



May 16, 2012

The Honorable Jeff Bingaman
United States Senator
703 Hart Senate Office Building
Washington, DC 20510

The Honorable David Vitter
United States Senator
516 Hart Senate Office Building
Washington, DC 20510

Dear Senator Bingaman and Senator Vitter:

On behalf of the Generic Pharmaceutical Association, I am writing to express our opposition to legislation that you have authored, S.1882, the FAIR Generics Act. We understand that it is your intent to offer your legislation as an amendment to the Food and Drug Administration Safety and Innovation Act when it comes to the Senate floor in the coming week. The generic pharmaceutical industry will no longer be able to support the user fee bill if this provision is added.

The Hatch-Waxman law has been a tremendous success. Over the past decade, generic drugs have saved the American health care system \$931 billion. A large part of the success of Hatch-Waxman is attributable to the incentives it provides to generic companies to challenge brand-name drugs patents. Instead of encouraging more timely access to low cost pharmaceuticals, S. 1882 would disincentivize generic pharmaceutical companies from challenging patents, jeopardizing consumer savings and disrupting the current climate of innovation and competition that has served patients so well since the creation of the generic industry.

As you know, current law provides 180-days of marketing exclusivity to the first generic company to challenge patents protecting the brand-name drug by submitting a paragraph IV application. Revenues from this incentive allow generic companies to recoup their substantial investments, providing the capital necessary to develop additional products and undertake future patent challenges. Since generic companies sell their products at only a small fraction of the brand price, the sales generated during the exclusivity period are vitally important to many companies' ability to continue to develop new generic products, mount new patent challenges, and maintain employees, all benefits to both patients and to taxpayers.

S. 1882 in fact undermines the 180-day incentive by redefining which company is entitled to the exclusivity and creating scenarios where a "first applicant" can potentially share in or take exclusivity from other companies. This scheme creates a great deal of uncertainty about which players will be entitled to the incentive. As you may be aware, in 2003 significant changes were made to Hatch-Waxman; importantly, a provision was added that allowed multiple companies to qualify for first filer status. The current system clearly allows our member companies, both large and small, to have an equal opportunity to gain the rewards of their commitment to manufacturing generic products.

In the absence of Congressional hearings examining these concerns, or the opportunity for our industry to raise these concerns in a public forum with policy makers, we do not feel that the multiple changes to Hatch-Waxman called for by this bill have been fully considered. With thousands of American jobs and billions of dollars in savings at risk, we feel that careful vetting of these concerns is warranted, and we respectfully request that you not offer S. 1882 as an amendment to the Food and Drug Administration Safety and Innovation Act when it is considered by the full Senate. If you have any questions regarding this request, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "Ralph G. Neas". The signature is written in a cursive, flowing style.

Ralph G. Neas
President and CEO