



Consumer Federation of America

1620 I Street, N.W., Suite 200 * Washington, DC 20006



January 11, 2010

Representative Nancy Pelosi, Speaker
U.S. House of Representatives
235 Cannon House Office Building
Washington, D.C. 20515

Senator Harry Reid, Majority Leader
U.S. Senate
528 Hart Senate Office Building
Washington, D.C. 20510

Re: Expanding Access to Affordable Generics

Dear Representative Pelosi and Senator Reid:

We are the nation's leading consumer rights organizations and advocates for meaningful change in Americans' access to affordable prescription drugs, Families USA, US PIRG, the Consumer Federation of America, Consumers Union, Community Catalyst, the National Legislative Association on Prescription Drug Prices, and the American Antitrust Institute.¹ We appreciate your work in bringing crucial reform to our nation's health care system. Today, we are writing to encourage your support of Representative Rush's per se ban on reverse payment patent settlements as well as Senator Bill Nelson's bill that provides an incentive for multiple generic manufacturers to challenge patents.

Together, these provisions will help open up the market for affordable prescription drugs.

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 were disappointed to see that, despite Senator Kohl's leadership to champion such an amendment, the Senate health care bill did not contain a provision addressing this problem. 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, we support the inclusion of the provisions of S. 1315, introduced by Senator Bill Nelson, to foster even greater competition, and eliminate the distorted incentives stemming from the 180-day exclusivity right. If a first-to-file generic manufacturer's challenge is unsuccessful, then a right to an exclusivity period should not persist, destroying any incentive another manufacturer may have had to bring a subsequent challenge to a weak or illegitimate patent. S. 1315, introduced by Senator Bill Nelson, would permit manufacturers that file subsequent successful challenges to patents to share in the 180-day exclusivity period. Expanding the exclusivity period is vitally important, since it removes the barrier to entry that has protected collusive settlements between brands and first-filing generics. Including this language in the final health reform legislation would provide a strong complement to Representative Rush's *per se* ban on these payments.

We urge you to support Representative Rush and Senator Bill Nelson's innovative and effective solutions to this problem throughout the conference process. We sincerely hope the merged House-Senate health reform legislation will address the problem of

reverse payments 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 the conferees to discuss this matter further.

Signed,

The American Antitrust Institute

Community Catalyst

Consumer Federation of America

Consumers Union

Families USA

National Legislative Association on Prescription Drug Prices

US PIRG

ⁱ About our organizations:

The American Antitrust Institute is an independent non-profit education, research and advocacy organization. Since its formation in 1998, the AAI's mission has been 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. To learn more about the AAI, please visit www.antitrustinstitute.org

Community Catalyst is a national non-profit advocacy organization dedicated to making quality, affordable health care accessible to everyone. Since 1997, Community Catalyst has worked to build consumer and community leadership to transform the American health system.

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*.

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, we have earned a national reputation as an effective voice for health care consumers for 25 years.

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.