INTREPID ALLIANCE

INTERNATIONAL READINESS FOR PREVENTING INFECTIOUS VIRAL DISEASE

Catalyzing Funding for Antivirals, Preserving the Medical Countermeasures (MCM) Enterprise in the United States

AN INTREPID ALLIANCE PANEL DISCUSSION

BIO International Convention,
Boston, June 16, 2025

Foreword

Given the urgent need to increase research and development efforts on antivirals as an important countermeasure against emerging and existing pathogens, the INTREPID Alliance was pleased to convene a panel discussion as part of the 2025 BIO International Convention opening session "Partnering with the U.S. Government to Achieve Our National Security Mission." INTREPID's Antiviral Clinical and Preclinical Development Landscape highlighted the weak pipeline of antivirals against the viral families that represent the greatest public health and security threats.[1] It is clear that neither market dynamics nor current funding and partnerships are sufficient to strengthen the pipeline, and that the U.S. Government will be key in establishing the new public-private models and structures that we need.

INTREPID hosted the closing panel, entitled "Catalyzing Funding for Antivirals: Preserving the MCM Enterprise in the United States," which featured speakers with leadership experience spanning the private sector, finance, and key U.S. Government bodies. It built on the previous discussions throughout the morning of June 16, 2025, that included representatives from the U.S. Government, institutions and agencies involved in pandemic preparedness and response, as well as national security.

The BIO International Convention is the world's largest and most comprehensive biotechnology event, and brought together over 20,000 leaders from industry, government, academia, and finance to drive innovation and address global health challenges.

This Proceedings document is intended to capture and share the rich content of these discussions more widely. It starts with an executive summary of all the morning sessions to set the context, then moves into a detailed account of the INTREPID panel. The discussion underscored the vital role of small-molecule antivirals in treating and preventing viral threats, bridging gaps before vaccines are available, and strengthening preparedness for emerging health challenges. It also explored the weakness of the pipeline and options for catalyzing research and development in this area. We hope these Proceedings deliver actionable insights and inspiration to advance antiviral readiness and reinforce global health security.

Signed,

James Anderson, M.A., M.B.A.
Chair, INTREPID Alliance; Executive Director, R&D Innovation, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

Phyllis Arthur
Executive Vice President & Head of Healthcare Policy and Programs, Biotechnology Innovation Organization (BIO)

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Moderator: Emily Wheeler, *Vice President of Infectious Disease Policy, Biotechnology Innovation Organization (BIO)*

- Mark O'Neill, *Chief of Staff, Administration for Strategic Preparedness and Response (ASPR)*

Interviewed by Emily Wheeler, Mark O'Neill emphasized ASPR's role as the federal lead for disaster preparedness, response, and recovery—underscoring that every crisis has a health component. Drawing on his national security background, he highlighted priorities including strengthening the Strategic National Stockpile (SNS), ensuring efficient deployment of medical countermeasures, and bolstering domestic manufacturing to reduce reliance on foreign supply chains.

O'Neill stressed the importance of public-private partnerships through Biomedical Advanced Research and Development Authority (BARDA) programs, biotech portals, and venture-style initiatives—noting future funding must focus on companies with proven capacity, production, and sustainment capabilities. He also outlined ASPR's coordinating role across agencies such as the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and the Food and Drug Administration (FDA) to align countermeasure development with national needs and called for stronger communication with industry to foster innovation. Ultimately, he framed a resilient biodefense enterprise as one built on robust stockpiles, domestic production, state-level preparedness, and agile collaboration between government and biotechnology innovators.

PANEL 2

Securing the Biopharmaceutical Supply Chain: Strengthening America's Industrial Base

Moderator: Taylor Sexton, M.P.H., *Executive Director, Medical Countermeasures Coalition (MC2)*

- Wayland Coker, M.B.A., *Chief Supply Chain Strategist for Industrial Base Management and Supply Chain, Administration for Strategic Preparedness and Response (ASPR)*
- Joe Hamel, *Acting Enabling Innovations and Technologies Office Director and Senior Advisor, Center for Industrial Base Management and Supply Chain, Administration for Strategic Preparedness and Response (ASPR)*
- Arlene Joyner, *Deputy Assistant Secretary and Director of the Center for Industrial Base Management and Supply Chain, Administration for Strategic Preparedness and Response (ASPR)*

Moderator Taylor Sexton spoke with ASPR's Industrial Base and Supply Chain leaders—Wayland Coker, Joe Hamel, and Arlene Joyner—about reducing U.S. reliance on foreign active pharmaceutical ingredients (APIs) and key starting materials (KSMs); market consolidation; single-point failures exposed by COVID; and events such as saline shortages.

The panelists highlighted progress since the creation of the Center for Industrial Base Management and Supply Chain including investments to onshore critical medicines using agile and continuous manufacturing, reshoring APIs, KSMs, and Finished Dosage Forms (FDFs), and launching efforts such as a forthcoming Digital Stockpile & Manufacturing Response Network, alongside tight interagency work among FDA, NIH, Defense Advanced Research Projects Agency (DARPA), Department of Commerce, Department of State, Department of Veterans Affairs, and others. Near-term priorities over the next 12-18 months include onshoring and reshoring IV solutions and antibiotics, deeper supply chain mapping and data sharing, and adoption of commercialization/sustainment plans along with funding—for example, "Buy American" levers, regulatory alignment, and contract requirements for resilience. A recent win, "Operation Saline Shield," reflected rapid public-private action to import and clear supplies after a plant outage, and constituted an example of the agile, domestically anchored, and collaborative model that the panelists aim to scale.

PANEL 3

Securing the Future: Biodefense and Health Security Policy Outlook

Moderator: Mike Stebbins, Ph.D., *Senior Vice President, Advanced Technology International (ATI)*

- Jennifer Alton, *President, Pathway Policy Group*
- Kelly Childress Lange, *Partner, East End Group*
- Jill Hamaker, *Senior Partner and Chief Development Officer, CGCN Group, LLC*

Moderator Mike Stebbins led panelists Jennifer Alton, Kelly Childress Lange, and Jill Hamaker in a Congressionally-focused discussion tracing the policy arc from the Strategic National Stockpile (SNS) in 1999 to Project BioShield and the Pandemic and All Hazards Preparedness Act (PAHPA), which created ASPR and BARDA to bridge the "valley of death." With PAHPA still awaiting reauthorization and funding likely to be constrained under a probable fiscal 2025 continuing resolution, the panel urged rebuilding bipartisan champions, tying health security to national security, and sustaining onshoring priorities aligned with "Made in America" sentiments and policies. They argued that the medical countermeasures enterprise should remain integrated under ASPR (including the SNS), while the government provides clear requirements and predictable demand signals so that industry can invest and sustain capacity. Practical engagement advice included joining BIO and the Medical Countermeasures Coalition (MC2), leveraging ATI consortia, and proactively educating both agencies and members of Congress—especially newer ones—so public-private efforts remain aligned and durable.

PANEL 4

Advancing Defense Readiness: DOD Partnerships for Medical Countermeasures

Moderator: Chris Frech, *Chair of the Alliance for Biosecurity; Senior Vice President Global Government Affairs, Emergent BioSolutions*

- Barry Datlof, M.B.A., *Chief, Business Development and Commercialization, Office of Medical Technology Transfer, U.S. Army Medical Research and Material Command*
- Jeremiah Kelly, *Partner, Venable LLP*
- Tracie Lattimore, *Acting Deputy Assistant Secretary of Defense, Health Readiness Policy and Oversight (HRP&O)*
- Vic Suarez, *Founder & Principal Growth Partner, Blu Zone Bioscience & Supply Chain Solutions*

Moderator Chris Frech led panelists Barry Datlof, Jeremiah Kelly, Tracie Lattimore, and Vic Suarez in discussing how to work with the Department of Defense (DoD)** on medical countermeasures—starting with where health readiness, Defense Health Agency (DHA), DARPA/Defense Threat Reduction Agency (DTRA), and acquisition fit into the DoD's structure and why requirements differ across "above the line" policy and oversight and "below the line" execution. Speakers urged companies to engage through consortia (e.g., Medical CBRN* Defense Consortium (MCDC)/ Medical Technology Enterprise Consortium (MTEC)) and to tailor solutions to evolving warfighting needs—especially dispersed, contested Indo-Pacific operations that favor agile, on-demand manufacturing and resilient logistics. They highlighted flexible contracting tools—especially Other Transaction Authorities (OTA), commercial solutions offerings, and experimental supply contracts—and the importance of early, frank negotiation on intellectual property (IP) and technical data rights and FDA regulatory strategy. Success will hinge on true public-private partnerships like Operation Warp Speed (OWS) which emphasized aspects including, shared accountability, clear and stable requirements, rapid bidirectional communication, and risk-tolerant problem-solving. Practical tips included using small pilot Cooperative Research and Development Agreements (CRADAs) to get in the door, leveraging field testing within DoD, and timing/persistence to navigate multiple entry points.

