

More than 20 biopharmaceutical companies launch billiondollar fund to sustain antibiotic pipeline, prompts policymakers to look at incentives

Global launch highlights from Washington, D.C., July 9, 2020

On Thursday, July 9, the <u>AMR Action Fund</u>, a ground-breaking partnership that aims to bring 2-4 new antibiotics to patients by 2030, was launched during a live, virtual event in Washington, D.C.

Novel antibiotics are urgently needed to address the rapid rise of antibiotic-resistant infections - also called antimicrobial resistance, or AMR. More than 20 leading biopharmaceutical companies have stepped up to the challenge and raised nearly US\$1 billion in funding to support R&D of innovative new antibiotics to address the most resistant bacteria and life-threatening infections. The Fund will



From top left: Stephen Ubl, PhRMA, Albert Bourla, Pfizer, Ken Frazier, Merck, and David Ricks, Eli Lilly and Company

bridge innovative candidates in the pipeline through the most challenging later stages of drug development - with both funding and technical support - ultimately providing governments time to make the necessary policy reforms to enable a sustainable antibiotic pipeline and safeguard our future.

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The concept of the AMR Action Fund was developed in collaboration with the World Health Organization (WHO), European Investment Bank (EIB), and Welcome Trust. The AMR Action Fund global launch events, led by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and in partnership with local and regional industry associations, took place in Washington, D.C. and Berlin simultaneously on July 9, with an event in Tokyo on July 10. More details on the D.C. launch event program can be found here.

Highlights

To launch the AMR Action Fund, the virtual event in Washington D.C. featured remarks from **Dave Ricks, CEO** of Eli Lilly and Company, Ken Frazier, CEO of Merck, Albert Bourla, CEO of Pfizer, Steve Ubl of PhRMA, and Michelle McMurray-Heath of BIO. Later in the event, policymakers and key AMR stakeholders underscored the threat of AMR and the importance of the new initiative. In total, there were 16 participants in the D.C. launch event, representing industry, academic, scientific, and political sectors. The event kicked off with a firsthand account of a patient experience with AMR from former NFL player Brandon Noble. Following the launch of the AMR Action Fund, ADM Brett P. Giroir, M.D., Assistant Secretary for Health at HHS, Senator Bob Casey (D-PA) and Senator Bill Cassidy, MD (R-LA) spoke about the steps the Administration and Congress were taking to tackle AMR. A panel of key stakeholders, including Scott Gottleib, American

Enterprise Institute and former FDA Commissioner; Helen Boucher, MD, Infectious Disease Society of America; Kathy Talkington, The Pew Charitable Trusts; Kevin Outterson, CARB-X; Ramani Varanasi, X-Biotix; and Michael Boyd, Cystic Fibrosis Foundation. In total, the D.C. launch event attracted approximately 1,000 viewers.

There were robust discussions about the threat of AMR, the insufficient pipeline of new antibiotics, and the urgent need for policy action on reimbursement reform and novel incentives. While speakers welcomed the launch of the AMR Action Fund, they noted that it should only be seen as a first step to strengthen the antibiotic pipeline while policymakers put in place the necessary reforms to create a sustainable market.

The links between AMR and COVID-19 were impossible to miss, not least because of the virtual nature of the event. Many of the panelists took time out from actively working on the COVID-19 pandemic to highlight their concerns about AMR, and nearly all of them noted the connection between the two health crises. **Dave Ricks, Eli Lilly and Company CEO,** remarked, "AMR is like a COVID-19 pandemic nearly every year."

AMR is having a significant impact on patients

In launching the AMR Action Fund, **Dave Ricks, Eli Lilly and Company CEO** said, "Public health experts, industry participants all recognize this, that antimicrobials are really like the mortar holding the building of healthcare together and without effective antibiotics, even basic routine procedures like root canals or treatment with cancer care cannot function properly."



From left: Michelle McMurray-Health, BIO; Brandon Noble, former NFL player

There were several powerful examples of the impact of AMR on patients. Former **NFL player**, **Brandon Noble**, spoke with **Michelle McMurray-Health**, **BIO**, about his personal experience with AMR. He shared, "At the time I was in the best shape of my life and I had been floored by something that I've never heard of and didn't even know what it was." He commended the objectives of the AMR Action Fund and called for action: "AMR isn't going away. It's been here and the bug will keep evolving, so we've got to stay in front of this. And we let it get ahead. And we've got to continue to catch up and then get in front."

Several other speakers reflected on their experiences confronting AMR in the clinic:

- **ADM Brett Giroir, HSS:** "Literally not a day went by that I did not have a child struggling for survival in a life and death battle with a resistant organism...Resistant microbes killed my patients, our nation's children." He went on to say, "AMR is the existential threat of this century."
- Helen Boucher, IDSA: "(This patient) in the prime of her life who had beaten cancer ended up dying from the drug-resistant infection."
- Michael Boyle, Cystic Fibrosis Foundation: "And as people with cystic fibrosis live longer lives, we're running out of treatment options for these infections. As a physician, it is heartbreaking to know exactly what the infection is that's causing a problem, and yet have to tell a patient and their family that we really don't have an effective treatment for it."

Speaking on behalf of the AMR Action Fund investors, **Ken Frazier, Merck CEO**, said, "We see AMR as one of the most pressing public health crises the world is facing. In the long term, it has the potential to cause even greater mortality and economic damage than COVID-19 if we don't address it... This is a powerful example of how the pharmaceutical industry can come together to make a huge difference for patients and society."

