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BIO 2025: Building biosecurity through public-private partnership

By Karen Carey, Senior Managing Editor and Chief Analyst

The COVID-19 pandemic sent the world into a tailspin, raising ongoing concerns about biosecurity, a subject that encompassed the better part of the morning June 16, the first day of the Biotechnology Innovation Organization's annual conference in Boston.

Susan Dentzer, president and CEO of America's Physician Groups

Developing vaccines and antivirals to combat a virus that has killed more than 7 million people worldwide in the past five years, according to the World Health Organization, is one thing; supplying those products globally is quite another, a feat often dependent on access to materials sourced in China and India. Another major concern is pulling together the funding and public-private partnerships needed to incentivize companies to conduct the requisite R&D before an emergency situation arises again.

"There are alarming gaps in antiviral R&D that if not corrected will leave us extremely vulnerable" to another pandemic, Susan Dentzer, president and CEO of the nonprofit America's Physician Groups, told attendees.

Raj Panjabi, former senior director for Health Security and Biodefense with the National Security Council, and currently a senior partner with Flagship Pioneering

Securing vaccines for COVID-19 was vital, said Raj Panjabi, former senior director for Health Security and Biodefense with the National Security Council, and currently a senior partner with Flagship Pioneering. But, he said, "antivirals are our first line of defense. If any of us remember five years ago when COVID felt like a raging elephant and we were fighting it with what felt like pea-shooters," the essential medicine at the time was remdesivir (Veklury, Gilead Sciences Inc.). "It allowed people who were very sick to have a reason to seek care."

The INTREPID Alliance (International Readiness for Preventing Infectious Viral Disease) recently put out its latest overview of the antiviral landscape, finding that there are only 27 compounds across 12 viral families, outside of COVID, that

are in clinical development today, despite there being 13 viral families with the greatest risk of pandemic potential. In clinical development are candidates for mpox, dengue, Ebola, Lassa fever, polio, rhinovirus, influenza and others. There is nothing in clinical development for paramyxoviridae, which is associated with measles, mumps and respiratory tract infections, or for certain infections caused by contact, such as hantaviridae (hantavirus), peribunyaviridae and togaviridae.

"I'd like to see each one with at least four or five compounds, so we're short quite a bit," said John Pottage, lead scientific consultant for the INTREPID Alliance. But "funding is very uncertain," including R&D, manufacturing and stockpiling. "We need a continuity of funding," he stressed, referring to early discovery and development work interrupted while National Institutes of Health funding is reassessed.

Ruxandra Draghia-Akli, chair of the INTREPID Alliance advisory board

Financing antiviral research

Securing grants, partnering with government and engaging venture capitalists are all ways that antiviral companies can gain funding for their research. Panjabi said he would like to see companies working with AI and computational learning to find lead molecules more quickly, although he acknowledges that there is an "unclear market demand."

"We have been incredibly lucky with SARS-CoV-2," said Ruxandra Draghia-Akli, chair of the INTREPID

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Alliance's advisory board, and executive vice president and head of R&D at Novavax Inc. Researchers have looked for decades for vaccines to prevent certain infections, highlighting the need for antivirals to fill that gap, she said. Even once a vaccine is secured, antivirals are needed to treat those with vaccine hesitancy or with breakthrough infections. They can help "improve patient outcomes, alleviate disease burden, reduce the risk of complications, reduce hospitalizations and transmissions."

Dawn O'Connell, the former assistant secretary for the Administration for Strategic Preparedness and Response (ASPR), who held the position from January 2021 to January 2025, stressed that Project Bioshield, established in 2004 to support development and stockpiling of medical countermeasures, is "only targeted for intentional threats. It came after September 11 … which means these naturally occurring threats of pandemic potential … those are not included in Project Bioshield funds." That left a significant gap through 2020 when funding came through Operation Warp Speed and other efforts. She mentioned that one occurrence in Iowa of Lassa fever in October received no funding from the Biomedical Advanced Research and Development Authority (BARDA). "Thank goodness that Iowa hospital was able to contain it and the risk didn't spread." O'Connell said she believes government and industry should continue focusing on domestic manufacturing and attaining more funding for BARDA to address naturally occurring biological threats.