* Chemical, Biological, Radiological, and Nuclear materials

** On September 5, 2025 President Trump signed an executive order changing the Department of Defense's name to the Department of War as a secondary title. At the time of these proceedings the change had not yet taken place.

PANEL 5

Catalyzing Funding for Antivirals, Preserving the MCM Enterprise in the U.S.

Moderator: Susan Dentzer, M.S., *President and CEO, America's Physician Groups*

- Ruxandra Draghia-Akli, M.D., Ph.D., *Chair, Scientific Advisory Board, INTREPID Alliance; Executive Vice President and Head of R&D, Novavax*
- Dawn O'Connell, J.D., *Former Assistant Secretary for Preparedness and Response (ASPR), U.S. Department of Health and Human Services*
- Raj Panjabi, M.D., *Former Senior Director for Health Security and Biodefense, National Security Council; Senior Partner, Flagship Pioneering*
- John C. Pottage, Jr., M.D., *Lead Scientific Consultant, INTREPID Alliance*
- Bryan Shuy, *Former Chief of Staff to House Appropriations Agriculture & FDA Subcommittee Chairman, Former Deputy Assistant Secretary and Chief of Staff to the Assistant Secretary for Preparedness and Response (ASPR); Senior Vice President, The Conafay Group*

The panel—organized by the INTREPID Alliance and moderated by Susan Dentzer, —argued that small-molecule antivirals (SMAVs) are indispensable alongside surveillance, diagnostics, vaccines, and public communication in countering viral threats. Speakers highlighted antivirals' versatility for both treatment and prevention, their role in bridging the gap before vaccines exist, and their importance even after vaccines are available (e.g., as was the case with remdesivir early in COVID-19 and Paxlovid™ later). Yet INTREPID's updated pipeline "landscape analysis" shows that the United States and the rest of the world are glaringly underprepared: The World Health Organization has identified 13 viral families that are most likely to cause the next pandemic. Outside of coronavirus, only 27 antiviral candidates are in clinical development across 12 viral families, with far too few additional molecules in preclinical stages given decade-long development timelines and high attrition. The result is a flashing red light for preparedness amid active threats like mpox, Ebola/Marburg, avian flu, and dengue.

> ***INTREPID's analysis of where the nation and the world stands in antiviral research and development demonstrates how far we are from being prepared for the next pandemic, which has an estimated 30 percent chance of occurring in the next decade. It is a call to action for the United States and the world.***
>
> **—SUSAN DENTZER, M.S.**
> President and CEO, America's Physician Groups

Panelists tied these gaps to inconsistent funding and weak market pull. They called for sustained, predictable investment, stronger public-private partnerships, and concrete policy fixes, including: expanding BARDA/Project BioShield beyond the current focus on intentional threats to include naturally occurring pathogens; adequately funding and aligning the SNS with BARDA outputs; restoring and modernizing incentives such as priority review vouchers; bolstering domestic manufacturing and supply chains; and giving ASPR the contracting, staffing, and construction authorities needed for rapid response.

On the innovation side, the panelists underscored the existence of a paradox—the "breathtaking" breakthroughs in understanding the underlying biology of antivirals alongside the underutilization of computational biology and artificial intelligence (AI) applied to antiviral development. They urged co-development of preclinical platforms employing AI and machine learning, tighter NIH-BARDA coordination, and advance market commitments—in effect, employing an "off-cycle" Warp Speed mentality—guided by national biodefense goals (rapid repurposing within ~90 days and novel antivirals within ~180 days) and reauthorization of PAHPA. The message: biology isn't the bottleneck; policy, incentives, and execution are, and these factors must be addressed now. The stakes are clear: Without these measures, the U.S. and the world risk entering the next pandemic dangerously unprepared.

PROCEEDINGS

The INTREPID Panel discussion, "Catalyzing Funding for Antivirals, Preserving the MCM Enterprise in the U.S.," took place at the 2025 BIO International Convention in Boston on June 16, 2025, during the full morning BIO session on "Partnering with the U.S. Government to Achieve Our National Security Mission."

The INTREPID Alliance is a non-profit consortium of seven pharmaceutical companies and affiliates. Its mission is to accelerate the development of new treatments—specifically, small-molecule antivirals—for emerging and future endemic and pandemic threats as part of countermeasure development for the health care ecosystem. Models developed in 2024 estimate nearly a 30 percent chance that another global pandemic on the scale of COVID-19 could occur within the next 10 years.[2] There are alarming gaps in antiviral R&D that amount to a flashing red light in pandemic preparedness—as identified in the INTREPID Alliance's 4th edition of the Antiviral Clinical and Preclinical Development Landscape, published on April 30, 2025, and using data through December 18, 2024.

The discussion featured a distinguished panel, whose full biographies are included in the appendix.

PANEL 5

INTREPID Panel Discussion, "Catalyzing Funding for Antivirals, Preserving the MCM Enterprise in the United States"

Moderator: Susan Dentzer, M.S., *President & CEO, America's Physician Groups*

- Ruxandra Draghia-Akli, M.D., Ph.D., *Chair, Scientific Advisory Board, INTREPID Alliance; Executive Vice President and Head of R&D, Novavax*
- Dawn O'Connell, J.D., *Former Assistant Secretary for Preparedness and Response (ASPR), U.S. Department of Health and Human Services*
- Raj Panjabi, M.D., *Former Senior Director for Health Security and Biodefense, National Security Council; Senior Partner, Flagship Pioneering*
- John C. Pottage, Jr., M.D., *Lead Scientific Consultant, INTREPID Alliance*
- Bryan Shuy, *Former Chief of Staff to House Appropriations Agriculture & FDA Subcommittee Chairman, Former Deputy Assistant Secretary and Chief of Staff to the Assistant Secretary for Preparedness and Response (ASPR); Senior Vice President, The Conafay Group*

Panelists addressed the following topics:

- The indispensable value of antivirals in combatting viral outbreaks and pandemic preparedness and the need for antivirals as part of a strengthened MCM infrastructure.
- Current gaps in antiviral R&D.
- Actions needed to catalyze sufficient investment in antiviral R&D—and to create a sound MCM enterprise—by pharmaceutical companies, other private-sector players, and the federal government.

More than 500 stakeholders attended the session from the Department of Defense, U.S. Department of Health and Human Services, ASPR, security policy and supply chain consultancies, the biopharmaceutical industry, medical societies, and patient groups.

PANELIST RECOMMENDATIONS AND KEY TAKEAWAYS

1. The Value of Antivirals in Pandemic & Endemic Preparedness

- **Critical Component of the Countermeasures Ecosystem:** Antivirals are part of the broader ecosystem of countermeasures needed to respond appropriately—not just to pandemics, but also to epidemics and endemic outbreaks that threaten public health in the United States and globally.
- **Vital Complement to Vaccines:** Although vaccines are a fundamental tool for managing infections in large populations, the world may not always be able to develop vaccines in time to prevent widespread infections for all people.
- **Essential to Optimal Patient Outcomes:** Antivirals reduce hospitalizations, transmission, and mortality—making them vital for health security. Antivirals can be used for treatment in both in-patient settings and out-patient settings as well as for effective pre-and post-exposure prophylaxis.
- **Useful Versatility of Approaches:** Antivirals can be broad-spectrum, targeting entire viral families as well as more narrowly targeted, and are essential for both acute outbreaks (COVID, Ebola, influenza) and chronic infections (HIV, hepatitis C).