Much more than a fund - Pharma investors will collaborate and share knowhow with biotechs

In recognizing the similarities between COVID-19 and AMR, panelists highlighted the value of collaboration to save lives. "COVID-19 has shown that in crisis mode, collaboration is important. There is no one alone who can address the issues as effectively as when they partner with others... [The AMR Action Fund] should be perceived as the contribution of a group of companies, and should be an example to legislators and others to take steps to address [AMR], because this is a very big problem," said **Albert Bourla, CEO of Pfizer**. **Steve Ubl, CEO of**

PhRMA pointed out that "the fund is a highly collaborative effort involving a broad range of biopharmaceutical companies, philanthropies, development banks and multilateral organizations."

Industry's essential role in helping bring novel antibiotics to patients also lies in the necessity of the resources industry can bring to small biotech companies. As a part of its investment, the AMR Action Fund will provide technical support to portfolio companies, giving them access to the deep expertise and resources of large pharmaceutical companies, to strengthen and accelerate antibiotic development.



ADM Brett P. Giroir, M.D., Assistant Secretary for Health at HHS

ADM Brett Giroir, HHS expressed gratitude for the launch of the Fund, saying, "This is bold, pretty gutsy, potentially transformational, but this kind of effort is absolutely essential. I do think this partnership represents the best of corporate responsibility. The money is impressive, but money alone can't buy the intellectual commitment and intellectual resources, and history of innovation that this partnership represents. The U.S. government can't do this alone. We need to do more, and we need to do different. I'm confident your new partnership will do both... So, after this justified celebration today, all of us in government and civil society and industry, I think we're already to roll up our sleeves and work with you."

Policy reform is urgently needed to ensure a robust and sustainable pipeline of new antibiotics

While participants of the launch event recognized the AMR Action Fund as a vital investment by the pharmaceutical industry, they lamented that it would be a "bridge to nowhere" without policy changes and efforts by other stakeholders. **Kevin Outterson, CARB-X** classified industry's investment as "a billion dollar down payment...(that buys) a little bit of breathing room to get reimbursement fixed" and remarked, "The timing of this AMR Action Fund is lifesaving to these research companies and actually it's lifesaving to the world to keep this research going forward. And so, we should really take a moment to recognize and thank the leadership exhibited today by these CEOs, these companies. No one forced them to come here today with a billion dollars for this important mission, and so I'm grateful that they have. But let me be very blunt, unless the US government changes antibiotic reimbursement, today's excitement will end in bankruptcy...We are on the cusp of disaster."

Several policymakers and government officials spoke about their optimism around the launch of the AMR Action Fund, knowing how essential it is to revitalize the antibiotic pipeline before AMR becomes the next pandemic. They spoke about how the Fund addresses the gap that has caused other efforts to develop novel antibiotics to fail, namely getting over the finish line from R&D to patient access.

Senators Bob Casey (D-PA) and Bill Cassidy (R-LA) also spoke of the challenges they are working to address through the DISARM Act (Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms), and their commitment to continuing efforts to get this legislation passed to, as Senator Casey said would "create a stable marketplace for antibiotics." **Senator Cassidy** stressed the urgency of addressing AMR: "This [Fund] is something being done that's proactive, and I thank you for that...The next pandemic may be a superbug, and there will be people alive because of this development that otherwise would not have been."

The final panel featured some of the foremost experts in the field of AMR, focusing on the AMR ecosystem challenges and opportunities for change. Moderator **Scott Gottlieb** opened the panel by emphasizing the hard lessons from COVID-19: "As we grapple right now with a once in a generation pathogen and a historic pandemic... almost guarantees that we're going to think much differently about infectious disease and the capacities to develop therapeutics against dangerous pathogens. And going forward, the capacity to develop antibiotics to infectious agents, I think, is going to be seen as a matter of national security."



From top left: Scott Gottlieb, AEI, Kevin Outterson, CARB-X, Kathy Talkington, Pew, Ramani Varanasi, X-Biotix, Helen Boucher, MD, IDSA, Michael Boyle, MD, Cystic Fibrosis Foundation

The panelists highlighted the unique challenges posed by antibiotic development. **Kathy Talkington, Pew:** "We have too few products that are in development to meet both current needs and the future needs that we know are on the horizon. The constantly evolving nature of resistance demands a constantly evolving arsenal of antibiotics to defeat them. So, there will be no one antibiotic is going to solve this problem, hence, the need for a robust pipeline to address this unique issue. And while we didn't know COVID was coming, we know antibiotic resistance is not only coming, it's here. And so, we have no excuse not to be prepared. We must take urgent action to increase the pipeline." **Ramani Varanasi, X-Biotix**, described the multiple "valleys of death" faced by antibiotic-focused biotechs as a "one, two, three punch for companies in this space" and underscored that "unless the macro environment changes, the players such as X-Biotix will not be able to thrive or survive."

The event closed with remarks by **Ken Frazier, Merck,** saying, "While coronavirus was not known before January 2020, AMR is a threat today, and we know exactly what has to be done. AMR is a predictable and preventable crisis, and it's a problem that we can no longer afford to ignore. With the AMR Action Fund, industry is taking action now to sustain the fragile antibiotic pipeline, which ... is close to collapse. But the Fund is just a temporary and time limited bridge that will only work if key governments, including the US make the necessary reforms to create a sustainable market."

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