



the campaign for
environmentally responsible
health care

CAMPAIGN HEADQUARTERS

12355 SUNRISE VALLEY DRIVE
SUITE 680
RESTON, VA 20191
T: 703.860.9790
F: 703.860.9795
EMAIL: INFO@HCWH.ORG
WWW.NOHARM.ORG

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As health care professionals, we are writing in strong support of S. 185, the Promise for Antibiotics and Therapeutics for Health (PATH) Act. This legislation would establish a new, limited population, antibacterial drug approval pathway for antibiotics to treat serious or life-threatening infections for which there are few or no other treatment options. Without such a pathway, we fear that antibiotic research and development efforts will continue to lag, and patients will continue to die without effective treatments.

Antibiotic resistance remains a serious patient safety, public health, and national security concern. As a 2014 report by the President's Council of Advisors on Science and Technology (PCAST) noted, the development of antibiotic resistance is occurring at an alarming rate and far outpacing the development of new antibiotics. Antibiotic development has dwindled, with 29 new antibiotics approved during the 1980s, 23 in the 1990s, and only 9 in the decade that followed. One key reason has been the lack of a **clear pathway** for Food and Drug Administration (FDA) approval of antibiotics for limited populations of patients with some of the most serious infections caused by multidrug-resistant (MDR) pathogens. This is exactly what the PATH Act would address. The legislation also contains several important provisions to help guide the appropriate use of antibiotics approved under this new pathway. These protections will be critical to delivering optimal patient care while limiting the emergence of resistance to these new antibiotics. The PATH Act would also **maintain the existing standards of safety and effectiveness** that drugs have to meet for the U.S. Food and Drug Administration (FDA) to approve them.

Bringing Antibiotics to Patients Who Most Need Them

One of the main challenges in the development of new drugs that treat highly resistant bacterial infections identifying and enrolling infected patients in sufficient numbers to conduct traditional, large-scale clinical trials. PATH would address this challenge by allowing FDA to approve antibiotics that treat serious or life-threatening infections on the basis of human clinical trials in limited populations of patients who have an unmet medical need.

Under this legislation, FDA would consider the benefits and risks for the sickest patients with few or no treatment options against patients who may tolerate a higher level of risk than patients who have other options. However, the legislation does not lower the approval standard. A drug developer would still be required to demonstrate to FDA that the drug is safe and effective in the limited population of patients.

Appropriate Use of Antibiotics

Treating patients with severe infections is challenging—particularly when a patient presents with a new emerging infection for which there are no existing treatments. This bill would not limit a physician’s ability to choose the most appropriate drug. In such instances, a physician must have the ability to use his or her best clinical judgment to provide the best available antibiotic. Importantly, the bill does contain several important provisions that would greatly **reduce the likelihood that limited-population drugs would be used in patients for whom the drugs may not be appropriate**. The bill requires that the drug bear a label that would signal to prescribers and dispensers that the drug was approved under this alternate pathway. The bill would also give FDA the authority to review promotional materials about the drug prior to their distribution, exactly as is done under the existing Accelerated Approval pathway. In addition, it would require that the Department of Health and Human Services monitor the use of antibiotics approved under this pathway and assure they are being used as intended.

We recognize that the PATH Act alone will not solve the problem of antibiotic resistance. We are working tirelessly on other efforts to promote antibiotic stewardship in all settings including advocating for judicious use in food production, surveillance of current use, and education of patients and peers on this issue. However, the PATH Act will encourage the development of urgently needed new antibiotics to treat highly resistant infections currently causing life-threatening complications and death among our patients.

We hope Congress recognizes the urgency of this problem by passing PATH and will continue to champion legislative action to monitor and end the inappropriate overuse of antibiotics.

Sincerely,

The undersigned health professionals: