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# United States Senate

COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510-6275

FEDERAL TRADE COMMISSION
05 MAY 11 AM 8:45
CONG. CORRES. BRANCH

May 9, 2005

Chairman Deborah Platt Majoras
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dear Chairman Majoras and Commissioners:

It has come to our attention that the practice of "authorized" generic drugs may produce anti-competitive results and, thus, present an issue worthy of study by the Federal Trade Commission.

The amendments to the Hatch-Waxman Act of 1984, enacted as part of the Medicare Modernization Act (Title XI, PL 108-173), provide that, in general, a generic company that successfully challenges the patent of a name brand pharmaceutical company earns 180 days of marketing exclusivity on that generic drug. The legislation was designed to strengthen incentives for generic manufacturers to bring generic drugs quickly to market, and thus promote competition and lower prices for consumers.

We have heard concerns that the practice of "authorized" generics could have a negative impact on competition for both blockbuster and smaller drugs, because the generic industry would be less inclined to invest in their production. Consequently, if the generic industry were to be less incentivized to produce such generic drugs to compete with name brand drugs, it is possible that fewer generic drugs would come to market and the prices for certain drugs would remain high for consumers.

We are interested in determining the short term and long term effects on competition of the practice of "authorized" generics. Consequently, we request, pursuant to § 6(b) of the Federal Trade Commission Act, that the Commission conduct a study on this issue. We ask that this study look into the short term competitive benefits of introduction of "authorized" generics during the 180 day market exclusivity period. We also ask that the study look into the long term impact of the practice of "authorized" generics on competition in the drug market and on the price of drugs, as well as on the viability of the generic drug industry.

If such a study were to prove unfeasible, we hope the FTC will be able to conduct a workshop on this issue in the near future. If you have any questions about this request, please feel free to contact Susan Davies of Senator Leahy's office, Rita Lari Jochum of Senator Grassley's office, or Jocelyn Moore of Senator Rockefeller's office. They can be reached at (202) 224-7703 (Sen. Leahy), (202) 224-5564 (Sen. Grassley), or (202) 224-6472 (Sen. Rockefeller), respectively.

Sincerely,

PATRICK LEAHY
United States Senator

CHUCK GRASSLEY
United States Senator

JOHN ROCKEFELLER
United States Senator

cc: Commissioner Pamela Jones Harbour
Commissioner Thomas Leary
Commissioner Jon Leibowitz
Commissioner Orson Swindle