Consumers Union
Nonprofit Publisher of Consumer Reports

CFA

Consumer Federation of America
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U.S. PIRG

NLARx
National Legislative Association on Prescription Drug Prices

March 10, 2010

President Barack Obama
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

[via electronic mail]

Re: Expanding Access to Affordable Generics

Dear President Obama:

We are the nation's leading consumer rights organizations and advocates for meaningful change in Americans' access to affordable prescription drugs, Consumers Union, US PIRG, Consumer Federation of America and the National Legislative Association on Prescription Drug Prices. [1]

Today, we are writing to thank you for including a ban on pay-for-delay settlements in your new proposal for health care reform legislation. However, simply including a ban on these settlements will fall short of fixing the problem. We urge you to include legislation that would address the 180-day market exclusivity period for generics that makes pay-for-delay settlements so attractive. A provision providing an incentive for multiple generic manufacturers to challenge patents, contained in Senator Bill Nelson's and Congressman Alcee Hasting's proposals in S. 1315 and H.R. 3777, would eliminate the root cause of pay-for-delay settlements and ensure strong competition in the market for generic drugs. Accordingly, the Nelson/Hastings proposal must be included in any

ban on pay-for-delay settlements in order to effectively and definitively end the ability of conspiring generic and brand drug companies to game the system at an enormous cost to consumers.

Prescription drugs represent the most rapidly growing segment of health care spending. Generic drugs, when available, introduce the forces of competition to the market for a particular prescription drug and bring costs down dramatically. When patents are weak or illegitimate, drug manufacturers have the opportunity to challenge those patents and, if successful, to introduce affordable generics to the market in a shorter timeframe than they otherwise would.

The Hatch-Waxman Act, however, grants a 180-day exclusivity period to the first generic manufacturer attempting to market their generic. The first-to-file manufacturer retains this six-month exclusivity regardless of whether or not their challenge is successful, or if they are paid off by the branded drug manufacturer to stay out of the market. When this occurs, no other manufacturer has the opportunity to bring that generic drug to the market, resulting in consumer harm. This practice, known as pay-for-delay settlements or exclusion payments, will cost Americans more than $35 billion during the next 10 years, according to the Federal Trade Commission.

These payments are anticompetitive and should be considered per se illegal: they prevent *any* generic manufacturer with a legitimate challenge to a patent from potentially entering the market. We support the inclusion of the House language, championed by Representative Rush, which clarifies that these payments are per se illegal, as an essential means to save consumers and health plans billions on future drug costs.

In addition, it is imperative that the provisions of S. 1315/HR 3777, introduced by Senator Bill Nelson and Congressman Alcee Hastings, be included in any provision aimed at ending the settlement problem. S. 1315/HR 3777 would correct the systemic flaw in the Hatch-Waxman Act that is the root cause of the settlement problem. Enactment of S.1315/HR 3777 will ensure that 180-day exclusivity periods that are "parked" in settlements between the first-to-file generic manufacturer and its conspiring brand partner can no longer block subsequent generic challengers who prevail in their patent challenges from making their competing products immediately available to consumers.

Indeed, the critical need to address the systemic Hatch-Waxman flaw that enables "parked" exclusivities to delay full and fair generic competition was underscored by the Federal Trade Commission's January 2010 report on settlements. That report observed that the first generic to seek entry prior to patent expiration – the one who has the ability to "park" the 180-day exclusivity period – is involved in most of these collusive arrangements. According to settlement data reported to the FTC between 2004 and 2009, 51 of the 66 "pay-for-delay" agreements (77%) by the generic and brand drug industries during that time "were between the brand pharmaceutical company and the generic company that was the first to seek entry prior to patent expiration for the relevant brand name drug." Expanding the exclusivity period to include generic challengers who prevail

in their patent litigation at a time when no commercial marketing has yet begun, as proposed by S. 1315/HR 3777, is vitally important. Permitting this exclusivity to be shared with a subsequent generic challenger that successfully challenges the patent would remove the barrier to entry that brand and first-to-file generic companies exploit to delay timely consumer access to full and fair generic competition.

We urge you to support this innovative and effective solution to the problem of pay-for-delay settlements in your proposal and in future discussions of health care reform legislation. We sincerely hope the ultimate health reform legislation will address the problem of pay-for-delay settlements and provide a clear avenue for consumers to gain access to affordable generics as soon as possible.

We appreciate your consideration of our views in this challenging time. We would be happy to meet with you and your staff to discuss this matter further.

Signed,

Consumer Federation of America

Consumers Union

National Legislative Association on Prescription Drug Prices

US PIRG

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[1] About our organizations:

The Consumer Federation of America (CFA) is composed of over 280 state and local affiliates representing consumer, senior, citizen, low-income, labor, farm, public power and cooperative organizations, with more than 50 million individual members. CFA represents consumer interests before federal and state regulatory and legislative agencies, participates in court proceedings and conducts research and public education.

Consumers Union is the independent, non-profit publisher of *Consumer Reports.*

The National Legislative Association on Prescription Drug Prices (NLARx), is a nonprofit, nonpartisan organization of state legislators from across the country working to reduce prescription drug costs and expand access to medicines. Many of our member state legislators have sponsored and passed legislation addressing pricing and PBM transparency. NLARx has drafted model PBM transparency legislation and has filed amicus briefs in support of state legislation regulating PBMs.

U.S. PIRG, the federation of state Public Interest Research Groups (PIRGs), stands up to powerful special interests on behalf of the American public, working to win concrete results for our health and well-being. With a strong network of researchers, advocates, organizers and students in state capitols across the country, we take on the special interests on issues, such as product safety, political corruption, prescription drugs and voting rights, where these interests stand in the way of reform and progress.