Written Testimony
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Superbugs have long been the enemies of civilization. From the Black Death in the Middle Ages (plague bacteria), to the recognition that cholera was caused by something in the water at the Broad Street pump, to modern bacterial and fungal infections – we have been locked in a ceaseless struggle with these microscopic foes.

For a brief period in the 20th Century, it looked like we had the upper hand. Antibiotics like penicillin were life savers – beginning with soldiers in World War 2. But even at the celebration the Nobel Prize for penicillin in 1945, we knew that every time we use these drugs, we reduce their effectiveness for future patients. Unlike any other drug class, anti-infectives[2] decline in effectiveness through use. Genetic mutations and transfers amongst microbial life eventually result in superbugs immune to our best drugs.

For superbugs, past innovations aren't enough. We must continually innovate to remain one step ahead. The global death toll today is staggering: almost 5 million deaths per year from bacterial infections, 1.3 million of those from bacteria that now evade our drugs.[3]

In the US, resistant bacteria cause 2.8 million infections, kill more than 35,000 Americans per year, and sicken many more of our citizens who survive.[4] COVID only made things worse, with a 15% increase since 2020.[5] The economic damage is also significant. The most serious resistance threats add at least $1.9 billion in Medicare costs and more than 400,000 hospital days annually. They add more than $4.6 billion each year in additional costs to our healthcare system.[6] This estimate does not include productivity losses in economic activity and does not put any price on the human lives lost. These estimates are only from drug-resistant bacteria and don't yet include estimates from other superbugs like the fungi on the CDC threat list.

Americans rely on effective antibiotics. Every hospital in your district, every cancer patient, every new mom with a C-section, any soldier with infections, or even folks my age thinking about knee or hip surgery – all of us depend on effective antibiotics to enable modern medicine. But resistance eats away at the effectiveness of these wonderful drugs, like rust weakens a bridge. When

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[1] I testify today in my personal capacity. My testimony is not necessarily the opinion of Boston University, CARB-X, or any CARB-X funder.
[2] Including antibacterials, antifungals, antiretrovirals, antivirals, and antiparasitics.
[3] IHME. The burden of antimicrobial resistance in G7 countries and globally. https://www.healthdata.org/research-analysis/library/burden-antimicrobial-resistance-g7-countries-and-globally
[4] https://www.cdc.gov/drugresistance/national-estimates.html
[5] https://www.cdc.gov/drugresistance/pdf/covid19-impact-report-508.pdf
[6] https://www.cdc.gov/drugresistance/solutions-initiative/stories/partnership-estimates-healthcare-cost.html

antibiotics become less effective, everything in modern medicine becomes more difficult and dangerous.

Between 2019 and 2023, the CDC reported a 460% spike in infections caused by a highly resistant superbug NDM-CRE increased "nightmare bacteria" which are difficult to treat, associated with high rates of morbidity and morality, and have the potential to spread quickly through health care systems and the community. [7]

This is a national security issue: it threatens the readiness of American troops as well as the American workforce and health care system, imposing needless death, suffering, and expense on our people. But remember that antibiotic and antifungal drugs used today are gradually losing effectiveness. They must be continuously replaced to avoid falling behind.

Superbugs need new drugs

On new drugs, I have some good news and bad news. For the past two decades, I have studied the pipeline for these drugs. First, the bad news. For drugs already in human testing, there is an embarrassing shortfall: about four dozen antibiotics compared to more than a thousand cancer drugs. Cancer drugs make money, so future cures are always moving towards patients. Antibiotics lose money in our current reimbursement system, with predictable results on innovation.

But there is also good news. BARDA has played a critical role in strengthening the antibacterial innovation ecosystem. This has included launching and being a critical partner to CARB-X, a successful push incentive that I lead, that is helping sustain an early-stage pipeline of innovative products, that contribute to U.S. health security and preparedness. The National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH) also plays an important role as another long-standing partner to CARB-X, providing important in-kind scientific and preclinical development support.

The preclinical pipeline is filled with outstanding products, the fruit of investments by CARB-X. Since being launched, CARB-X has garnered support from 6 of the G7 Governments, the European Commission, and three large Foundations. We have been successful these first 10 years in our primary mission, by delivering 28 therapeutic, diagnostic, and prevention products into first-in-human clinical testing. This preclinical pipeline is amazingly innovative, but fragile from the need for additional public push incentives and private investment. Data from the Global AMR R&D Hub suggests that push incentives are underfunded by several hundred million dollars per year globally if the goal is to bring 6 highly impactful new antibiotics to FDA approval in the next decade.[8]

Holding antibiotics in reserve drives companies into bankruptcy or to other therapeutic areas

Antibiotics are valuable, but the market is broken: scientists work on new antibiotics for decades. Most fail because science is hard. FDA approval is a time for celebration in all other therapeutic areas – but for new antibiotics, the payday never comes. Because of resistance, doctors rightly

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[7] https://www.cdc.gov/media/releases/2025/2025-cdc-report-finds-sharp-rise-in-dangerous-drug-resistant-bacteria.html

[8] Kevin Outterson, Presentation at the Meeting of the Global Leaders Group on Antimicrobial Resistance, Feb. 8, 2023.

want to reserve the newest antibiotic for the future, putting them on the shelf, behind glass like a fire extinguisher. The fire extinguisher company gets paid when preparedness starts, not when the fire starts. We are paying for new antibiotics only after the fire. A new drug that isn't used much in the early years can't make money.

