

May 8, 2020

Rep. Nancy Pelosi
Speaker of the House of Representatives
1236 Longworth H.O.B.
Washington, DC 20515

Sen. Mitch McConnell
Senate Majority Leader
317 Russell Senate Office Building
Washington DC 20510

Rep. Kevin McCarthy
House Minority Leader
2468 Rayburn House Office Building
Washington, DC 20515

Sen. Chuck Schumer
Senate Minority Leader
322 Hart Senate Office Building
Washington, D.C. 20510

Dear Speaker Pelosi, House Minority Leader McCarthy, Senate Majority Leader McConnell, and Senate Minority Leader Schumer:

We are writing to urge swift Congressional action to combat the growing and urgent threat of antibiotic-resistant bacteria as part of the ongoing COVID-19 response.

Antibiotics underpin all of modern medicine and effective antibiotics are needed to help protect us from multidrug-resistant bacteria that will inevitably emerge in the future, but they also are essential now. As we are facing the COVID pandemic, we need to remember that antibiotics are needed to protect [COVID-19 patients](#) who have weakened immune systems, or those who may be on ventilators, and are therefore at increased risk for secondary bacterial infections. According to recent studies in The Lancet, there is already some evidence of secondary infections among coronavirus patients.^{1,2} And many [healthcare leaders](#) are expressing concern about the risks of bacterial infections associated with COVID- 19.

Unfortunately, [Pew's most recent assessment](#) shows that far too few antibiotics are in development with even the potential to treat the most dangerous superbugs. And that is unlikely to change without meaningful government intervention to fix what has become a [broken antibiotic market](#). In 2019, two companies with recently FDA-approved antibiotics filed for bankruptcy. Earlier this year, a third company, also with a recently FDA-approved drug, was acquired for only \$14.4M.

At the same time, the uptick in global use of antibiotics during this pandemic is going to [accelerate the emergence of resistance](#) and amplifies the need for effective and robust antibiotic stewardship and surveillance. The aforementioned Lancet publication noted the use of antibiotics as part of treatment strategy for patients hospitalized with COVID-19 infections to thwart potential secondary bacterial infections^{3,4,5}, hence increasing likelihood of resistance to these critical drugs.

Among the many grim reminders of COVID-19 has been the critical importance of preparedness. There is no time to waste. We urge you act now to enact a package of incentives that would stabilize the antibiotic market and address the challenges that make antibiotic development economically infeasible for both small and large companies, while ensuring patient access and preserving the effectiveness of existing drugs. This package should include a combination of reimbursement reform, such as the DISARM Act, along with additional AMR-targeted funding for BARDA to support commercialization and for CDC to improve stewardship (including program implementation at hospitals) and surveillance.

These alone will not fix the market failure. We need an ecosystem that supports sustainable discovery, development, and commercialization of novel, innovative antibiotics, and preserve these vital drugs and the health care advances they make possible. Hence, a program for market entry rewards for successful development of FDA-approved antibiotics is needed. [GAO](#), in a report issued last month, recommends a strategy to incentivize research and development for antibiotics, including post-market financial incentives such as market entry rewards. One type of reward that recently has gained traction is a subscription model, which provides antibiotic developers a return on investment that is not dependent on

volume of sales.

¹ <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2930183-5>

² [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30566-3/fulltext#tbl2](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30566-3/fulltext#tbl2)

³ <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2930183-5>

⁴ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30211-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30211-7/fulltext)

⁵ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30566-3/fulltext#tbl2](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30566-3/fulltext#tbl2)

Market entry reward policies, including those for subscription models, should incorporate these key principles:

1. Eligibility should be determined based on unmet medical needs, with considerations for novelty of antibiotics as well as other innovative attributes of the drug. This determination should be made with input from external stakeholders with expertise in antibiotics R&D and commercialization, infectious disease, economic implications of AMR, and public health.
2. Size of the award should be sufficient to revitalize the market and support reinvestment in R&D. The program could also include value-based tiering to provide flexibility for awarding diverse product profiles and adjust award size.
3. Incentives should be paid out over a period of years after FDA approval rewarding only successful development of novel antibiotics that address the greatest public health need.
4. The program should include a mechanism to make companies accountable for surety of supply.
5. The program should provide some measure of predictability for drug developers so that participating companies can commit development funding up front with some assurance that the economic incentive will be available if the new drug meets eligibility criteria.
6. Incentives must be aligned with appropriate antibiotic stewardship, diagnostic testing and surveillance activities.

Any such policies must be paired with efforts to ensure the drugs are used appropriately, including by effectively leveraging diagnostic testing and laboratory expertise, along with measures to track antibiotic use and resistance rates. This requires adequate federal funding for hospitals, especially small, rural and critical access hospitals to help them establish stewardship programs and begin reporting antibiotic use and resistance data to CDC. Such support could be provided in conjunction with this program.

As Congress considers additional action in the fight against COVID-19 and examines how the U.S. can be better prepared for emerging public health challenges, please remember the fundamental importance of antibiotics. These lifesaving drugs not only help to protect patients during a pandemic, they also make possible modern medicine as we know it.

Thank you for continued work to protect your constituents and our country from the public health and national security threats posed by antibiotic-resistant bacteria.

Sincerely,

Accelerate Diagnostics,
Inc. AdvaMedDx
American Academy of Allergy, Asthma and
Immunology American Gastroenterological Association
American Society of Tropical Medicine and
Hygiene Association of Public and Land-grant
Universities BIO
Center for Disease Dynamics, Economics &
Policy CommonSpirit Health
Cystic Fibrosis
Foundation
GlaxoSmithKline
Health Care Without Harm
Infectious Diseases Society of America

Making-A-Difference in Infectious
Diseases Merck & Co.
Michigan Antibiotic Resistance Reduction Coalition
National Association of Pediatric Nurse Practitioners
National Tuberculosis Controllers Association
Sepsis Alliance
Small World
Initiative Spero
Therapeutics Stop TB
USA
Summit Therapeutics
The Emory Antibiotic Resistance
Center The Gerontological Society of
America
The Johns Hopkins Center for a Livable
Future The Pew Charitable Trusts
The Society of Critical Care Medicine
The Tufts Center for Integrated Management of Antimicrobial Resistance (CIMAR)
Trust for America's Health