PUBLICCITIZEN
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Dear Senator,

Public Citizen, a patient advocacy organization with more than 350,000 members and supporters nationwide, writes in coordination with the Patient, Consumer, and Public Health Coalition to express our strong opposition to the Promise for Antibiotics and Therapeutics for Health (PATH) Act (S 185), introduced by Senators Orrin Hatch and Michael Bennet.

We urge you not to support this bill, and we agree with other patient groups that the bill would be very dangerous to patients across the country.

We also agree that the purpose of the PATH Act, as stated at the beginning of the act, has been incorrectly described as covering antibacterial drugs only. As written, beginning on October 1, 2016, it would apply to *any* drug intended to treat a serious or life-threatening disease, condition, or infection, unless the FDA opts out of the expansion. This means the statute could apply far beyond antibiotics to include drugs for diabetes, heart disease, obesity, cancer, and many other diseases.

This bill would dangerously lower the standards for FDA approval of such drugs. Currently, the FDA usually requires that new drugs be approved based on evidence from one or more large, randomized, well-controlled clinical trials, or "Phase III" trials demonstrating safety and effectiveness. This bill would allow approvals based on much weaker evidence, which can include "alternate endpoints," "small clinical data sets," and "preclinical evidence, pharmacologic or pathophysiologic evidence, nonclinical susceptibility, pharmacokinetic data, and other such confirmatory evidence as the [FDA] deems appropriate."

Supporters of the bill have attempted to cover up this change in approval standards by adding a "rule of construction" stating that the current statutory standard for FDA approval will not be altered. Like the title of the bill, this language is misleading. The current statute requires evidence from "adequate and well-controlled investigations, including clinical investigations."[1] The FDA has long interpreted this to mean evidence from Phase III clinical trials. Yet, as noted above, the PATH Act would direct the FDA to consider much weaker types of evidence. The only possible effect of such language would be to pressure the FDA to grant approvals where strong evidence from well-designed, appropriately sized Phase III trials is lacking.

Worse, the general public would have little warning that the products approved under the PATH Act were not well tested. The drugs' labeling would read only that they had been tested and approved for use in a "limited population." Since every drug is tested and approved for use only among certain patients, this phrase would be meaningless to physicians and patients alike.

[1] 21 U.S.C. § 355(d).

The PATH Act has similarities to the very flawed Antibiotic Development to Advance Patient Treatment (ADAPT) Act, originally introduced in the House of Representatives by Congressman Phil Gingrey. However, the PATH Act is much broader, applying to virtually any innovative drug approved by the FDA, while the ADAPT Act would apply only to antibiotics.

Public Citizen is concerned about the problem of antibiotic resistance, but neither the PATH Act nor the ADAPT Act is the right way to combat this problem. We hope that you will work with patient groups to ensure that new antibiotics being approved for use in the U.S. are safe and effective, and also to preserve the long-term usefulness of these important drugs.

We would welcome the opportunity to speak with you further about this important public health issue.

Sincerely,

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