In the last decade, just eleven antibiotics have been approved by the FDA from small companies.[9] Every one of them has either gone bankrupt or their R&D investors lost their shirts, as non-generic sales of antibiotics are in free fall over the past two decades.[10]

Data from my 2023 publication in *Nature Reviews Drug Discovery* demonstrates the $150 billion revenue gap in on-patent antibiotic sales since 2001, which has driven so many companies from the field.

Contract models can restore innovation at an affordable price

Antibiotic contract mechanisms should be carefully crafted to ensure that taxpayers get a good deal. They must focus only on the most promising new drugs. The required size of these antibiotic contracts is well understood. Payments from contracting mechanisms can start at an appropriate point and increase over time if stronger evidence is presented on the importance of the new drug. We should pay for secure supply chains, not just the cheapest.

Now is the time to respond to this national security crisis. We must change the way we pay for antibiotics. After nearly two decades studying this problem,[11] G7 governments are creating antibiotic subscriptions to reward innovation while allowing the new antibiotic to be used sparingly at first.[12] If Congress creates a contract model program, Americans will get the new antibiotics we need – sitting on the shelf ready to go, like that fire extinguisher – and the companies will also get what they need to incentivize their R&D activities, commercial viability instead of bankruptcy. Action by the US would also galvanize other G7 countries to contribute their fair share as well.

Antibiotic contract models should be crafted carefully to ensure that U.S. taxpayers get what they need without overpaying. For example, they must focus only on the most promising new drugs, which has been the consensus position since the Chatham House report in 2015.

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[9] zoliflodacin (2025, Innoviva), sulopenem (2024, Iterum). Cefepime/ enmetazobactam (2024, Allecra / Orchid), Vowst (2023, Seres), sulbactam/ durlobactam (2023, Entasis), Lefamulin (2019, Nabriva), omadacycline (2019, Paratek), eravacycline (2018, Tetraphase), plazomycin (2018, Achaogen), meropenem/ vaborbactam (2017, Melinta), delafloxacin (2017, Melinta).

[10] Madden J, Outterson K. Trends in the global antibiotics market. Nat Rev Drug Disc. 2023 Mar; 22(3):174.

[11] Major reports include Bad Bugs, No Drugs (IDSA, 2004), ASPE/HHS (2014), President's Council of Advisors on Science & Technology (2014), Chatham House (UK, 2015), AMR Review (UK, 2016), GUARD/BCG (German Federal Ministry of Health, 2017), PACCARB (2017), DRIVE-AB (EU, 2018), GAO (2020), Duke-Margolis (2020), BCG (2022), PwC for HERA (EU, 2022), London School of Economics for the Swedish Presidency of the Council of the European Union (2023). I was a co-author of three of these reports and was interviewed or testified as an expert for eight others. Believe me when I say this problem has been adequately studied by governments and think tanks.

[12] Subscription programs or revenue guarantees are officially launched or announced in England and Japan. The EU Council and Parliament has included Transferable Exclusivity Vouchers (a form of pull incentive) in the update to the EU General Pharmaceutical Legislation. Canada is in the final stages of designing a pull incentive pilot, to improve antibiotic access in Canada.

While earlier proposals suggested paying pull incentives in a lump sum (often called a market entry reward), DRIVE-AB suggested it could be paid over longer periods of time to reduce the risk of lemons or non-compliance. The UK subscription adopted a 10-year payment period and the re-introduced PASTEUR Act in the 119th Congress spreads the pull incentive over the longer of 10 years or the remaining patent and exclusivity period, which will incentivize the sponsor to minimize patent extensions and facilitate generic entry after the contract is concluded. The BEAM Alliance, representing small antimicrobial companies in Europe, has previously proposed key features of pull incentives:

- The call for rapid implementation reflects the urgency of the medical situation, as well as the business urgency for small companies with less than a year of cash on hand with which to fund R&D operations.

- Delinking revenues from sales solves the key problem with antibiotics and antifungals by rewarding the sponsor for bringing a high-quality new drug to the market, even if it will be used only in modest volumes in the early years. Delinking also supports proper stewardship since incentives to oversell are no longer present.

- On the issue of "sufficient magnitude", *Health Affairs* published my comprehensive estimate of the appropriate size of antibacterial subscriptions in 2021, using only publicly available data in a fully transparent expected net present value model.[13] The "fair share" of these costs that should be borne by each G7 government + the European Union has been presented in several conferences[14] and was adopted in a November 2019 analysis by the Center for Global Development.[15] As a result of this work, we now know the required size of an antibiotic subscription in the US, as well as the fair share for other wealthy countries.

