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June 6, 2006

Donald S. Clark, Secretary
Federal Trade Commission
Office of the Secretary
Room H-172
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Re: Authorized Generic Drug Study: FTC Project No. P062105

Dear Secretary Clark:

As advocates of the public interest, the American Antitrust Institute, Consumer Federation of America, Families USA, and US PIRG, appreciate this opportunity to comment on the Federal Trade Commission's ("FTC's") proposed study of the competitive effects of authorized generic drugs in the prescription drug marketplace. By initiating this study, the FTC has demonstrated its commitment to ensuring that the anticompetitive practices of brand name drug manufacturers do not threaten Americans' access to low cost generic drugs. We share with the FTC this commitment to protecting consumers, and therefore are grateful for the chance to provide suggestions on how best to achieve this critical goal.

The role of the FTC as law enforcer and advisor to both Congress and regulators has led to substantial benefits to competition and consumers in the pharmaceutical marketplace. Because of several antitrust enforcement actions brought by the FTC against brand name pharmaceutical manufacturers, efforts by those manufacturers to delay generic entry have been forestalled. These enforcement actions have saved consumers and the health care system hundreds of millions of dollars.

As critical has been the FTC's role in performing studies, regulatory advocacy, and advising Congress and the Food and Drug Administration how to prevent abuse of the regulatory process. Indeed, the FTC's 2002 landmark study on the generic pharmaceutical industry—Generic Drug Entry Prior to Patent Expiration: An FTC Study—provided critical insights on how brand name firms manipulated the regulatory process in order to improperly extend product monopolies. As the Commission is well aware, abuse of the regulatory process is one of the most egregious forms of anticompetitive conduct because the market cannot correct itself. The

FTC Generic Drug Study demonstrated that brand name firms aggressively exploited legal and regulatory loopholes in order to forestall generic entry.[1]

Congress responded to the guidance provided by the FTC's Generic Drug Study and amended the Hatch-Waxman Act in the Medicare Modernization Act. Those amendments sought to close unintended loopholes by limiting brand name firms to a single 30-month stay, clarifying a generic firm's right to a declaratory judgment, and creating a notification system for patent settlements. However, over the past few years since the enactment of the MMA, brand name firms have found and exploited other legal and regulatory loopholes in order to attempt to prevent the entry of generic drugs. We believe that authorized generics, rather than being a new form of competition offering benefits to consumers, are actually a carefully devised subterfuge to undermine the incentive of generic firms to invent non-infringing drugs or challenge brand name patents. Ultimately consumers will not benefit from this strategy of brand name firms to market pseudo-generics.

It is particularly important for the FTC to study authorized generics and other forms of anticompetitive conduct in the pharmaceutical market at this time, as over the next three years alone, prescription drugs worth over an estimated $50 billion in U.S. sales will go off patent.[2] Prescription drug spending is the fastest-growing component of health care costs in the United States.[3] Between 1990 and 2003, spending for prescription drugs increased nearly 445%, from $40.3 billion to $179.2 billion.[4] Not surprisingly, rising prices for brand name drugs contributed significantly to this astounding increase in pharmaceutical expenditures.[5] Between 1998 and 2003, for example, the price of one commonly prescribed brand name drug increased by nearly 64%, while the prices of four others increased by nearly 20% or more.[6] Because generic drugs cost, on average, 30% to 80% less than their brand name counterparts, they are crucial to consumers and their ability to purchase affordable medications.

When dominant firms face the threat of new entry they often turn to strategic conduct to hold rivals at bay. Facing the inevitable decrease in market share (and consequent decline in sales revenue) that follows the loss of patent protection and introduction of generics, brand name drug manufacturers increasingly have turned to underhanded means to delay competition. The use of authorized generics is merely one in a long list of tactics employed by these manufacturers to delay generic entry.

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[1] Not surprisingly, the association for the brand name companies, PhRMA, opposed the FTC study as unnecessary. Congress relied on the study and its recommendations extensively in reforming the Hatch-Waxman Act.
[2] Herman P. Maradia, *Dr Reddy's, Ranbaxy...Are They Back or What?* (May 8, 2006), http://www.indiainfoline.com/nevi/zoco.html.
[3] International Trade and Pharmaceuticals Hearing before the Sen. Comm. on Finance, 108th Cong. 2 (April 27, 2004) (written statement on behalf of Families USA).
[4] Kaiser Family Foundation, Prescription Drug Trends (Nov. 2005), http://www.kff.org/insurance/upload/3057-04.pdf.
[5] International Trade and Pharmaceuticals Hearing before the Sen. Comm. on Finance, 108th Cong. 2 (April 27, 2004) (written statement on behalf of Families USA).
[6] *The Government Performance Project: A Case of Neglect*, Governing Magazine (Feb. 2004).

