Consumer Federation of America
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September 22, 2009

Senator Patrick Leahy, Chairman
Committee on the Judiciary
483 Russell Senate Office Building
United States Senate
Washington, D.C. 20510

Re: S. 369 -- "Preserve Access to Affordable Generics Act of 2009."

Dear Chairman Leahy:

We are the nation's leading consumer rights organizations, Consumers Union, the Consumer Federation of America, US PIRG and Community Catalyst. We write to clarify our position on S. 369 and to strongly urge you to include the provisions of S. 1315, proposed by Senators Kohl and Nelson, in the final version of the bill.[1]

Several of our groups wrote to you earlier this year in support of S. 369, the "Preserve Access to Affordable Generics Act" with the understanding that the legislation would establish a

[1] This letter explains why the Committee should include the provisions of S. 1315 in its approach to patent settlement reform. AARP has already expressed its support for the provisions of S. 1315 in a letter sent to Senator Nelson in June of this year. Their letter is attached.

bright line rule to prevent settlements that include exclusion payments. We now understand that certain provisions in the bill have been changed to require the FTC to engage in a complicated and lengthy litigation process. Although we would prefer a per se ban to these exclusion payments, we urge you to pass the revised S. 369 which will help clarify the law and will serve as a significant deterrent to these illegal settlements.

This legislation, however, should be significantly strengthened by eliminating a bottleneck created by the market exclusivity provisions of the Hatch-Waxman Act. Legislation proposed by Senators Kohl and Nelson (S. 1315) will correct the incentive system under the Hatch-Waxman Act to give later filers the opportunity to share in market exclusivity. Manipulation of the exclusivity provision is the cause of these illegal settlements and reforming these provisions is necessary to eliminate the settlement problem.

Rarely have the results of antitrust cases had as profound an effect on consumers as have the results in the pharmaceutical exclusion payment cases. The reality is simple: if courts permit exclusion payments, pharmaceutical patentees will use them to terminate patent challenges that would otherwise generate *billions* of dollars in consumer savings. The FTC has estimated that the potential loss to consumers from these settlements over the next ten years will exceed $35 billion. It is critical to prevent these exclusion payments so that consumers can benefit from a competitive market for generic drugs.

S. 369 Should be Amended to Eliminate the Exclusivity Bottleneck

As we suggested in our previous letter, any attempt to remedy the patent settlement problem must attack the true source of the problem: manipulation of the 180-day exclusivity period. Reverse payments are simply a symptom of the greater problem: the fact that under the existing Hatch-Waxman structure, only the first to file to challenge the patent has the right to market exclusivity. By limiting that right only to the first to file, Congress creates the incentive to enter into these settlements and deters other firms from challenging invalid patents or inventing noninfringing uses of the patented drug. Ultimately consumers lose.

As this Committee knows, the 180-day exclusivity period is the major reward for generic entry. After that period expires, profits are relatively minimal. Congress enacted the 180-day exclusivity period, to encourage generic firms to *challenge* patents. Originally courts interpreted the statute to give that exclusivity period to the first firm to successfully challenge the patent. Unfortunately, after the *Mova* decision, courts ruled that exclusivity went only to the first firm to challenge the patent.

Since the *Mova* decision some branded and generic firms have found that the preferable course to fighting a patent challenge is to settle and share the branded firm's monopoly. In other industries such a settlement may not be problematic because other firms can bring their own challenges and enter the market. But this is not true in the pharmaceutical industry – even if a later filer succeeds in invalidating the patent it cannot enter until after the first filer enters and secures its 180-day period of exclusivity. Without any opportunity to secure market exclusivity, there is little incentive for later filers to aggressively pursue patent challenges.

Every day that the first filer does *not* launch their generic drug, consumers lose out on potential savings. The exclusivity period itself has created an incentive to engage in these patent settlements, and only by attacking the exclusivity period will the patent issue be most effectively resolved.

Senator Kohl and Nelson's amendment provides a careful revision to the Hatch-Waxman Act to eliminate this unnecessary bottleneck to generic competition. It provides that if a later filer successfully challenges a patent, it can share in the 180-day exclusivity period.

We urge you to include a provision that fixes the distorted incentives created by granting the 180-day exclusivity period solely to the first firm to file a challenge. It is in the interest of consumers for invalid patents to be challenged and for generic drugs to enter the market as soon as possible. As S. 369 currently stands, potential subsequent filers have no incentive to challenge patents and offer their low-cost alternatives to consumers in dire need of affordable drugs.

The stated purpose of S. 369 is to "enhance competition in the pharmaceutical market." In order to create such a competitive market, Congress must eliminate the bottleneck of the current exclusivity provisions and create an incentive for firms to attack invalid patents or patents that may not be infringed. The most appropriate approach to this problem is by including the provisions of S. 1315.

We appreciate your consideration of our views as you grapple with this vital issue.

Sincerely,

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Appendix A

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

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.

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.

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.