THE PEW CHARITABLE TRUSTS

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December 12, 2013

The Honorable Phil Gingrey
U.S. House of Representatives
442 Cannon House Office Building
Washington, DC 20515

The Honorable Gene Green
U.S. House of Representatives
2470 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Gingrey and Green:

The Pew Charitable Trusts thanks you for your continued leadership in addressing antibiotic resistance. You have already demonstrated your commitment to invigorating the antibiotic pipeline by championing the Generating Antibiotics Incentives Now (GAIN) Act, which was signed into law in July, 2012. The Antibiotic Development to Advance Patient Treatment (ADAPT) Act, introduced today, builds on that important legislation and is a welcome step towards establishing a new regulatory pathway to bring desperately-needed antibiotics to the patients who need them most.

Today, patients need treatments for increasingly common life-threatening infections such as those caused by carbapenem-resistant Enterobacteriaceae, or CRE. The Centers for Disease Control and Prevention recently classified CRE as an urgent threat, a "nightmare bacteria" that is resistant to our strongest antibiotics and is rapidly spreading across the U.S.

Your legislation would help streamline the regulatory pathway for antibiotics that could address CRE and other dangerous pathogens. It directs the Food and Drug Administration to approve new antibiotics for specific, limited populations of patients with life-threatening infections where few or no treatment options currently exist. Drugs approved under this pathway would be studied for use in smaller populations than other antibiotics. This will help lower development costs and make clinical trials more feasible. To reduce the likelihood that these drugs will be used in broader populations where the risk-benefit profile may be different, this legislation has several important safeguards. For example, it gives FDA the authority to review promotional materials before marketing and monitors how antibiotics approved under this pathway are being used.

The legislation also has some labeling requirements intended to communicate to physicians and other healthcare providers that these drugs have only been demonstrated to be safe and effective in limited populations. While these labeling requirements are a step in the right direction, we urge you to further strengthen them by requiring prominently placed language or other visual elements, so that the need to use these drugs prudently is immediately clear. Stronger labeling provisions would enhance the utility of this pathway and help ensure that patients who can be treated with other antibiotics are not put at unnecessary risk. Using these drugs in such a manner will also help preserve the effectiveness of these vital medicines.

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Lastly, we urge you to limit this bill to drugs for bacterial infections, as the need for new antibiotics, the dearth of new products in late-stage clinical trials, and the challenges associated with their development have been well-documented, as have the risks of indiscriminate prescribing. While new drugs for fungal infections would also be welcome, it is less clear that a limited population approach would be suited to antifungal development.

This new pathway tackles an important health problem with an approach that is good for public health and good for drug development. We look forward to working with you and other stakeholders to further improve the labeling language. Thank you again for your continued commitment to this important issue.

Sincerely,

Nicole Mahoney
Senior Officer, Antibiotics and Innovation
The Pew Charitable Trusts

Allan Coukell
Senior Director, Drugs and Medical Devices
The Pew Charitable Trusts