Authorized Generics Distort Congressional Intent

The Hatch-Waxman Act involves a careful balance of incentives and burdens to facilitate competition between branded and generic firms. In order to reward branded firms for the risks and costs of inventing new drugs, the Hatch-Waxman Act provides for an extensive period of exclusivity and patent extensions. To provide further incentives for branded firms to engage in additional important product improvements, additional market exclusivity is provided. One example is the additional three years of market exclusivity for research on the treatment of drugs for new medical uses.

Generic pharmaceutical companies play a vital role in providing a competitive balance in the pharmaceutical marketplace. Generic pharmaceutical companies attempt to enter the market by either inventing non-infringing versions of branded drugs or successfully challenging the patents of branded pharmaceuticals. In order to provide an incentive for generic companies to challenge those patents and invent non-infringing drugs, the Hatch-Waxman Act provides a 180-day period of exclusivity. This period of exclusivity is critical to the incentives provided for generic pharmaceuticals, since in many cases it provides the vast majority of profits a generic pharmaceutical company may ultimately earn by entering the market, revenue that can be reinvested in future patent challenges.

In creating the Hatch-Waxman generic approval system, Congress recognized that the brand name companies may attempt to exploit the system to extend product monopolies and, thus, provided an incentive for generic companies to actively police this system by challenging questionable brand name patents which in turn act as artificial market barriers. Without this full exclusivity incentive, we are very concerned that generic companies may elect not to pursue all relevant future challenges or create non-infringing versions of the drug, resulting in a substantial delay in access to cost effective generics.

These incentives must be considered within the ultimate goal of the Hatch-Waxman Act. One of Congress' primary goals in enacting Hatch-Waxman was to increase competition in the pharmaceutical arena by expediting the approval of lower-cost generic drugs. As the D.C. Circuit has observed a key goal of Hatch-Waxman was to "get generic drugs into the hands of patients at reasonable prices - fast."[7] See also H.R. Rep. No. 98-857, pt. II (1984), reprinted in 1984 U.S.C.C.A.N. 2716-17 (declaring that one of the principal policy objectives of Hatch-Waxman was to "[g]et safe and effective generic substitutes on the market as quickly as possible after the expiration of a patent").

An authorized generic is a brand-sponsored drug marketed by either a subsidiary of the brand company or a generic drug company through an agreement with the branded firm (e.g., the drug is manufactured by the producer of the branded drug). Some of these generic companies are legitimate generic manufacturers, others, as recognized by the proposed study, are no more than store fronts, providing a name for an alliance but little else. Of course there has been no

[7] *In re Barr Lab., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991).

significant analysis of the long-term competitive impact of authorized generics.[8] But our observations suggest they are no bonanza for consumers. Understandably, the branded firms are not interested in aggressive competition that may threaten to cannibalize their sales. Based on our observations of the market, we believe these drugs generally enter only when a legitimate generic is about to enter. The branded firm, not surprisingly, is disinterested in creating an aggressive competitor which may cannibalize the sales of the patented drug.[9]

Authorized Generics should be evaluated with other Anticompetitive Practices

It is important not to perceive authorized generics in a vacuum. Rather they are part and parcel of a set of practices engaged in by brand name firms to delay generic entry. The ultimate strategy of the brand name firms is to create regulatory and litigation obstacles that create uncertainty and raise the cost of generic entry into the market. Some of the other strategies engaged in by brand name firms include the following:

- **Filing Sham Citizen Petitions**. As the FTC's earlier Generic Drug Study recognized, the FDA citizen petition process can provide a significant opportunity for low cost efforts to create regulatory barriers to delay generic entry. Citizen petitions are frequently filed to delay the entry of generic drugs. Even though these petitions are ultimately rejected they can delay entry for a substantial period of time, often as long as six months to years in some cases. Although the FTC 2002 Study identified this as a competitive problem, the FDA has not acted and problems over citizen petitions have become more significant. Since there are no penalties imposed for meritless petitions, there is little to counterbalance or deter this type of anticompetitive conduct.

