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May 7, 2012

Dear Chairman Pitts and Ranking Member Pallone,

On behalf of the Pew Health Group, I am writing to express our strong support for the legislation to authorize the user fee agreements that the Health Subcommittee of the Energy and Commerce Committee will be considering on May 8, 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 legislation you will be considering also includes three important policy initiatives that will promote public health and protect patients. We also support these provisions. They are:

**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.

**Antibiotic innovation:** The legislation includes the bipartisan Generating Antibiotic Incentives Now (GAIN) Act. The policies proposed in this bill will grant an economic incentive for the development of new antibiotics by granting exclusivity for certain qualified products. We encourage a continued effort to ensure that this incentive will squarely target the development of the drugs patients need most—those to treat serious or life-threatening diseases, such as healthcare-associated and community-associated pneumonia, complicated skin, intra-abdominal and urinary tract infections, sepsis, tuberculosis, meningitis, and other infections of vital organs and systems.

**Medical device safety and innovation:** This package includes several initiatives related to medical devices that would protect patients and streamline innovation, such as expanding Sentinel to include medical devices and reforming the *de novo* pathway. We support these provisions. However the legislation also contains provisions that restrict FDA's oversight of medical device clinical trials and require FDA to report to Congress before issuing a new guidance on 510(k) modifications. These provisions impose burdens on the agency and will not significantly advance either safety or innovation. We encourage the committee to narrow those provisions to ensure that they do not compromise the safety and effectiveness of medical devices. We also urge the committee to codify the agency's ability to order post-approval studies at the time a medical device is approved and to require that postmarket surveillance studies (known as 522 studies) are initiated within 15 months of the agency's order. These postmarketing surveillance measures will ensure that patients and clinicians have critical safety information about the products they are using.

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, please do not hesitate to contact me at (202) 540-6392 or [acoukell@pewtrusts.org](mailto:acoukell@pewtrusts.org).

Sincerely,



Allan Coukell  
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Pew Health Group