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April 23, 2012

Dear Chairman Harkin and Ranking Member Enzi,

On behalf of the Pew Health Group, I am writing to express our strong support for the legislation to authorize the user fee agreements the Health, Education, Labor and Pensions committee will be considering on April 25, 2012.

Based on data, science, and non-partisan research, the Pew Health Group works to reduce risks to the health, safety, and well-being of American consumers. Pew applies a rigorous, analytical approach to improve public policy, inform the public, and stimulate civic life. The Pew Health Group operates a range of initiatives related to the safety and effectiveness of medical products and the regulatory framework that protects consumers and facilitates innovation.

Since 1992, user fee agreements have given the Food and Drug Administration (FDA) significant and sustained resources that allow the agency to review new products quickly. In fact, preliminary findings of a study that Pew has funded show that FDA reviews new drugs faster than its counterparts in the European Union and Canada. This bipartisan agreement will guarantee that FDA has the funding necessary to carry out its important public health mission.

We are particularly pleased that the Committee will be considering the Generic Drug User fee agreement. This landmark measure will enable FDA not only to review generic drug applications, but also to inspect overseas drug manufacturing facilities more regularly. Eighty percent of the ingredients in our pharmaceuticals come from foreign suppliers. Yet, while FDA inspects American manufacturers every two years, it lacks the resources to conduct effective inspections of facilities in places such as China and India. In fact, FDA inspects overseas facilities on average every nine years. Addressing this disparity will help protect patients from substandard drugs and will provide a level playing field for generic drug makers that manufacture their products and source their ingredients domestically.

The manager's amendment also includes three important policy initiatives that will promote public health and protect patients. We also support these provisions. They are:

1. **Drug supply chain safety:** The language regarding drug supply chain safety offers a comprehensive set of meaningful policies to reduce risks in our drug supply and increase patient safety. In particular we strongly support provisions that remove geographic disparities in FDA oversight of drug manufacturing, and ensure company oversight and control of drug ingredient supplies. Measures in this legislation to improve FDA's drug registration system will be critical to achieving these aims. We also support

increasing information flow to the FDA, including targeted authority to share confidential information with trusted regulators, as well as industry reporting of drug theft and counterfeiting. Finally, we support the numerous improvements made to border control systems, including FDA authority to turn away an imported drug if the plant making it has refused an inspection.

2. **Medical device safety and innovation**: This package includes a number of important provisions, such as expanding Sentinel to include medical devices that would strengthen the post-market safety system for these products. These measures would serve to better protect patients and generate much needed information about the safety of medical devices already on the market.

   We also applaud the Committee's proposals to advance a more efficient device regulatory scheme that facilitates innovation. Measures such as streamlining the "*de novo*" application process and reducing administrative barriers to classifying devices into the appropriate risk category will help ensure patients can access safe and effective medical devices in a timely manner.

3. **Antibiotic development:** The manager's amendment includes the bipartisan Generating Antibiotic Incentives Now (GAIN) Act. The policies proposed in this bill will help to spur the development of new antibiotics, and, in particular, focus incentives on new antibacterial drugs that treat serious and life-threatening infections. With the inclusion of this language, GAIN squarely targets the development of the most-needed new drugs—those to treat disease such as healthcare-associated and community-acquired pneumonia, complicated skin, intra-abdominal and urinary tract infections, sepsis, tuberculosis, meningitis, and other infections of vital organs and systems.

Thank you again for your commitment both to ensuring that FDA has the resources to review new products as quickly as possible and to making improvements to FDA's authority so that the agency can continue to promote the health of Americans. We urge you to pass this legislation quickly. If there is any additional information we can provide you, please do not hesitate to contact me at (202) 540-6392 or acoukell@pewtrusts.org.

Sincerely,

Allan Coukell
Director of Medical Programs
Pew Health Group