2. Current Gaps in Antiviral R&D

- **Severe Shortages:** The INTREPID Landscape Analysis revealed that there are only **27 compounds in clinical development across 12 viral families of the 13 priority viral families (the 13th being *Coronaviridae*)**, with many viral families having no compounds under clinical development at all. Preclinical efforts are also meager, with ~40 compounds total across all viral families, far below what is needed.
- **Long R&D Timelines & High Attrition:** It typically takes up to 10 years for an antiviral to be licensed and become available for patients, and only 1 in 10 compounds successfully completes the development process all the way to regulatory approval, meaning we should expect very few new antivirals in the next 5-10 years. In addition, regulatory approval for special populations such as pediatrics or pregnant women takes even longer.

- **Flashing Red Light:** Without significant acceleration, the world will be critically unprepared by 2035.

3. Barriers to Investment

- **Unpredictable Market Demand:** Investors often prioritize research and development in fields such as oncology or other chronic diseases, both with more predictable markets compared to antivirals, for which demand can be episodic and unpredictable.
- **Policy Instability:** Stop-and-start funding cycles for antiviral research undermine progress and weaken industry's confidence in investing and staying the course on R&D.
- **Lack of Incentives:** Expired regulatory provisions for priority review vouchers (PRVs) and insufficient "push" and "pull" mechanisms reduce private-sector motivation. There are no incentives for early-stage clinical development milestones that would help position novel antiviral candidates for rapid clinical testing during emerging outbreaks.

4. Policy & Funding Solutions

- **Dedicated BARDA Funding for Naturally Occurring Threats/Emerging Infectious Diseases:** We are encouraged by BARDA's launch of the Antiviral Prize Competition to develop early-stage antivirals for emerging infectious diseases, but recognize the need to sustain investment through regulatory approval. Current frameworks such as Project BioShield focus primarily on intentional threats. Funding specifically dedicated to the advanced research and development of agents designed to combat naturally occurring pathogens is needed to establish a response-ready antiviral armamentarium.
- **Strategic National Stockpile (SNS) Improvements:** There should be stronger alignment between the SNS and BARDA and increased resources for the expansion, replenishment, and readiness of medical countermeasures in the stockpile.
- **Domestic Manufacturing Capacity:** The ability to produce medical countermeasures within U.S. borders is essential for reliable and timely availability.
- **Reauthorization of PAHPA:** Extension of the law's provisions and additions of new ones are urgently needed to restore authorities that are critical for rapid response.

5. The Role of Partnerships & Ecosystem Thinking

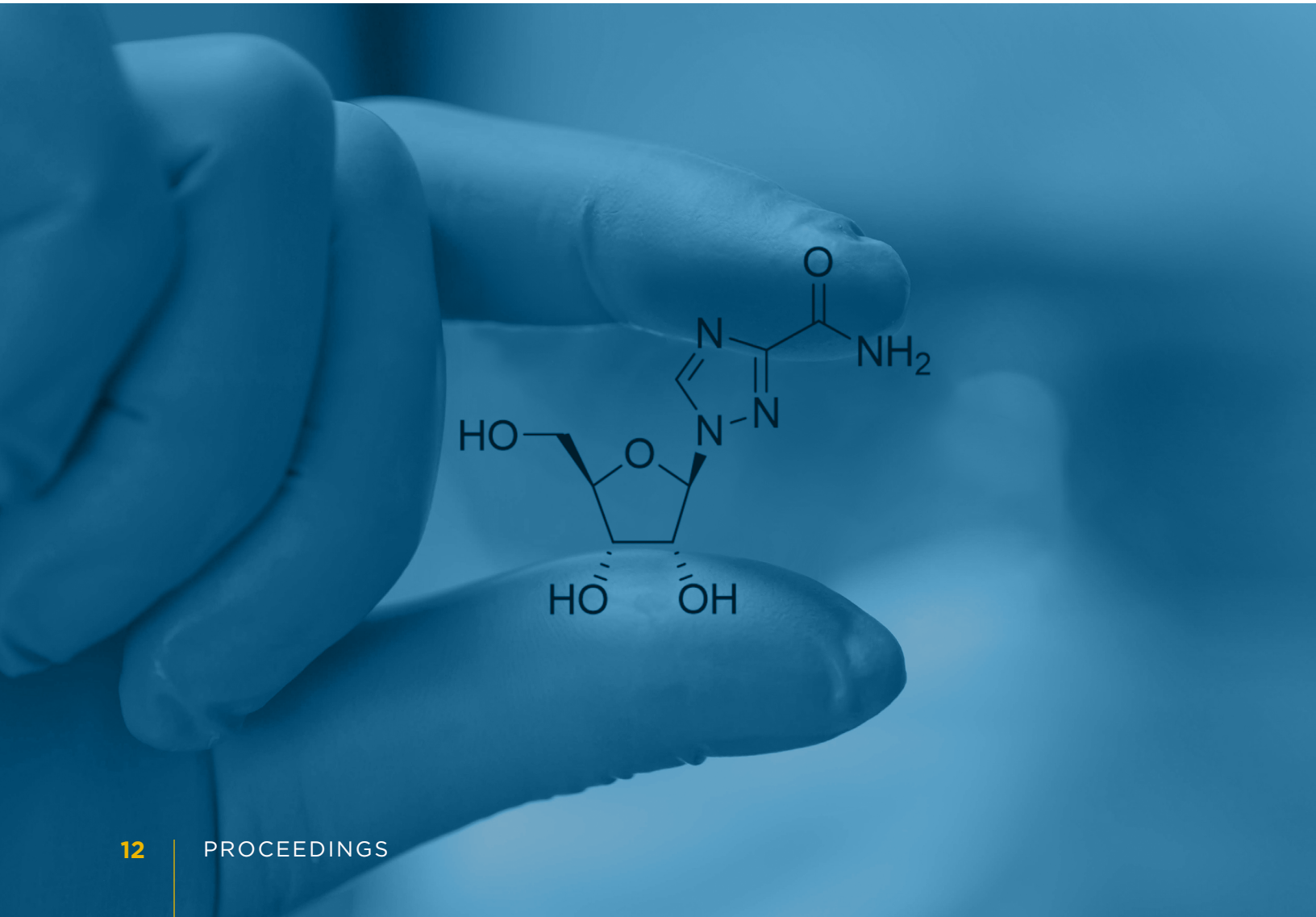
- **Public–Private Collaboration:** True partnerships, modeled after Operation Warp Speed, are needed beyond traditional contracting.
- **DoD & Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Integration:** Strong DoD participation in the PHEMCE would improve readiness.
- **State-of-the-Art Infrastructure:** To accelerate the design and preclinical development of novel antivirals, state-of-the-art infrastructure, tools and capabilities—including innovative diverse chemical libraries, automated screening,

validated animal models as well as AI, computational chemistry, and machine learning—should be more broadly applied to antiviral R&D with an exclusive focus on pandemic and emerging viral infections.

- **Holistic Ecosystem Approach:** Success depends on every ecosystem component—surveillance, diagnostics, vaccines, treatments, and education—working together with consistent funding.

6. Call to Action from the Panelists

- **Continuity in Funding and Incentives for All Phases of R&D:** Avoiding R&D gaps is critical. This goal can be achieved in part by:
  - Renewed and increased funding of the Antiviral Drug Discovery Centers for Pathogens of Pandemic Concern (AViDD Centers) and reauthorization of the Medical Countermeasure Priority Review Voucher Program.
  - BARDA funding for additional emerging naturally occurring infectious diseases.
  - Reauthorization of PAHPA.
  - Expanded Strategic National Stockpile and alignment with BARDA.
- **Focus from the U.S. Government on Co-developing Preclinical Platforms** to take advantage of novel computational biology and advances in machine learning, other forms of AI, and biotechnology.



