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Congress of the United States
House of Representatives
Washington, DC 20515–0530

HENRY A. WAXMAN
30TH DISTRICT, CALIFORNIA

SENIOR DEMOCRATIC MEMBER
COMMITTEE ON
GOVERNMENT REFORM

MEMBER
COMMITTEE ON
ENERGY AND COMMERCE

September 13, 2005

Deborah Majoras
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, D.C. 20580-0002

Dear Chairman Majoras:

I am writing to request that the Federal Trade Commission conduct a study pursuant to section 6(b) of the Federal Trade Commission Act on the impact of so-called "authorized generics" on competition in the prescription drug marketplace. I recognize that the Commission may also be considering a workshop on this subject, but rise of authorized generics raises serious competitive issues and requires a full study.

As you know, authorized generics are generic drugs that enter the market under the aegis of the brand name drug manufacturer. There is evidence that brand name drug companies are increasingly using authorized generics to undermine one of the incentives to increase competition created by The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments).

The Hatch-Waxman Amendments provide a special incentive to generic companies that challenge patents on the brand name drug – in exchange for undertaking the costs and risks of patent litigation, the successful challenger is given 6 months of marketing without any other generic competition. The purpose of this incentive is to encourage challenges to patents that otherwise would inappropriately block competition. Brand name companies, however, are now increasingly arranging for authorized generics to enter the market during the 6-month period of generic exclusivity, substantially reducing the value of that exclusivity to the generic drug manufacturer who challenged the patent.

As the Commission has documented, there have been a large number of successful patent challenges since enactment of the Hatch-Waxman Amendments, bringing generic drugs to market much earlier than would otherwise have occurred.[1] If the rise in authorized generics causes generic drug manufacturers to stop challenging patents for certain products, generic competition will be significantly delayed, and consumers, businesses, and governments will unnecessarily pay monopoly drug prices for much longer periods.

[1] FTC, "Generic Drug Entry Prior to Patent Expiration: An FTC Study," Chapter 2, July 2002.

In 2002, the Commission issued a landmark report detailing tactics then being used by the pharmaceutical industry to delay generic competition months and even years past the time intended by Congress, at a cost of billions of dollars.[2] Congress responded to that study by enacting legislation in 2003, closing loopholes in the Hatch-Waxman Amendments. I do not believe it is a coincidence that brand name companies began to exploit the practice of authorizing generics after the closing of those loopholes.

To follow up on the Commission's 2002 report, a study on the impact of authorized generics on competition is urgently needed. Such a study should examine (1) whether the 6-month exclusivity period provided by the Hatch-Waxman Amendments to the first generic drug manufacturer to challenge a patent is a significant incentive for patent challenges; (2) whether the increasing use of authorized generics has reduced, or is likely to reduce, the number of patent challenges or to otherwise delay or decrease generic competition, e.g., by reducing the number of generic drugs brought to market; and (3) whether prescription drug consumers benefit more from the short-term competition offered by authorized generics or by the earlier marketing of generic drugs that are the subjects of successful patent challenges, to the extent that the 6-month exclusivity is responsible for such challenges.

If you have any questions about this request, please contact Ann Witt of my staff at (202) 225-3976.

With kind regards, I am

Sincerely,

Henry A. Waxman

HENRY A. WAXMAN
Member of Congress

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[2] Id.