Dentzer noted that mpox is ravaging Sierra Leone and the Democratic Republic of the Congo, while Marburg virus, the avian flu, dengue and other flaviviruses, as well as a new COVID variant "face us at any time across all continents," and the world is "just a few mutations away from any of them becoming a pandemic agent." Some models, she said, suggest there is a 30% chance that in the next 10 years there will be "another global pandemic similar in scope to COVID-19."

Another point Dentzer made: "We all know that we're living in interesting times with respect toward multiple consideration attitudes toward science. … Many disparate voices are being heard. … We have to acknowledge that our discussion today about antivirals is also taking place amid this broader discussion. … This is all a new and different context and it may require new and different solutions from those in the past."

Partnering with government

"There are no shortage of threats out there and they continue to evolve," said Mark O'Neill, chief of staff for ASPR, who was appointed by U.S. President Donald Trump after working 27 years in national security for the U.S. Department of Defense.

"ASPR is the lead federal coordinator for the preparation response and discovery to any disaster that this country faces," O'Neill said during a fireside chat, adding later that he's particularly focused on the strategic national stockpile (SNS), which includes $13 billion in medical countermeasures. Partnering with industry "is critical to advance our national security," he continued, suggesting various ASPR portals such as TechWatch, which is administered by BARDA, or IBx Connect and the Biomap Consortium, which are looking at manufacturing solutions.

Mark O'Neill, chief of staff for ASPR, who was appointed by President Trump after working 27 years in national security for the U.S.

Through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), ASPR helps create partnerships between public and private entities. "I'm sure everyone wants to know more about the PHEMCE budget," O'Neill said. " … That's not out yet because we want to make sure it aligns with the president's budget."

But ASPR is looking specifically to partner with companies that have not only capacity, but production and sustainment as well, he said. During COVID, the U.S. government "threw a lot of money at companies to build capacity, but they didn't really do due diligence," ensuring they had production capabilities. "That money was essentially flushed away. So we can't do that. We can't afford to do that in this fiscal climate." He acknowledged that medical countermeasures may not have a commercial market, but where there is one, it should be accessed.

BARDA, O'Neill said, has brought to FDA approval 105 products in the past 20 years., and those medicines are all within the SNS. To bring more medical countermeasures to the SNS, manufacturing capacity is important.

"The investment in the domestic supply chain, I think, is sorely needed. We've got to start producing more APIs [active pharmaceutical ingredients], key starting materials … here, in the United States. Right now we're too dependent on foreign countries." ASPR is working with the White House's Made in America Office "to reshore or onshore" APIs and finished products, an area that he expects will continue to be a large budget priority. ASPR has "awarded 27 contracts in this space over the last few years because we recognize that domestic production makes us the most resilient," O'Neill said.

Arlene Joyner, deputy assistant secretary and director of the Center for IBMSC

During the COVID response, the Center for Industrial Base Management and Supply Chain (IBMSC) within ASPR was created to help improve the supply chain, including personal protective equipment, testing and diagnostic materials and critical medicines.

"The critical medicines, we're recognizing, is one of our biggest, with 70% to 90% of components, APIs, coming from overseas," said Arlene Joyner, deputy assistant

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secretary and director of the Center for IBMSC. "A couple major countries that supply those [materials], India and China, if they close their doors, we'd be in a lot of trouble." Antibiotics is one of the critical areas, she said.

Barry Datlof, the chief of business development and commercialization in the Office of Medical Technology Transfer, part of the U.S. Army Medical Research and Material Command, encouraged companies to seek out CRADAs (Cooperative Research and Development Agreements) and to license IP. "We've got so many different parts of the elephant in motion. Whatever new pathogen comes up, the government's role is that we're ready in the background and ready to partner with you."

He encouraged companies to tap into biodefense grants and contracts, as well as securing venture capital when possible, and to communicate by pivoting "from what you think we need, to what you say we need" when the timing is right. Acknowledging that there are many different directions that companies need to pursue, he noted, "Wouldn't it be great if we had the universal application that the college kids do."

The 2025 BIO International Convention, which has more than 19,600 registrants from 68 countries, runs through Thursday, June 19.