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Open a 'PATH' for new antibiotics

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The new outbreaks of so-called “nightmare bacteria” in California and North Carolina are a tragic reminder that strains of bacteria are evolving quickly to withstand every antibiotic we have at our disposal. Meanwhile, the pace of development for new antibiotics has slowed. The so-called “superbugs” are winning the race against time -- a race humankind can't afford to lose.

The bacteria known as CRE, or *carbapenem-resistant Enterobacteriaceae*, are highly resistant to antibiotics. Patients who contract these infections are often already sick, and all too often succumb. The threat is spreading. In 2001, just one state, North Carolina, had seen an outbreak of CRE. By 2015, CRE had been found in 48 states, with only Idaho and Maine exempt so far. The latest outbreak in Los Angeles has claimed two lives, and sickened more than 50 people.

Public health authorities are sounding the alarm, and congressional leaders are investigating how patients were exposed. Preventing infections in the first place is the first line of defense, along with careful use of our existing antibiotics to preserve their effectiveness. But unfortunately prevention and good antibiotic stewardship are not enough.

It's clear that we must develop new antibiotics to combat resistant bacteria. However, the number of new antibiotics in the drug development pipeline has fallen dramatically in recent years. There were 29 new antibiotics approved during the 1980s, and 23 in the 1990s. Only nine were approved in the decade that followed.

Meanwhile, some of the most urgently needed medicines are held up in the approval process as researchers struggle to meet the requirements for traditional clinical trials. We don't have an efficient path in place to bring antibiotics to market to address some of the most serious, drug-resistant bacterial infections, such as CRE.

New legislation in Congress could clear some of the regulatory hurdles drug makers face. Introduced by Sens. Orrin Hatch (R-Utah) and Michael Bennet (D-Colo.), the Promise for Antibiotics and Therapeutics for Health, or “PATH” Act aims to promote antibiotic development by creating a new pathway to approve these new drugs for patients who are out of options. Similar legislation is being considered in the House Energy and Commerce Committee.

The bills provide for more feasible clinical trials with limited numbers of patients who are battling dangerous bacterial infections like CRE – patients with few, if any, options for treatment. They also outline safeguards to make sure the drugs are used with great care, and their approval does not contribute to the problem through overuse.

The latest outbreaks demonstrate the continued and growing threat of antibiotic resistance. As physicians who are deeply troubled to see more and more patients with drug-resistant infections, we are gratified to see more attention to this issue. We hope Congress continues to recognize the urgency of this problem and passes PATH soon – for the sake of every patient, and the safety of society as a whole.

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