



April 25, 2012

The Honorable Tom Harkin  
Chairman  
Senate Committee on Health, Education,  
Labor, and Pensions  
428 Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Michael B. Enzi  
Ranking Member  
Senate Committee on Health, Education,  
Labor, and Pensions  
835 Hart Senate Office Building  
Washington, D.C. 20510

Dear Chairman Harkin and Ranking Member Enzi:

On behalf of the Generic Pharmaceutical Association (GPhA), we write in support of your work and the work of your staff on the Food and Drug Administration (FDA) user fee agreements that the Committee on Health, Education, Labor and Pensions is currently considering. GPhA applauds and shares your commitment to act without delay on the historic user fee proposals recently negotiated by industry and the FDA for both generic drugs and biosimilar products. These user fee programs will help ensure that American consumers continue to receive the significant cost savings from generic medicines that, over the past dozen years, have provided more than \$1 trillion in savings to our nation's health care system.

As you know, GPhA, the FDA and other stakeholders collaborated last year in the development of the proposed user fee programs. The intent of the programs is to provide FDA with additional resources and ensure all participants in the U.S. generic drug system, whether U.S.-based or foreign, comply with our country's strict quality standards. Most importantly, the programs will make certain that all Americans receive timely access to safe, effective and affordable generic drugs.

The Generic Drug User Fee Act (GDUFA) calls for the generic drug industry to pay \$299 million annually in user fees for the next five years, beginning October 1, 2012. This funding supplements federal funding appropriated each year by Congress. The additional user fees will help enhance the FDA's Office of Generic Drugs by obtaining the scientific resources and staff necessary for timely approval of generic medicines as well as generic manufacturer facility inspections – a requirement before FDA can approve new medicines. The Biosimilar User Fee Act (BSUFA) will benefit both industry and patients by providing a higher degree of certainty in the timeliness of application reviews. The program creates a separate review platform for biosimilar sponsors, to be financed annually through \$20 million of appropriated funds and supplemented by user fees equivalent to those under the Prescription Drug User Fee Act. It is vital that the Committee and the full Senate approve these agreements in a timely manner so that patients, the FDA, and generic manufacturers can begin to see their many benefits.

We are also supportive of the measure on drug shortages. This provision will increase communication between industry and FDA and will help mitigate prescription drug shortages. Moreover, GPhA and its members are currently working on the Accelerated Recovery Initiative (ARI), which provides a private/public sector solution to drug shortages. The ARI is part of GPhA's multipronged effort to ensure that patients have access to lifesaving generic medicines. We are confident that the ARI, coupled with the increased communication language in the underlying bill and the additional resources provided under the GDUFA agreement, will limit the duration and lessen the occurrences of prescription drug shortages.

Additionally, GPhA supports your language clarifying a provision in the Food and Drug Administration Amendments Act of 2007 with respect to restricted access drugs. This language will greatly improve the safety of our nation's drug supply and expedite consumer access to generic versions of these products. GPhA and its membership thank you for your assurance that this section will apply to biologic drugs, and we look forward to working with you and your staff to provide technical assistance related to bioequivalence protocols.

GPhA strongly urges the Committee to address the unintended consequences of the 30-month forfeiture provision in the Medicare Modernization Act (MMA) of 2003. The MMA established a number of situations in which a first generic filer may forfeit its 180-day market exclusivity, including if the applicant does not receive tentative approval from the FDA within 30-months of the date of receipt of its application. The median review and approval time for a generic application (ANDA), however, has increased since 2003 from 16 months to approximately 30 months. This unprecedented increase in approval time has caused several first filers to forfeit the 180-days of exclusivity, which was clearly not the intent of Congress. GPhA respectfully requests that the Committee address this unintended consequence by temporarily increasing the 30-month period to reflect today's increase in median ANDA approval time.

Finally, GPhA, along with numerous supply chain stakeholders including generic, brand and biologic manufacturers; large and secondary wholesalers; and chain and independent pharmacy (a group known as the "Pharmaceutical Distribution Security Alliance" or PDSA) have agreed to a consensus model for tracking drug products. Under the "RxTEC" model, manufacturers have committed to serializing products at the unit level and to maintaining databases capable of managing and verifying the serial numbers—two foundational aspects necessary to any drug tracking system. GPhA urges the committee to adopt the proposal that Senator Bennet and Senator Burr will offer to increase drug supply chain security.

We hope that the Committee will provide additional consideration of these policy provisions. We fully recognize the magnitude of the work you and your staff have been doing to move expeditiously the underlying user fee agreements. Nothing is more important to our industry than ensuring patients have access to the lifesaving and affordable generic medications they require. These historic agreements provide a critical step toward accomplishing this goal. Thank you again for your efforts and commitment. Please do not hesitate to contact GPhA if we can be of assistance in any way or provide any needed additional information.

Sincerely,

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

Ralph G. Neas  
President and CEO  
Generic Pharmaceutical Association