend a great deal on this product competition. OTA Study at p. 27.

25. Emphasizing product competition over price competition is a rational strategy for pharmaceutical companies operating in a market that is not very sensitive to price differentials among similar compounds. If prescribing physicians will not be swayed by lower prices, it would be foolhardy for firms to set prices for their products much lower than those of competitors. OTA Study at p. 27.

26. Pharmaceuticals are sold through multiple distribution channels, and pharmaceutical companies can set different prices to different kinds of buyers. For example, companies can sell direct to health maintenance organizations or large hospital chains and offer lower prices than they charge for drugs sold to community pharmacies. The ability to charge different prices to different kinds of buyers is referred to as price discrimination. Price discrimination increases profits by separating buyers who are price sensitive from those who are not. OTA Study at pp. 27-28.

27. Generic drug manufacturers compete largely on the basis of price, since they can claim no quality advantage over the brand-name drug. OTA Study at p. 30.

28. Private and public health insurers have initiated programs to encourage the dispensing of cheaper versions of multisource compounds (those with generic equivalents on the market). These strategies include using mail-order pharmacies, waiving beneficiaries' cost-sharing requirements when prescriptions are filled with generic versions, or refusing to pay more than a certain amount for a drug with a generic competitor.

Medicaid, the government health insurance program for the indigent, mandates substitution with cheaper generic drugs unless the prescribing physician specifically prohibits it in writing on the prescription form. These programs have substantially reduced brand-name compounds' unit sales and revenues. OTA Study at p. 30.

29. When research and development take place under conditions of rivalry, as in the pharmaceutical industry, that rivalry can lead to wasteful and duplicative R&D efforts and lower returns to the public as a whole than to private industry. That is, the public can end up paying too much for the benefits it receives from the competitive R&D. OTA Study at p. 32.

30. Because the "appropriate" level of demand for prescription drugs in the United States cannot be inferred from the existing level of demand, it is impossible to know whether on the whole there is too much R&D or too little R&D on new drugs. OTA Study at p. 32.

31. The Hatch-Waxman Act benefits consumers by bringing lower priced generic versions of previously approved drugs to market, while simultaneously promoting new drug innovation through the restoration of patent life lost during the Food and Drug Administration's regulatory review. The award of a 180-day period of market exclusivity for applicants filing certain Abbreviated New Drug Applications ("ANDA") with so-called paragraph IV certifications was designed to maintain this balance by rewarding generic firms for their willingness to challenge uneforceable and invalid innovator patents, or design noninfringing drug products. Recently, however, this balance has been upset and generic competition impeded, in part through the establishment of certain licensing agreements or other commercial arrangements between generic and innovator companies. FDA Proposed Rule at 42,882.

32. Under current FDA regulatory provisions, the first generic applicant to file a substantially complete ANDA with a paragraph IV certification can delay generic competition by entering into certain commercial arrangements with an innovator company. The result may be that, notwithstanding the intent of the Hatch-Waxman Act, rewards are directed to generic companies for hindering rather than speeding generic competition. A necessary condition for such arrangements is that the economic gains to the innovator from delaying generic competition exceed the potential economic gains to the generic applicant from 180 days of marketing exclusivity. Such instances are becoming more frequent because a successful strategy to extend market exclusivity can mean tens of millions of dollars in increased revenue for an innovator firm. Under such circumstances, it can be mutually beneficial for the innovator and the generic company that is awarded 180 days of generic exlusivity to enter into agreements that block generic competition for extended periods. This delayed competition harms consumers by slowing the introduction of lower priced products into the market and thwarts the intent of the Hatch-Waxman Act. FDA Proposed Rule at 42,882-83.

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For the reasons discussed above, we respectfully request that Your Honor take official notice of the facts set forth above, as well as the figures, tables, and diagrams attached to this motion.

Respectfully Submitted,

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Martha H. Oppenheim

Counsel Supporting the Complaint

Bureau of Competition
Federal Trade Commission
Washington, D.C. 20580

Dated: December 14, 2001

CERTIFICATE OF SERVICE

I hereby certify that this 14th day of December 2001, I caused an original, one paper copy and an electronic copy of Complaint Counsel's Motion for Official Notice to be filed with the Secretary of the Commission, and two paper copies to be served by hand delivery upon:

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

The following persons were served with one paper copy by first class mail and Federal Express:

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Martha H. Oppenheim
Counsel Supporting the Complaint

Tab 1

Tab 2

Tab 3

Tab 4

Tab 5