

U.S. PIRG



Consumer Federation of America

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Nonprofit Publisher
of Consumer Reports

June 17, 2010

The Honorable Bill Nelson
United States Senate
716 Senate Hart Office Building
Washington, D.C. 20510

Dear Senator Nelson:

We are the nation's leading consumer rights organizations and advocates for meaningful change in Americans' access to affordable prescription drugs, Consumer Union, Consumer Federation of America, Families USA and U.S. PIRG.¹

We are writing to express our strong support for your amendment, SA 4361, to the American Workers, State and Business Relief Act, H.R. 4213. Your amendment will

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*.

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.

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.

address a major barrier to consumers' access to affordable generic drugs and the fundamental cause of pay-for-delay settlements, the anticompetitive arrangements that delay generic entry. These settlements cost consumers \$3.5 billion a year in lost savings, according to the Federal Trade Commission, and your legislation would help return those savings to American 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 the first generic challenger agrees to park its exclusivity in a pay-for-delay settlement, no other generic manufacturer can bring its competing product to market before the settling manufacturer uses its 180 day generic drug exclusivity rights – even if that doesn't occur for years. This eliminates the incentive for other generic competitors to fight to bring their competing versions to market early, thus fueling the settlement problem and turning the intent of the Hatch-Waxman act on its head. Instead of expediting timely consumer access to drugs, the Hatch-Waxman Act, through flaws in its structure, is being systematically exploited to delay timely consumer access to generics instead of facilitating it.

We support Senator Kohl's amendment to the same bill, SA 4332, which defines these settlements as illegal. However, it is imperative that the provisions of SA 4361 be included in any provision aimed at ending the settlement problem. Senator Nelson, your amendment would correct the systemic flaw in the Hatch-Waxman Act that is the root cause of the settlement problem and which costs consumers billions of dollars annually.

We thank you for introducing such important and necessary legislation, and we sincerely hope that it is enacted for the benefit of American consumers.

Signed,

Consumer Federation of America

Consumers Union

Families USA

US PIRG