- **Strengthened PHEMCE** with increased DoD participation.
- **Policy Consistency Across Administrations:** Encouragingly, both Trump- and Biden-era biodefense strategies advanced antiviral readiness during the COVID pandemic; this momentum must continue.
- **Champions Needed:** Policymakers, scientists, and private-sector leaders must frame antivirals as a **national security imperative**, not a partisan issue.

INTREPID PANEL DISCUSSION

Susan Dentzer introduced the panelists and began by asking Ruxandra Draghia-Akli this question: What is the value of antivirals, and what role do you see small-molecule antivirals, in particular, playing in health security and future pandemic preparedness?

RUXANDRA DRAGHIA-AKLI: Antivirals as part of an ecosystem. First, antivirals are part of the broader ecosystem of countermeasures needed to respond appropriately—not just to pandemics, but also to epidemics and endemic outbreaks that threaten public health in the United States and globally.

> ***Antivirals are essential tools for improving patient outcomes, reducing disease burden, and impacting global health. They lower the risk of complications, cut down on hospitalizations, and help reduce transmission.***
>
> **—RUXANDRA DRAGHIA-AKLI, M.D., Ph.D.**
> Chair, Scientific Advisory Board, INTREPID Alliance; Executive Vice President and Head of R&D, Novavax

Vaccines are, of course, a foundational tool for managing infections in large populations, but the world may not always be able to develop vaccines in time to arrest widespread infections or modulate their effects. We were incredibly fortunate with SARS-CoV-2, but when I think about other diseases, such as HIV, where, after 30 or 40 years of dedicated R&D, we are still searching for a vaccine. I realize how critical it is to have antivirals as a complementary tool. Antivirals serve as a crucial component of countermeasures—alongside surveillance, diagnostics, and vaccines—by offering treatment or prevention options that bridge the gap until a vaccine is developed, or for those who become infected despite vaccination, or who cannot or choose not to be vaccinated. To me, that makes antiviral treatments extraordinarily important.

Versatility. Second, antivirals are highly versatile. They can be designed to target a specific pathogen, but they can also have broad spectrum activity and thus applicability within a family of pathogens. For example, when I think about dengue and possible warfighter interventions in the Pacific region, I see how flaviviruses can become a focus of attention for the U.S. government. Developing antivirals effective against viral families, even before it is known what specific variant may cause a pandemic, may help accelerate development of a targeted antiviral to address infections, reduce transmission, and improve quality of life among infected individuals. Antivirals also play a central role in managing chronic infections such as HIV or hepatitis C. For these, they ensure not only that we have effective treatment options, but

> *The power of public-private partnerships (PPPs) lies in combining unique strengths to create results greater than the sum of their parts. These collaborations have driven breakthroughs from biomarkers and imaging tools to genetic tests and in silico models, making PPPs a vital part of the innovation engine.*
>
> **—LYDIA OGDEN, Ph.D.**
> Secretary, INTREPID Alliance; Health Policy and Engagement, Johnson & Johnson

also prevention and public health strategies that improve the quality of life for affected individuals while reducing transmission.

Tools for patient outcomes. Third, antivirals are essential tools for improving patient outcomes, reducing disease burden, and impacting global health. They lower the risk of complications, cut down on hospitalizations, and help reduce transmission. And yet, despite their proven efficacy, the relative ease of administration—and in many cases—simpler logistical needs compared to vaccines, antivirals remain significantly underfunded. This is not a new problem—it's a chronic one. That lack of investment undermines our ability to respond swiftly and comprehensively when a new pathogen emerges.[3]

SUSAN THEN ASKED RAJ PANJABI WHAT HE WOULD ADD TO THIS DESCRIPTION OF THE VALUE OF ANTIVIRALS, BASED ON HIS EXPERIENCE AT FLAGSHIP PIONEERING AS WELL AS AT THE NATIONAL SECURITY COUNCIL, LEADING SOME OF THE RESPONSE TO THE COVID-19 PANDEMIC.

RAJ PANJABI: First line of defense. Antivirals are truly our first line of defense. Five years ago, when COVID-19 felt like a raging elephant, we were initially fighting it with what felt like peashooters. At Mass General Brigham Hospital, I was working in COVID testing clinics alongside colleagues. We were getting reports from our intensive care unit that it was four or five times fuller than it should have been. At one point, there were about 350 patients in Mass General Hospital with severe COVID, many of them on ventilators.

In that moment, the antiviral that became absolutely essential was remdesivir, which was first developed to block viral RNA polymerase in RNA viruses like Ebola and Marburg. I grew up in West Africa, and I remember vividly how Liberia was on the front lines of the Ebola outbreak response from 2014 to 2016. Without that early investment in research, remdesivir may never have been ready when COVID-19 hit—and it became vital before vaccines were available later in 2020.

Remdesivir gave people who were desperately ill a reason to seek care, which was lifesaving in itself but also essential for the broader public health response. When patients who were most infectious came into the hospital for treatment, it not only helped them survive but also reduced the likelihood that they would transmit the virus to others.

Vaccines and antivirals. Antivirals can also be a critical adjunct to effective vaccines against a pandemic agent, once the latter are developed. The COVID-19 vaccination campaign was extraordinary—in the United States alone, more than 3 million lives were

saved, more than 18 million hospitalizations were averted, and nearly $1 trillion in savings was realized in just the first two years, according to the Commonwealth Fund's report on the U.S. campaign.[4] Many of you here today helped make that possible.

And yet, even with hundreds of millions of doses administered in the U.S. and billions worldwide, some people were hesitant to take the vaccine. For them, another antiviral, Paxlovid, became critical. Others, despite being vaccinated, were still vulnerable—because of underlying health conditions or because their immunity waned between doses—and they, too, needed antivirals. That's why the U.S. government, working with community pharmacy partners, made an extraordinary effort to ensure Paxlovid was available within five miles of 95% of the American public. It became a central part of our U.S. and global COVID-19 strategy.

So, in the end, antivirals serve as an essential first line of defense before vaccines are developed, but they also remain essential long after vaccines are available.

SUSAN NEXT TURNED TO JOHN POTTAGE, ASKING HIM TO PRESENT THE LANDSCAPE ANALYSIS DEVELOPED BY INTREPID ALLIANCE AND WHAT IT SHOWED WITH RESPECT TO THE CURRENT STATE OF ANTIVIRAL R&D.

JOHN POTTAGE: In brief, the landscape analysis that INTREPID conducted and first published in January 2024 shows that the world is not at all prepared for another pandemic with respect to research and development of antivirals.

Since its initial publication, the analysis has been updated quarterly. The summary slide below is from the latest update in December 2024.

FIGURE 1: INTREPID Alliance Antiviral Landscape

INTREPID Alliance Antiviral Landscape: Overview of 13 Priority Viral Families*

As of December 18, 2024, for the 13 Viral Families with Greatest Risk of Pandemic Potential, Only 27 Preclinical Compounds Across 12 Viral Families, Backing Out *Coronaviridae*

Primarily Respiratory Transmission

Pillar	Disease Indication (n)** Preclinical (103)	Clinical (39)
Adenoviridae	X	• HuAdeno A-G (1)
Coronaviridae	• COVID-19 (74) • MERS-CoV (5) • SARS-CoV-1 (5) • Seasonal CoV (1)	• COVID-19 (25)
Orthomyxoviridae	• Influenza (12)	• Influenza (10)
Paramyxoviridae	• Hendra virus (1) • Measles (1) • Nipah virus (3) • Parainfluenza (1)	X
Picornaviridae	X	• Polio (2) • Rhinovirus (1)

X = absence of preclinical or clinical phase antivirals

Primarily Contact/Vector-Mediated Transmission

Pillar	Disease Indication (n)** Preclinical (22)	Clinical (13)
Arenaviridae	• Junin virus (1) • Lassa fever (1)	• Lassa fever (3) • Chapare hem. fever (1)
Filoviridae	X	• Ebola (2)
Flaviviridae	• Dengue (5) • West Nile (1) • Yellow fever (1) • Zika (2)	• Dengue (3)
Hantaviridae	X	X
Nairoviridae	X	• Crimean Congo hem. fever (2)
Peribunyaviridae	X	X
Poxviridae	• Mpox (8)	• Mpox (2)
Togaviridae	• Chikungunya (3)	X

*As of December 18, 2024; **Number of compounds in ongoing development.

