THE PEW CHARITABLE TRUSTS

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Senator Orrin Hatch
104 Hart Senate Office Building
Washington, DC 20510

Senator Michael Bennet
458 Russell Senate Office Building
Washington, DC 20510

Dear Senator Hatch and Senator Bennet,

On behalf of the Pew Charitable Trusts, a nonpartisan, nonprofit policy and advocacy organization, we are writing to thank you for reintroducing the Promise for Antibiotics and Therapeutics for Health (PATH) Act. We are grateful for your leadership in addressing antibiotic resistance.

According to the Centers for Disease Control and Prevention, 23 thousand Americans a year die from resistant infections. Organisms such as the increasingly common carbapenem –resistant Enterobacteriaceae, or CRE, are "nightmare bacteria" that are resistant to our strongest antibiotics. Yet few new drugs for CRE are in development.

The PATH Act would establish a new regulatory pathway to bring desperately-needed antibiotics to the people who need them most. It directs the Food and Drug Administration to approve new antibiotics that are demonstrated to be safe and effective for specific, limited populations of patients with life-threatening infections where few or no treatment options currently exist. Drugs approved under this pathway could be approved based on more limited datasets – meaning potentially fewer or smaller studies – 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 requires that drugs approved under this pathway bear a label or logo to communicate to physicians and other healthcare providers that these drugs have only been demonstrated to be safe and effective only in limited populations. This will help ensure that patients who can be treated with other antibiotics are not put at unnecessary risk and will also help preserve the effectiveness of these vital new medicines. The legislation also gives FDA the authority to review promotional materials before marketing and requires that the Department of Health and Human Services monitor how antibiotics approved under this pathway are being used.

While we are supportive of this pathway for drugs to treat serious and life-threatening bacterial infections, we ask that you consider limiting the legislation to antibiotics. 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. It is less clear that a limited population approach would be suited to other therapeutic areas.

This new pathway tackles the important problem of a dwindling pipeline of new antibiotics to treat patients with serious unmet needs with an approach that is good for both public health and drug development. Thank you again for you continued commitment to this important issue.

Sincerely,

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