

BIO Leads New Group Pushing For Antibiotic Incentives, DISARM Act

By David Roza August 23, 2019 at 4:04 PM

A new group led by the Biotechnology Innovation Organization (BIO) is urging Congress to create additional incentives for drug and biologic makers to develop innovative antibiotics, starting with passage of the Medicare add-on payments included in the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act of 2019.

The group, Working to Fight AMR, includes representatives from Merck, Novo Holdings, Paratek Pharmaceuticals and Boston University School of Law. Greg Frank, the director of the group and director of infectious disease policy at BIO, said his new cohort might also lobby for market entry rewards, which could provide a return for companies that invest in successful, critically needed antibiotics.

"Working to Fight AMR aims to enact a package of incentives--policies and programs that would reinvigorate the pipeline of antibiotics for the long term, while ensuring patients can easily access treatments and that these medicines are used safely and appropriately," Frank wrote to *Inside Health Policy*.

The new group announced its formation on Wednesday (Aug. 21), the same week FDA approved Xenleta, <u>a first-in-class antibiotic for pneumonia</u>, <u>and six days after the agency approved Pretomanid</u>, a new drug for treatment-resistant forms of tuberculosis. With each announcement, stakeholders called attention to the difficulty of developing new antibiotics, especially when health care providers are encouraged to use new drugs sparingly to slow the growth of antibiotic resistance.

Working to Fight AMR is the latest group calling for better incentives for antibiotic development, and for now its prime objective is to get the bipartisan DISARM Act passed. Introduced by Senate health committee members Bob Casey (D-PA) and Johnny Isakson (R-GA) in June, and by Reps. Danny Davis (D-IL) and Kenny Marchant (R-TX) in July, the bill would allow Medicare to offer an add-on payment to inpatient hospitals that use a qualifying antibiotic to treat a serious or life-threatening infection.

In order to qualify for the payments, hospitals must participate in the Centers for Disease Control and Prevention's antibiotic stewardship program.

In a press release, Casey said he hopes the bill will strengthen the antibiotic development pipeline, which has come under fire from experts for not moving fast enough to meet a surge of antibiotic resistance.

Frank believes DISARM could do just that by appropriately reimbursing hospitals that use new therapies.

"By tying higher payments to stewardship programs, hospitals will be more likely to use newer, more advanced therapies," Frank said. "In turn, that helps to create a market for companies to develop new treatments we desperately need to combat drug-resistant infections."

Frank added that DISARM is one piece of a package of incentives that Working to Fight AMR hopes to enact. The group also wants to see a "pull" incentive, which would reward companies for successful FDA approval of new antibiotics that meet critical public health needs. A pull incentive could spur a long-term, sustainable model for new antibiotic development, Frank said.

Many stakeholders have called for similar incentives in the past. In February, <u>BIO and 12 other signees sent a letter</u> to the Senate health and Finance committee leaders asking them to pass a package of new incentives, including a subscription- or population-based reimbursement system where hospitals would play a flat rate for

access to a certain number of doses of a new antibiotic. <u>Former FDA Commissioner Scott Gottlieb called for a similar system</u> in September.

The signees included The Pew Charitable Trusts, the Infectious Diseases Society of America (IDSA) the Antimicrobial Innovation Alliance and the Antimicrobials Working Group, which includes 14 pharmaceutical and other medical product companies.

Adding to the long list of antibiotic-focused alliances, there is also the Stakeholder Forum on Antimicrobial Resistance (S-FAR), a partnership of more than 100 health organizations convened by IDSA and dedicated to advancing federal policy on antibiotic development. S-FAR is a much broader coalition of stakeholders than Working to Fight AMR, an IDSA spokesperson explained, but the two do share many of the same goals.

"IDSA is not an explicit partner in the new Working to Fight AMR coalition led by BIO because this new coalition is industry focused," the spokesperson said. "However, IDSA continues to work closely with BIO, other industry partners and other key stakeholders to advance policies to spur antibiotic R&D and advance antibiotic stewardship, including the DISARM Act." -- David Roza (droza@iwpnews.com)

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