- **Abuse of the Declaratory Judgment System**. As the FTC knows, Congress attempted to amend the declaratory judgment provisions under the Hatch-Waxman Act so that generic pharmaceutical companies could seek a declaratory judgment to establish their rights to enter the market if they had not been sued by a branded pharmaceutical company. Unfortunately, branded pharmaceutical companies have continued to engage in delaying tactics by refusing to file patent challenges. In turn, the courts have failed to interpret the provisions of the MMA correctly, creating a new loophole that can be readily exploited by brand name pharmaceutical companies.[10] Simply generic firms have no ability to begin the litigation process necessary for entry.

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[8] One study of authorized generics in the Paragraph IV context relies on only a study of three drugs, only looks at the short-run effect of the practice, and ignores the impact of reduced profits to the Paragraph IV filer on its incentive to challenge a patent. *See* Ernst R. Berndt, et al., *Authorized Generic Drugs, Price Competition and Consumer's Welfare* (October 26, 2005), http://www.aei.org/docLib/20051103_AuthorizedGeneric.pdf.

[9] As Professor Tomas Philipson has noted, it is hard to see how authorized generics in Paragraph IV cases can be profitable for the branded firm except as a means to deter patent challenges by generic drug firms. *See* AEI Seminar: Authorized Generics, Part of The Solution or Part of the Problem, October 31, 2005, http://www.aei.org/events/filter.all,eventID.1177/summary.asp.

[10] FTC Brief, *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, No. 04-1186 (Fed. Cir.) (Feb. 8, 2005).

- **Product Switching**. Several pharmaceutical companies have attempted to extend patent life by making small changes to drugs near the time of anticipated generic entry. In some cases, such as Abbott's drug Tricor, the branded firm has engaged in successive product switches close to generic entry after the generic has won hard fought patent battles.[11] These successive switches have kept generics off the market for several years costing consumers hundreds of millions in higher prices. The Commission is not a stranger to these types of anticompetitive strategies. This type of brand switching conduct was recognized as a potential competitive harm in the Cima/Cephalon merger in which the Commission required the licensing of a patent to facilitate generic entry to prevent this anticompetitive conduct.[12]

- **Problematic Settlements**. As the Commission is well aware from its past enforcement actions, patent challenges by generic firms play a critical role in invalidating patents or narrowing their scope, permitting generic entry. Consumers benefit when generic firms have the full incentive and ability to "fight, not settle." The combined effect of authorized generics and the current Hatch-Waxman system, which is devoid of a viable declaratory judgment provision, may effectively force generic firms to the settlement table. Authorized generics diminish the rewards for the legitimate generic firm that undertakes the burden to challenge patents, invent non-infringing versions, produce and market the drug. As FTC Commissioner Leibowitz has noted, "the growing threat of authorized generics may diminish a generic's incentive to fight. If a first-filer believes that the brand will sponsor an authorized generic—something that many expect today on any significant drug—the profits to be made in the 180-day exclusivity period are reduced substantially, perhaps even cut in half. So the generic firm's calculus in the fight-versus-settle equation may now be more heavily weighted towards settling."[13]

The FTC Should Broaden the Study to Evaluate All Types of Anticompetitive Conduct, Secure Qualitative Data, and Conduct Hearings

The FTC seeks comments on "[w]hether the proposed collections of information are necessary for the proper performance of the function of the FTC, including whether the information will have practical utility." We believe that the information that the Commission seeks to gather is important, but is too limited in several respects.

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[11] Memorandum Opinion, *In re Tricor Antitrust Litigation*, 02-cv-1512 (D. Del. May 26, 2006).
[12] In the Matter of Cephalon, Inc., and CIMA Labs, Inc., FTC File No. 041-0025, http://www.ftc.gov/os/caselist/0410025/0410025.htm.
[13] Jon Leibowitz, Remarks, Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust (April 24, 2006), http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf.

First, by focusing only on authorized generics, the Commission will miss the impact of all the other types of anticompetitive strategies discussed above. Authorized generics are simply one tool in the arsenal in anticompetitive conduct used by brand name pharmaceutical companies. To understand their impact on competition, the Commission needs to consider how all of these practices work together. From the perspective of consumers, authorized generics are one of several threats used to delay entry into the market.[14]

Second, the Commission should recognize that authorized generics are a recent strategy. Conclusions based on data regarding a strategy of limited duration may be misleading. This is particularly a concern for a practice like authorized generics in which the long-term competitive impact may be far more substantial than any short-term impact. Authorized generics began only 2 years ago. Since the decision by a generic firm to enter is typically made several years before entry, the more significant long-term effects will not be identified by current quantitative data.

