June 4, 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 Fred Upton
Chairman
House Committee on
Energy and Commerce
2183 Rayburn House Office Building
Washington, D.C. 20515

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

The Honorable Henry Waxman
Ranking Member
House Committee on
Energy and Commerce
2204 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairmen Harkin and Upton and Ranking Members Enzi and Waxman:

On behalf of the Generic Pharmaceutical Association (GPhA) and its member companies, we want to congratulate you on passing your respective bills to reauthorize the Prescription Drug and Medical Device User Fee Acts and to authorize the Generic Drug and Biosimilar User Fee Acts. Your bipartisan pieces of legislation are a testament to what Congress can do when it works together collaboratively and with industry stakeholders. The strong votes in the Senate and the House for your legislation are evidence of your hard work. As you begin to merge the Senate and House bills into a final package, we want to take this opportunity to express our support and concerns for certain provisions in each respective package.

GPhA strongly supports Section 862 of H.R. 5651, which addresses the unintended consequences of the 30-month forfeiture provision in the Medicare Modernization Act (MMA) of 2003. The MMA provision provided that a first generic filer forfeits its 180-day market exclusivity if the applicant does not receive tentative approval from the FDA within 30 months. The median review and approval time for a generic drug application (ANDA), however, has increased since 2003 from 16 months to more than 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. Section 862 of H.R. 5651 addresses this unintended consequence by temporarily increasing the 30-month period to 45 months to reflect the increase in ANDA approval times, then gradually phasing the period back down to 30 months as the FDA eliminates the backlog of pending applications. GPhA respectfully requests that the House provision be adopted.

Additionally, GPhA supports inclusion of Section 1131 of S. 3187. This language, which industry stakeholders carefully negotiated with the Senate Committee on Health, Education, Labor, and Pensions, clarifies a provision in the Food and Drug Administration Amendments Act (FDAAA) of 2007 with respect to restricted access drugs. This provision will greatly improve the safety of our

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nation's drug supply and expedite consumer access to generic versions of these products, while saving the federal government $750 million over the next decade. GPhA strongly supports the inclusion of this important provision within the final user fee measure. The alternative revenue raiser in H.R. 5651 is a modest change in the statutory language regarding citizen petitions. While the list of products that participate in REMS programs is definitive and competition on these products can be effectively predicted, the future filing of an unknown number of citizen petitions and the timelines and decisions of FDA in response to those petitions is entirely speculative. As such, forecasts of what, if any, budgetary effect the statutory change will have is highly uncertain. Given this uncertainty and the importance of prudent fiscal discipline, we encourage you to consider the REMs provision as a more reliable offset.

GPhA also supports the framework included in the Senate legislation for increasing drug supply chain security, and urges Congress to continue working to include a complete system in the final bill. The model proposed by Senator Bennet and Senator Burr is supported by the Pharmaceutical Distribution Security Alliance (PDSA) — a multi-stakeholder initiative whose membership, including GPhA, spans the U.S. pharmaceutical distribution system — and would increase patient access to safe medicines while improving the security of our country's drug distribution system. We recognize that discussions are still ongoing between Congress, the Food and Drug Administration (FDA), and stakeholders regarding a downstream supply chain security measure, but it is our hope that the final bill will contain a provision similar to the workable and effective model offered by PDSA.

Lastly, GPhA opposes Section 1141 of S. 3187, which would reschedule hydrocodone combination products from Schedule III to Schedule II. GPhA and the generic industry are strenuously committed to curbing the misuse of pain medications, but we are concerned that this provision would have the unintended consequences of restricting patient access to needed medicine and increasing costs to our health care system. These at-risk patients include seniors, the terminally ill, and patients with ailments such as upper respiratory infections and bronchitis. The Drug Enforcement Administration (DEA) and FDA routinely review the scheduling of all controlled substances, including hydrocodone, and that open, ordered process should be allowed to continue. For these reasons, GPhA urges that the Senate provision not be adopted in the final user fee legislation.

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,

Ralph G. Neas
President and CEO
Generic Pharmaceutical Association

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