Ranges are appropriate for contract payments, with higher payments going to drugs meeting higher standards. With the evidence available at FDA approval, qualifying drugs can start at an appropriate point and increase over time if stronger evidence is presented of the importance of the new drug.[16]

The contract model in PASTEUR will be remarkably good value for the US taxpayer. The Center for Global Development forecasts a financial return on investment for Americans of 6:1 over a decade, and 28:1 over 30 years.[17]

From data I published in *Nature Reviews Drug Discovery*, we know that a US contract mechanism would cost less than what we spent on on-patent antibiotics just five years previously.[18] This is

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[13] Outterson K. Estimating the appropriate size of a global antibacterial pull incentive. Health Affairs. 2021; 40(11):1758-1765.
[14] E.g., Outterson, K. ISPOR (Vienna, Austria, Nov. 8, 2022); HGPI (Tokyo, Japan, Sept. 22, 2022)
[15] https://www.cgdev.org/blog/world-needs-new-antibiotics-proposed-us-program-develop-them-would-pay-281.
[16] Rex JH, & Outterson K (2016). Antibiotic reimbursement in a model delinked from sales: a benchmark-based worldwide approach. *LANCET INFECTIOUS DISEASES*, *16*(4), 500-505. doi:10.1016/S1473-3099(15)00500-9.
[17] https://www.cgdev.org/blog/world-needs-new-antibiotics-proposed-us-program-develop-them-would-pay-281.
[18] Madden J, Outterson K. Trends in the global antibiotics market. Nat Rev Drug Disc. 2023 Mar; 22(3):174.

affordable because we did it ourselves, very recently. It is time to invest in the future of antibiotics and antifungals once again.

By restoring some common sense to the market for antibiotics, new contracts with the USG will bend the curve towards innovation. Globally, the health impact is striking: subscriptions will save 9.9 million lives over the next 3 decades, according to the Center for Global Development.[19]

I know this not just based on the work of many experts, but because in a sense, I have seen the future. At CARB-X, we see the most promising new antibiotic candidates 10 – 15 years before their potential FDA approval. That future is bright so long as you continue to support push incentives and complement them with a new pull incentive like the antibiotic subscription in the re-introduced PASTEUR Act. At CARB-X, we mainly work with very small start-up companies with highly innovative new products, including phages, diagnostics, vaccines, and many first-in-class products. More than two dozen of these companies have initiated first-in-human testing. The future can be filled with a sustainable supply of new antibiotics. I am confident because at CARB-X we know this pre-clinical pipeline intimately. The key barriers today are economic, which is why we need both push and pull incentives.

Threats from bacteria are significant today and will be worse tomorrow. If you want a steady stream of life-saving innovation in a decade, you must act today. We need the fire extinguisher before the fire starts. Let's be well prepared, so bacteria don't steal a march on the health of Americans.

Thank you for your attention today. Additional background on CARB-X is found in Appendix A.

[19] https://www.cgdev.org/blog/world-needs-new-antibiotics-proposed-us-program-develop-them-would-pay-281.

Appendix A: CARB-X background

CARB-X is a push incentive supported by a global consortium of governments and private health foundations, including 6 of the G7 governments, the European Commission, Wellcome, Gates Foundation and the Novo Nordisk Foundation.

The first-ever independent, peer reviewed evaluation of a push incentive to address antimicrobial resistance found that R&D projects supported by CARB-X have nearly five times greater odds to advance into clinical development than projects of similar quality that were not funded by the global initiative. Researchers also observed positive associations with patent activity and the continued operation of both the project and firm, though the latter were not statistically significant.

CARB-X funds the development of antibiotics, preventatives, rapid diagnostics and other life-saving projects that target the most dangerous resistant bacteria, syndromes with high morbidity and mortality, and performance characteristics necessary to aid clinicians' infection response and improve patient outcomes. The CARB-X portfolio has consisted of 124 innovative antibacterial projects since 2016, advancing 28 into first-in-human clinical trials. Thirteen developers have advanced development partnerships to support their projects after completing the CARB-X program. Three products have reached the market, including two diagnostics and one antibiotic. All recipients receiving CARB-X funding are contractually obligated to develop a Stewardship and Access Plan, outlining strategies to ensure responsible stewardship and appropriate access for their products.

CARB-X supports product developers with milestone-gated, non-dilutive funding and customized business, technical, and scientific expertise. In 2020, CARB-X launched Portfolio Acceleration Tools that serve as standardized validated models to optimize product development across the portfolio. This enterprise-level approach shares research, results, and data sets across the entire portfolio to assist developers in addressing common challenges and avoiding expensive mistakes. These tools drive a greater foundational understanding of the antibacterial development ecosystem.