SOURCE: https://www.intrepidalliance.org/antiviral-pipeline/

The World Health Organization has identified 13 viral families that are most likely to cause the next pandemic. In Figure 1 below, the left side shows those families that are transmitted through the respiratory route, and the right side of Figure 1 shows those transmitted through personal contact or vector-based modes. We've further divided the antiviral R&D work underway in these viral families into preclinical and clinical development stages.

Discovery, development time, and attrition. Two principles are foundational in antiviral R&D. First, roughly ten years typically elapses from the time that discovery and development of an antiviral begins to when it's actually available to patients. Second, the attrition rate of compounds along the R&D pathway is staggering. If you start with a compound at the early discovery stage or in early lead identification, only one in ten will ever make it to a patient. That means we need a very high number of "shots on goal" if we're going to succeed.

Scarcity of compounds under development. The low number of compounds available today for pandemic preparedness is deeply concerning. Across 12 viral families—excluding coronaviruses—the landscape analysis found only 27 compounds in clinical development. Out of 13 viral families, only two could reasonably be considered in "okay" shape with respect to the status of clinical development. But even within those, you have to dig into the details to truly understand the situation.

> ***The mission is staring us in the face. The need is stark, and the message is clear—we must invest in antivirals and give it the attention it demands, or we will not be prepared for the next pandemic.***
>
> **—JOHN C. POTTAGE, JR., M.D.**
> Lead Scientific Consultant,
> INTREPID Alliance

To put it in perspective, if there are 27 candidates across 12 families, that's barely more than two per family on average. To feel even somewhat reassured, at least four or five clinical candidates per family is essential. That means we're short by more than 50 compounds. And these candidates aren't evenly distributed across viral families, either, since there is nothing in the pipeline at all in several viral families.

If we step back further to look at preclinical development, the picture isn't much better. Outside of COVID, we see only about 40 preclinical candidates across all families. For adequate coverage, I'd like to see at least ten per family, which means we should have well over 100. Instead, we have just 40.

When you put the numbers together and consider how long it takes, the outlook for achieving a satisfactory state of development by 2035 is bleak. If we don't accelerate progress, we could have virtually nothing available by then. Even if we push the numbers up to the minimum level I'd consider acceptable, we might only end up with one or two compounds per family by that time—and that's still far from where we need to be.

I'll end on this point: It is also a time of opportunity. The mission is staring us in the face. The need is stark, and

the message is clear—we must invest in this area and give it the attention it demands, or we will not be prepared for the next pandemic.

SUSAN SUMMARIZED JOHN'S COMMENTS BY NOTING THAT THE LANDSCAPE ANALYSIS CONSTITUTES A "FLASHING RED LIGHT FOR THE WORLD." NOT ONLY ARE WE MANY COMPOUNDS AND MANY VIRAL FAMILIES AWAY, BUT WE ARE ALSO MANY YEARS AWAY FROM BEING WHERE WE SHOULD BE ON THE PRECLINICAL AND CLINICAL RESEARCH AND DEVELOPMENT TIMELINE.

SHE THEN TURNED TO THE STATUS OF FUNDING FOR R&D IN THESE CATEGORIES, AND ASKED: WHERE DO WE STAND?

JOHN: When it comes to antiviral funding, it is essential to note that all aspects of antiviral production—not just R&D, but also manufacturing, stockpiling, and distribution—require sustained investment. And right now, this entire area is marked by great uncertainty.

Discontinuity in R&D. From my perspective, one of the most damaging things in R&D is the lack of continuity in funding. The start-and-stop cycle is incredibly detrimental. For example, some of the NIH-supported programs that focused on early discovery and development of compounds against pandemic pathogens were allowed to stop, with the thought that they might be restarted later. That kind of interruption is not helpful. For me, continuity is absolutely essential if we want to be ready for the next pandemic.

If I put myself in the shoes of a major pharmaceutical company deciding whether to invest in the next cancer compound versus an antiviral program, the calculus becomes clear. The first question is: Is there a need—that is, is there a market? Beyond that, companies ask whether it's a good fit for their portfolio, whether they have the expertise and the teams to carry it through—not just early- and late-stage clinical development, but full implementation.

Fundamentals of a compound. From my perspective as both a clinician and drug developer, I also look closely at the fundamentals of a compound. Does it have activity *in vitro* and *in vivo*? Is it safe? Do the toxicology results look reasonable? Do we have a dose that's achievable with solid pharmacology behind it? These are essential questions that matter. But then I ask: What does the clinical development pathway

look like? Who is this drug ultimately for? Patients, of course. Prescribers, certainly. But also, public health officials, who need evidence to guide decision-making.

No silos. That means I have to be able to show solid medical evidence that a drug is safe, effective, and feasible to implement. And importantly, there must be agreement across all stakeholders. We cannot afford to operate in silos, where compounds are simply pitched from one group to the next. Success requires everyone working together—from the very start of development all the way through to deployment and real-world use.

Outside of the antivirals already in development for COVID and pandemic influenza, and looking across other viral families and potential products, the reality is sobering. Antiviral preclinical development is still at an early stage, with many of the essential data points and answers required for downstream pharmaceutical development not yet available. What we need is not just more compounds, but also greater interest and momentum to bring them forward. I believe the biology and virology are there. The science is strong. What's missing is the financial incentive and investment. That's why public–private partnerships are so critical—they are often the driving force in advancing drugs against high-risk pathogens.

SUSAN ASKED RAJ, GIVEN HIS CURRENT ROLE ON THE INVESTMENT SIDE, WHAT HE THINKS THE BROAD PRIVATE SECTOR INVESTMENT COMMUNITY WOULD NEED TO SEE TO MAKE LARGE INVESTMENTS IN ANTIVIRAL R&D. IF THE FUNDAMENTAL BIOLOGY OF ANTIVIRALS IS NOT THE ISSUE, SINCE THAT IS ALREADY WELL UNDERSTOOD, WHAT WOULD GIVE INVESTORS MORE CONFIDENCE TO INVEST IN THIS SPHERE?

RAJ: First, there is what I call the **great antiviral paradox**. On the one hand, we have breathtaking advances in biology that I see every day at Flagship Pioneering. Flagship, based in Cambridge, Mass., is a bio-platform company that creates other platform companies designed to benefit human and planetary health. Right now, several of these companies are using AI and machine learning to scan the vast chemistry found in nature, and from that, derive potential hits, developmental candidates, and lead molecules faster than ever before. We're seeing this applied in oncology, autoimmune disease, neurodegenerative disease, and other chronic conditions.

And yet, here's the paradox: We're not seeing those same capabilities—the combination of AI, machine learning, and biological sciences—applied to antivirals.

Unclear market demand. Why not? Part of the reason is the unclear market demand. If you look at the landscape analysis (see Figure 1), it's not surprising that on the left side, you see a concentration of investment in preclinical and clinical pipelines for orthomyxoviruses such as influenza, or for coronaviruses. These have somewhat consistent market demand because they're now endemic. But on the right side, where you see viruses transmitted through personal contact—with far fewer compounds—you also see far less reliable demand.

When investors decide where to allocate resources, they're weighing talent and capital between areas of consistent market demand "pull"—such as oncology or neurodegenerative disease, which also have tremendous unmet need—versus antivirals for pathogens that may or may not emerge in any given timeframe.