Third, the Commission's focus on quantitative data is far too limited. The Commission appears to simply focus on the relatively narrow question of whether authorized generics appear to lead to lower prices. This data can be valuable in many respects, but in other respects will be uninformative. The more profound impact of authorized generics may be on the long-term incentive and ability of generic firms to engage in the costly and risky conduct of attempting to invent non-infringing drugs and challenge questionable patents. As representatives of consumers, we have serious concerns that the long term impact of these practices may relegate generic firms to the role of distributors of quasi-generics, rather than aggressive challengers to brand name monopolies.

Lastly, we strongly suggest that the Commission hold hearings on the impact of authorized generics and other practices by the pharmaceutical industry. We believe that the hearings approach can be particularly effective in accumulating evidence of the long-term competitive of these practices.[15] The FTC and DOJ have successfully used hearings to gather data and provide guidance on a wide variety of competitive practices in a broad range of industries including retailing, real estate, health care and intellectual property. The joint FTC/DOJ hearings on the intersection of IP and antitrust law provided a useful forum that brought together businesspersons, industry experts, academics, lawyers and economists to address broad issues on the competitive significance of many complex practices in industries such as software, biotech, computers and other high tech industries. That type of structure can be particularly effective in evaluating the difficult long-term questions posed by authorized generics and these other potentially anticompetitive practices.

In conclusion, we applaud the Commission for their diligence in policing the pharmaceutical marketplace, and their efforts to educate the Congress, regulators and the public

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[14] The FTC expanded the scope of the 2002 Generic Drug Study to include other practices not identified in the original proposal for the study.

[15] Hearings may also enable the Commission to secure information and establish a record to support the Commission's efforts to advocate before the FDA or before the courts as amicus. *See, e.g.*, FTC Brief, *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, No. 04-1186 (Fed. Cir.) (Feb. 8, 2005).

about potential anticompetitive practices. We believe that if the FTC broadens this study, it can make a substantial contribution in helping the courts and legislators in preventing anticompetitive practices in this vital market crucial to all U.S. consumers.

Thank you for considering our comments. If you have any questions, please contact me.

Sincerely,

David A Balto

David A. Balto
On behalf of the American Antitrust Institute,
Consumer Federation of America, Families USA,
and US PIRG

Appendix

American Antitrust Institute (AAI)

The American Antitrust Institute is an independent Washington-based non-profit education, research, and advocacy organization. AAI's mission is to increase the role of competition, assure that competition works in the interests of consumers, and challenge abuses of concentrated economic power in the American and world economy. They are, broadly, post-Chicago centrists dedicated to the vigorous use of antitrust as a vital component of national and international competition policy.

Consumer Federation of America (CFA)

The Consumer Federation of America (CFA) is a membership organization of some 300 nonprofit organizations from throughout the nation with a combined membership exceeding 50 million people, which enables CFA to speak for virtually all consumers. In particular, CFA looks out for those who have the greatest needs, especially the least affluent. Since 1968, CFA has provided consumers a well-reasoned and articulate voice in decisions that affect their lives. Day in and out, CFA's professional staff gathers facts, analyzes issues, and disseminates information to the public, policymakers, and rest of the consumer movement.

Families USA

Families USA is a national nonprofit, non-partisan organization dedicated to the achievement of high-quality, affordable health care for all Americans. Working at the national, state, and community levels, they have earned a national reputation as an effective voice for health care consumers for over 20 years. Families USA manages a grassroots advocates' network of the consumer perspective in national and state health policy debates; acts as a watchdog over government actions affecting health care; produces highly respected health policy reports; conducts public information campaigns about the concerns of health care consumers; serves as a consumer clearinghouse for information about the health care system; and provides training and technical assistance to, and works collaboratively with, state and community-based organizations as they address critical health care problems in their communities and state capitals.

US Public Interest Research Group (US PIRG)

The state PIRGs created U.S. PIRG in 1983 to act as watchdog for the public interest in our nation's capital, much as PIRGs have worked to safeguard the public interest in state capitals since 1971. The organization's roots at the state level, and U.S. PIRG members across the country, give them a unique "outside the beltway" perspective and provide the grassroots power necessary to influence the national policy debate. U.S. PIRG is an advocate for the public interest. When consumers are cheated, or our natural environment is threatened, or the voices of ordinary citizens are drowned out by special interest lobbyists, U.S. PIRG speaks up and takes action. They uncover threats to public health and well-being and fight to end them, using the time-tested tools of investigative research, media exposés, grassroots organizing, advocacy and litigation. U.S. PIRG's mission is to deliver persistent, result-oriented public interest activism that protects our environment, encourages a fair, sustainable economy, and fosters responsive, democratic government.