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August 1, 2019

Representative Danny K. Davis
2159 Rayburn House Office Building
Washington, DC 20515

Representative Kenny Marchant
2304 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Davis and Marchant,

I am writing in support of H.R. 4100, the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act of 2019 on behalf of The Pew Charitable Trusts – an independent, non-profit research and public policy organization with a number of initiatives focused on addressing the urgent public health threat of antibiotic resistance.

DISARM would provide an economic incentive for new antibiotic development by removing certain antibiotics from the Diagnosis-Related Group (DRG), thus removing the incentive for hospitals to choose lower-cost antibiotics. The legislation would also strengthen the stewardship of these critically important drugs by requiring participating hospitals to implement stewardship programs that meet the Centers for Disease Control and Prevention’s core elements of antibiotic stewardship programs.

The World Health Organization (WHO) ranks antibiotic-resistant bacteria as one of the top 10 most urgent global health threats of 2019, yet there are currently only 11 antibiotics in development with the potential to treat the antibiotic-resistant pathogens deemed most dangerous by WHO. Only a handful of these candidate drugs are likely to be approved and brought to market—too few to meet the growing threat. Already, more than 60 percent of infectious disease doctors in the United States have seen patients with infections that did not respond to any available antibiotics, and pathogens continue to evolve to resist available drugs. Without new antibiotics, we will revert to a time when “routine” infections become lethal and regular medical care and procedures far riskier. There is an urgent public health need to reinvigorate the antibiotic pipeline.

The market for small-molecule antibiotics is categorically different from other therapeutic areas. These drugs have low initial sales volume for a variety of reasons, including because older drugs are used preferentially to slow emerging resistance to newer drugs. Furthermore, pricing and reimbursement for new antibiotics is typically low, because most infections can be treated with existing drugs. These factors and others have led pharmaceutical companies to reduce or even abandon antibiotic research and development, and many remaining companies are struggling to sustain operations.

The solution will require a variety of economic incentives to reignite antibiotic discovery and development. Adjusting how Medicare reimburses antibiotics is one way to encourage drug development and ensure patient access to the most effective antibiotics. By carving antibiotics out of the DRG, DISARM would remove the incentive for hospitals to select lower-cost products, thus allowing companies to set higher prices for new antibiotics and, potentially, incentivizing their use. This could benefit patients in the specific instance that older drugs are being used even when newer products are clinically preferable. Higher reimbursement would help stabilize the market and guarantee these life-saving drugs are readily available when patients need them.

At the same time, taking antibiotics out of the DRG must not create a perverse incentive for inappropriate overuse of these drugs and we look forward to working with you and key stakeholders to ensure that this new reimbursement model does not encourage inappropriate use of these critical drugs. We strongly support the stewardship provisions included in DISARM. Requiring hospitals using this reimbursement to implement a stewardship program and participate in CDC's National Healthcare Safety Network Antimicrobial Use and Resistance Module is key to combatting the rise of resistant pathogens and preserving the effectiveness of the antibiotics we have today.

Antibiotic resistance poses a unique public health threat, and antibiotic developers face well characterized market failures that significantly impede the development of new drugs. It is this set of circumstances, which are specific to small molecule antibiotics, that this proposed reimbursement policy seeks to address. We applaud you for your leadership and dedication to addressing the pressing threat of antibiotic resistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Allan Coukell". The signature is fluid and cursive, with a large initial "A" and "C".

Allan Coukell
Senior Director, Health Programs
The Pew Charitable Trusts