> *To truly have a strong medical countermeasure enterprise, we must ensure we have both the raw materials and the production capacity here in the United States. Without that, even the best science won't translate into timely protection.*
>
> **—DAWN O'CONNELL, J.D.**
> Former Assistant Secretary for Preparedness and Response (ASPR), U.S. Department of Health and Human Services

Two key approaches to address the paradox. We can address this paradox through two key approaches. First, we need greater consistency in policy. We actually saw progress under the first Trump Administration, when Congress advanced the 2018 National Biodefense Strategy based on recommendations from the bipartisan Commission on Biodefense, now co-chaired by former HHS Secretary Donna Shalala and former Homeland Security Secretary Tom Ridge. I've had the opportunity to serve ex officio on that Commission and to see its history carried forward.

In the Biden Administration, we didn't scrap that strategy; instead, we built on it, as interagency colleagues recommended. We created an implementation plan, requested congressional funding, and established policy goals, including ensuring that antivirals across viral families could be made available within 90 days of a declared pandemic emergency, at least through repurposing existing drugs.

That's one of the great advantages of antivirals: You can already have a drug like remdesivir in hand before a pandemic strikes. At the same time, U.S. policy now calls for developing novel antivirals within 180 days of a pandemic emergency. Agencies like the Department of Defense and HHS are aligned in pursuit of that mission.

But the challenge is ensuring that there's enough momentum behind both advance market commitments—to create demand pull—and product development efforts. And this brings me to the second approach: We need to start earlier, at the preclinical stage, co-developing platform technologies. The same technologies being used today for oncology, neurodegenerative diseases, and chronic illnesses must also be applied to infectious diseases, including viral families of pandemic concern.

SUSAN TURNED NEXT TO DAWN O'CONNELL, ASKING HER MORE ABOUT CONSISTENCY OF POLICY FROM HER PERSPECTIVE AS THE FORMER ASSISTANT SECRETARY OF ASPR DURING THE BIDEN ADMINISTRATION. WHAT RELATED RECOMMENDATIONS WERE DEVELOPED AT ASPR UNDER HER TENURE, AND HOW CAN THE NATION BEST CONTINUE DEVELOPMENT OF THE MEDICAL COUNTERMEASURES AND INFRASTRUCTURE TO ENABLE A HEALTHY ECOSYSTEM FOR MCM PRODUCTION?

DAWN O'CONNELL: When I think about how we keep and strengthen our medical countermeasure enterprise, a few things stand out to me.

An addressable policy gap. Earlier, we heard about Project BioShield—a critical

bucket of funding that BARDA uses to create public–private partnerships with many pharmaceutical and biotechnology companies represented in the audience today. Project BioShield was created after 9/11, and it was designed to address intentional biological threats, such as the anthrax attacks that followed soon after 9/11. That means that BioShield's funding does not extend to conducting research and development on naturally occurring pathogens with pandemic potential—the very ones John showed on his slide earlier (see Figure 1).

As a result, BARDA only gets to use Project BioShield funds after the Department of Homeland Security (DHS) designates something as a material threat to the United States. From 2006 until COVID-19, DHS did not designate any new biological threats. The only ones on the list were older threats that are at risk of being weaponized, such as Ebola or Marburg. What about the other viruses we worry about, the ones that the WHO highlights every year on its list of top pathogens of pandemic potential? Many of those are not covered. That means BARDA has no funding available for them just as the Strategic National Stockpile (SNS) isn't accumulating countermeasures against these pathogens, and as a result, the U.S. has no tools ready to deploy against these agents.

Take a recent example: In October, Iowa had an "imported" case of Lassa fever when a state resident visited Liberia and returned with the infection. Lassa shows up on WHO's list every year, and it's a real risk. But because Lassa has never been weaponized, it isn't considered an intentional threat. BARDA isn't working on it, and the SNS doesn't have anything stockpiled for it. Thankfully, the Iowa hospital at which the patient was treated contained that case before it spread, but the episode illustrates the risk that we face. We feel reassured because of COVID programs funded by emergency supplemental federal funding, but as everyone here knows, supplemental funding often lags by four or five months after an outbreak starts. By then, we're already behind.

BARDA and naturally occurring threats. One of the things I would encourage us to do—and I can say this now that I'm no longer in government—is to talk with legislators about giving BARDA a dedicated bucket of funding for naturally occurring biological threats. That would allow us to get ahead of some of these viral families where we have clear antiviral gaps.*

Strategic National Stockpile (SNS). There are two additional areas where I think we need to strengthen the medical countermeasure enterprise. The first is the Strategic National Stockpile. For years, the SNS was housed in the Centers for Disease Control and Prevention (CDC), which meant that it was disconnected from BARDA and ASPR, and other agencies within the Department of Health and Human Services. It was finally moved under ASPR in 2018. In 2021, I was able to look across BARDA's

* Since the date of the panel, BARDA has announced the SMART Antiviral Competition, a multi-stage $100 million prize competition run through their accelerator network. It will focus on developing new early-stage antivirals for *Togaviridae* and *Flaviviridae*. The funding likely comes from BARDA's CBRN budget.

> *To me, the public–private partnership is more than just putting out an RFP or an RFI. It's about engaging in real dialogue with industry.*
>
> **—BRYAN SHUY**
> Former Chief of Staff to House Appropriations Agriculture & FDA Subcommittee Chairman, Former Deputy Assistant Secretary and Chief of Staff to the Assistant Secretary for Preparedness and Response (ASPR); Senior Vice President, The Conafay Group

budget and SNS's budget and encourage Congress to align them more closely. BARDA is well supported on the Hill—as it should be—because it drives innovation, even though not every area in which it invests succeeds. But the SNS has the responsibility of absorbing and stockpiling the products that BARDA develops. And that funding has not kept pace with the need. If we want BARDA to keep creating new medical countermeasures, the SNS must be resourced to stockpile them—not just once, but repeatedly, as products expire and need to be replenished.

Domestic manufacturing. Finally, we need to continue focusing on domestic manufacturing. To truly have a strong medical countermeasure enterprise, we must ensure we have both the raw materials and the production capacity here in the United States. Without that, even the best science won't translate into timely protection.

And I'll close by saying this: One of the encouraging things I've seen is the consistency across administrations. This mission has been carried forward, built upon, and strengthened—something I hope we continue to do.

SUSAN THEN TURNED TO BRYAN SHUY, ASKING HIM TO DRAW ON HIS PRIOR ROLES IN BOTH CONGRESS AND IN THE EXECUTIVE BRANCH, TO DISCUSS ADDITIONAL INCENTIVES AND OTHER ACTIONS NEEDED.

BRYAN SHUY: I want to quickly echo the point about the under-resourcing of the Strategic National Stockpile, which is a critical issue. When I was working as congressional staff, I was proud to work on getting more resources for it, but it's still nowhere near where it needs to be. The Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) is a coordination of a planned continuum of investment, development, and implementation. We have to treat it that way. We need to think about all the partners involved—CDC, VA, NIH, ASPR, BARDA, the SNS—they all play a critical role, and they are interdependent.

Strengthening PHEMCE. Working from PHEMCE backward to its components, we need to ensure that the Department of Defense is actively participating and coordinating within the countermeasure enterprise. The reality is that many of the same threats facing the nation's warfighters are also material threats to public health. I know that BARDA works closely with its agency partners, but when we think about how this enterprise functions, we also need to connect it more directly to industry as well.

To me, the public–private partnership is more than just putting out an RFP or an RFI. It's about engaging in real dialogue with industry: Here's where we're trying to go now, here's where we need to be in

> *If we take our foot off the gas pedal for biomedical research, the very wave that has been holding up progress in both chronic and infectious disease could collapse—and in a pandemic emergency, we would all go down with it.*
>
> **—RAJ PANJABI, M.D.**
> Former Senior Director for Health Security and Biodefense, National Security Council; Senior Partner, Flagship Pioneering

the future, what rate-limiting steps do you see, what's in your pipeline? That's why I was encouraged to hear comments earlier today about deepening those partnerships. Operation Warp Speed during the COVID pandemic was a great reminder—it doesn't happen without the partnership of industry.

