Center for American Progress

AP PHOTO/NATI HARNIK

Removing Obstacles to Generic Drug Competition

A critical priority for health care reform

David Balto June 2009

Introduction and summary

Thirty years ago former Supreme Court Chief Justice Warren Burger explained that "Congress designed the Sherman Antitrust Act of 1890 as a 'consumer welfare prescription,'"[1] to help average Americans benefit from the fruits of market-based competition by limiting monopolies and cartels in the U.S. economy. U.S. antitrust laws such as the Sherman Act and subsequent laws indeed assure that competition is the lodestar of the marketplace and that consumers receive the full benefits of competition in lower prices and better services.

One of the sectors in which antitrust enforcement is crucial is in the pharmaceutical industry, which accounts for an increasingly large part of our overall healthcare expenditures. Fortunately, during both the Clinton and Bush administrations, both state and federal antitrust enforcers, bolstered by private actions, began to approach pharmaceutical competition concerns in a disciplined fashion, bringing cases that clarified the law and stopped conduct that denied consumers the benefits of lower priced generic drugs. Despite these increased efforts, however, there are numerous forms of anticompetitive conduct that continue in pharmaceutical markets because of the ability of companies to manipulate the regulatory process and some misguided decisions of the courts.

Stopping these types of anticompetitive conduct could not be a greater priority for the Obama administration's antitrust enforcers. With more than $60 billion in drugs scheduled to go "off patent" during the remainder of the President's first term, stopping anticompetitive conduct in the pharmaceutical industry is crucial to controlling health care costs. If antitrust is a "consumer welfare prescription," then our health care system is certainly in need of a prescription for an added dose of enforcement in pharmaceutical markets.

This paper will begin by discussing the importance of ensuring competition from generic pharmaceutical companies once patents expire on drugs developed by brand-name pharmaceutical companies. It then describes several industry factors that make pharmaceutical markets different from other markets—differences that enhance the opportunity for abuses of market power and anticompetitive conduct more generally.

This paper then examines four types of anticompetitive conduct that may delay the emergence of generic drugs:

- Exclusion payments, or payments made by brand-name manufacturers to generic companies in settlements of patent litigation, which may delay the entry of the generic drug
- Product hopping, or extending the period of patent protection by obtaining patents on trivial modifications of a drug and switching the market to the new protected version
- Authorized generics, or drugs manufactured by brand-name companies sold under generic labels, which are designed to reduce incentives for generic companies to challenge patents
- Misuse of the regulatory system through sham filings with the Patent Office, the Food and Drug Administration, and in courts.

In each of these cases, the paper discusses possible remedial legislative and enforcement approaches. Specifically:

- Congress should pass legislation expressly prohibiting exclusion payments in patent settlements
- The Federal Trade Commission should investigate and bring cases to challenge product hopping where it has anticompetitive effects
- Congress should enact a ban on authorized generics and the Federal Trade Commission should bring cases to prevent their use
- The Federal Trade Commission should investigate and challenge the use of sham regulatory filings, such as citizen petitions and other efforts to subvert the regulatory process.

The Center for American Progress is a nonpartisan research and educational institute dedicated to promoting a strong, just and free America that ensures opportunity for all. We believe that Americans are bound together by a common commitment to these values and we aspire to ensure that our national policies reflect these values. We work to find progressive and pragmatic solutions to significant domestic and international problems and develop policy proposals that foster a government that is "of the people, by the people, and for the people."

Center for American Progress

1333 H STREET, NW, 10TH FLOOR, WASHINGTON, DC 20005 • TEL: 202-682-1611 • FAX: 202-682-1867 • WWW.AMERICANPROGRESS.ORG