Emerging infectious diseases. I also want to echo the point about emerging infectious diseases. Yesterday's Ebola can become today's material threat. We know that bad actors have weaponized biological agents for centuries, so this is not a novel idea. But the reverse is also true: Products developed to combat a material threat can often become critical tools against emerging infectious diseases. For what was originally developed to combat the material threat of smallpox ended up being used for mpox. That's a value chain that benefits the public in both directions.

Finally, I'll add a point about the contracting "umbrella." I won't go too deep into the weeds because earlier panels covered it well, but tools such as Other Transactional Authority (OTA)—the antitrust exemptions BARDA has, and the FOIA exemptions—all enable BARDA to have open, honest conversations with industry. And those conversations should be a two-way street.

So, when you put all of that together—yes, resourcing, or having the dollars to expend in these areas, is the most obvious need—but beyond that, strengthening PHEMCE's coordination, engaging DoD, building true public-private partnerships, recognizing the dual value of countermeasures, and leveraging flexible contracting authorities—those are the key pieces that will help sustain this enterprise and address the gaps on both sides of the list.

SUSAN NOTED THAT THE GOVERNMENT ACCOUNTABILITY OFFICE (GAO) BACK IN 2023 PUBLISHED A DOCUMENT LOOKING AT ANTIVIRALS AND WARNED THAT MARKET FORCES ALONE WILL NOT PRODUCE THE SUPPLIES OF COUNTERMEASURES NEEDED.[5] THE REPORT DISCUSSED A RANGE OF "PUSH AND PULL" INCENTIVES, INCLUDING THE PREVIOUS "PUSH" OF THE NOW-DISCONTINUED NATIONAL INSTITUTES OF HEALTH-FUNDED AVIDD CENTERS.[6] ONE OF THOSE "PULL" MECHANISMS IS PRIORITY REVIEW VOUCHERS (PRVS). SUSAN ASKED BRYAN TO DISCUSS WHAT SHOULD BE DONE IN THE REALM OF PRVS.**

BRYAN: There are currently three different **priority review vouchers** that apply to treatments for pediatric, tropical disease, and medical countermeasures in general. The tropical disease voucher is still in effect,

** Though the AViDD Centers had their funding canceled in 2025, the fiscal year 2026 draft appropriations bills from both the House and Senate included explanatory language supportive of their continued funding from NIH's budget.

but the other two expired in December 2024 and were not renewed by Congress. These vouchers are an important "pull" mechanism with industry because they don't cost the government much but create huge value by expediting review by the Food and Drug Administration. Having that front-of-the-line access is critical, and in the past, it's been used effectively across large, medium, and small biotechnology and pharmaceutical firms to drive development.

These vouchers are highly valuable not just in financial terms for their developers and manufacturers, but in what they signal to the investment community. Companies can point to a promising candidate and say, if we get this, we'll qualify for priority review, and that leverage can attract downstream investment. They're also tied to Project BioShield in the MCM category, helping with funding gates along the way. For me, the bottom line is simple: Priority reviews are an incredibly powerful tool, and we need to keep reinforcing their value with Congress and stakeholders.

SUSAN ASKED RUXANDRA WHAT SHE WOULD ADD AND ALSO ASKED DAWN ABOUT THE POTENTIAL REAUTHORIZATION OF THE PANDEMIC AND ALL HAZARDS PREPAREDNESS ACT (PAHPA) AND THE POTENTIAL TO BUILD ADDITIONAL INCENTIVES FOR INVESTMENT INTO THAT LAW.

RUXANDRA: I want to focus on R&D, and for me that means strengthening the entire ecosystem. To respond effectively to emerging infectious diseases, every link must work—surveillance, diagnostics, vaccines, treatments, and education for both the public and clinicians. If any part breaks, the response fails. The same is true for funding—we need strong support for basic science and AI, incentives for small enterprises to develop ideas, and reasons for larger companies to prioritize infectious disease alongside oncology or immunology. My wish for this panel is simple: Let's take a true ecosystem approach.

DAWN: It still astounds me that we haven't reauthorized PAHPA as it expired in 2023. Coming out of what we all hope was a once-in-a-generation pandemic, we had clear lessons to learn and changes we needed to make to strengthen the medical countermeasure enterprise. I'm encouraged by today's discussion that a serious bill might still be in play.

When I was in the lead role at ASPR, we looked at issues that weren't flashy but were critical. One example was contracting authorities. ASPR had to rely on DoD for

assisted acquisitions to execute contracts during COVID because DoD had access to contracting tools that HHS did not. That worked, but looking ahead, I don't know if DoD will be available to extend its contracting tools to other agencies next time. With climate change, global interconnectedness, and geopolitical instability, they may not be able to drop everything to help us during the next outbreak. That's why I pushed HHS to have its own contracting authorities—to buy medical countermeasures quickly when we need them.

We also asked for staffing authorities. At the start of the pandemic, we relied on the Federal Emergency Management Agency (FEMA) for surge staffing, and at one point the Coast Guard was running the response team simply because our teams were stretched too thin. We need a mechanism to "surge staff" quickly, and a reauthorized version of PAHPA would be the place to fix that.

Finally, we asked for construction authority to invest in domestic manufacturing. During COVID-19, we only got that authority through the enactment of the American Rescue Plan legislation, and when those dollars disappeared, so did the construction authority. If we want to sustain investments in public–private partnerships and build real bricks-and-mortar capacity, we need construction authority to carry forward.

SUSAN ASKED RAJ TO EXPAND MORE ON THE NEEDED INCENTIVES TO SURMOUNT THE "ANTIVIRAL PARADOX" THAT HE DESCRIBED EARLIER.

RAJ: I want to underscore many of the points Bryan and Dawn raised and add one more.

Computational biology and AI. We need much greater U.S. government focus on co-developing preclinical platforms that leverage the incredible advances in computational biology, AI, and biotech. If we bring that entire base to bear on this problem, we can move platform technologies forward to phase one clinical trials and even have manufacturing prototypes ready—so that when the time comes, we're prepared to take them further.

SUSAN ASKED WHAT WOULD HAVE TO OCCUR ON THE SIDE OF THE FEDERAL GOVERNMENT IN SUCH A CO-DEVELOPMENT STRATEGY.

RAJ: I think part of the solution is looking at BARDA, which focuses heavily on advanced R&D, and NIH, which focuses on preclinical R&D.

Strengthening and coordinating NIH and BARDA. With NIH funding under threat, many areas of biomedical research are at risk—especially fields such as antivirals that already receive less attention in comparison to vaccines or other interventions. If we take our foot off the gas pedal for biomedical research, the very basis of progress in both chronic and infectious disease could collapse—and in a pandemic emergency, we would all go down with it.

For me, the priority is making sure that both BARDA and NIH are as strong as possible, and then creating a holistic strategy that closes the gaps between them. That also means fostering greater coordination between these agencies and working closely with the biotechnology sector and especially with companies that are in the early stages of their business and growth.

Dedication of our champions. What's powerful about the people gathered in this room and listening to this session is that, out of the collective trauma that we've all

experienced, a growing group of champions has emerged over the past several years.

Protecting Americans is not political. It's our job to make sure that policymakers—across ideologies and parties—understand that protecting Americans and the world from biological threats is not political. It's about basic safety, which is something we all want. We have to step forward as champions, to educate, engage, and never give up—because this mission is sacred.

In all my years, I've never seen a group more dedicated than the U.S. biodefense enterprise, and the same is true on the private sector side. The fact that so many of you are here instead of in other rooms shows that we share the same common mission: keeping people safer from biological threats.

AUDIENCE Q&A

Chronicity of viral infections. One audience member questioned whether the field is too narrowly focused on acute viral infections at the expense of understanding and treating chronic consequences, such as long COVID. He suggested that reframing chronic viral conditions as distinct markets—similar to HIV and hepatitis C—could unlock investment and create sustained demand for antivirals. Raj Panjabi agreed that long COVID remains poorly understood, with mechanistic studies still in progress and no standard of care yet established. He noted that antivirals show promise both in prevention and treatment of long COVID, though more evidence is needed. John Pottage added that funding should expand to study host-virus interactions, immunology, and long-term outcomes, not just short-term infection, since viral evolution continually changes disease profiles.

Small companies and volatile funding. A second question focused on how small companies developing antivirals can sustain progress given the volatility of funding and shifting investor and government priorities. Raj Panjabi emphasized the importance of collaboration and coalition-building, noting that smaller firms often gain more traction when presenting as part of broader groups rather than alone. Such alliances make it easier to engage policymakers, share strategies for weathering funding cycles, and identify opportunities across adjacent areas of research. His advice underscored that resilience for startups in this space lies not only in scientific innovation but also in collective advocacy and partnership.

REFERENCES

[1] INTREPID Alliance. Antiviral Clinical and Preclinical Development Landscape— 4th Edition. 30 APRIL 2025. https://www.intrepidalliance.org/antiviral-pipeline/

[2] Airfinity. (2023, April 13). A strong pandemic defence system could reduce the chance of another COVID-like pandemic in the next ten years from 27.5% to 8%. https://www.airfinity.com/articles/a-strong-pandemic-defence-system-could-reduce-the-chance-of-another-covid

[3] Draghia-Akli, R., Hill, N. M., Altevogt, B., Bradley, K., Chibale, K., Cihlar, T., Clinch, B., Demarest, J. F., & Neyts, J. (2025). The indispensable value of small-molecule antivirals in epidemic and pandemic preparedness. Clinical Infectious Diseases. Advance online publication. https://pubmed.ncbi.nlm.nih.gov/40892067/

[4] Commonwealth Fund. (2022, December 13). Two Years of U.S. COVID-19 Vaccines Have Prevented Millions of Hospitalizations and Deaths. https://www.commonwealthfund.org/blog/2022/two-years-covid-vaccines-prevented-millions-deaths-hospitalizations

[5] U.S. Government Accountability Office. (2023, September 29). Antiviral drugs: Economic incentives and strategies for pandemic preparedness (Report No. GAO-23-105847). https://www.gao.gov/products/gao-23-105847

[6] National Institute of Allergy and Infectious Diseases. (2022, May 24). Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Concern. https://www.niaid.nih.gov/research/antiviral-drug-discovery-centers-pathogens-pandemic-concern

APPENDIX

SUSAN DENTZER, M.S.
PRESIDENT AND CEO OF AMERICA'S PHYSICIAN GROUPS

Susan Dentzer is President and Chief Executive Officer of America's Physician Groups, the nonprofit organization representing more than 360 large physician groups focused on patient-centered, coordinated, and integrated health care that is accountable for both costs and quality. Dentzer is a highly respected health and health policy thought leader, a frequent speaker and commentator, and an author of commentaries in Modern Healthcare, the New England Journal of Medicine Catalyst, the American Journal of Public Health, and other prominent publications. She is also the editor and lead author of the book Health Care Without Walls: A Roadmap for Reinventing U.S. Health Care. She is an elected member of the National Academy of Medicine and the Council on Foreign Relations and is a fellow of the National Academy of Social Insurance and the Hastings Center. Dentzer graduated from Dartmouth and also holds a master's degree in health care delivery science from the institution. She is a trustee emerita of Dartmouth, chaired the institution's Board of Trustees from 2001-2004, and also served on the board of Dartmouth Health as well as the Board of Advisors of the Geisel School of Medicine at Dartmouth. Dentzer serves on the advisory boards of the Robert J. Margolis Center for Health Policy at Duke University; the Center for Global Health Equity at Dartmouth; and the Philip R. Lee Institute for Health Policy Studies at the University of California, San Francisco (UCSF). From March 2021-March 2023, Dentzer chaired the Board of Directors of Research!America, which advocates for health-related research, and formerly chaired the board of the Global Health Council. Dentzer was also a member a longtime member of the Board of Directors of the International Rescue Committee, the organization that works in more than 40 countries to help those affected by humanitarian crises survive and rebuild their lives and currently serves on IRC's Board of Advisors.

RUXANDRA DRAGHIA-AKLI, M.D, Ph.D.

CHAIR, SCIENTIFIC ADVISORY BOARD, INTREPID ALLIANCE; EXECUTIVE VICE PRESIDENT AND HEAD OF R&D AT NOVAVAX

Ruxandra Draghia-Akli, M.D., Ph.D., is the Executive Vice President and Head of Research & Development (R&D) in Novavax, ensuring the company is maximizing the tremendous potential of Novavax's proven technology, including the Matrix-M™ adjuvant. She is the chair of the Scientific Advisory Board of the INTREPID Alliance, an organization focused on accelerating small-molecule antiviral R&D. Dr. Draghia-Akli previously served at Johnson & Johnson, as Global Head of Global Public Health R&D, and Merck, Inc. delivering groundbreaking innovations in drugs and vaccines to address climate-related, emerging and entrenched health threats. She also worked with the European Commission, supporting programmatic, legislative, regulatory and policy issues in medical research and innovation. Over her career, Dr. Draghai-Akli has authored many scientific publications and served on numerous boards and committees to help shape thinking on vaccine and public health issues. Dr. Draghia-Akli received an M.D. from the University of Medicine Carol Davilla, Romania and a Ph.D. in human genetics from the University of Medicine Carol Davilla and undertook additional doctoral and post-doctoral training at University Rene Descartes, France and Baylor College of Medicine, USA respectively.

DAWN O'CONNELL, J.D.

FORMER ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE (ASPR), U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

In this role, O'Connell led the nation in preparing for, responding to, and recovering from public health emergencies and disasters. During her tenure, O'Connell responded to 20 public health emergencies; dozens of natural disasters, including Hurricane Helene and the Maui wildfire; dozens of infectious disease outbreaks, including COVID-19, mpox, and H5N1; and over 400 cyber security incidents. Before joining the Biden Administration, she was the Director of the U.S. Office for the Coalition for Epidemic Preparedness and Innovation (CEPI), a global partnership to develop vaccines to stop future epidemics. As Director, she was responsible for managing the broad spectrum of CEPI's U.S. and North American interests, including its relationships with U.S. and North American-based stakeholders, government entities, and industry partners. Prior to her work with CEPI, O'Connell served as a Senior Counselor to Secretary Sylvia Burwell and Deputy Chief of Staff to Secretary Sebelius at the U.S. Department of Health and Human Services (HHS) during the Obama-Biden Administration. In these roles, O'Connell advised the Secretaries on high-priority domestic policy, global health and humanitarian issues, including infectious diseases, public health emergencies, and refugees. She worked with HHS leaders, the White House, and other federal and international partners, to resolve key policy challenges, lead implementation, and drive progress toward Administration goals. O'Connell received a Bachelor of Arts in Literature from Vanderbilt University and a Juris Doctor from Tulane University School of Law.

RAJ PANJABI, M.D.

FORMER SENIOR DIRECTOR FOR HEALTH SECURITY & BIODEFENSE, NATIONAL SECURITY COUNCIL; SENIOR PARTNER, FLAGSHIP PIONEERING

Raj Panjabi leads Flagship's Preemptive Health and Medicine Initiative, which is on a mission to detect and intervene in the progression of disease sooner. Raj previously served as White House Senior Director, and President Biden's top pandemic and health official at the National Security Council, where he played a pivotal role in the largest vaccination campaign in history against COVID-19 and responses to public health crises, including mpox, influenza and Ebola. He played a lead role executing the 2022 National Biodefense Strategy and American Pandemic Preparedness Plan, coordinating over $12 billion in annual investment across 16 federal agencies in biodefense. Raj is co-founder and former CEO of Last Mile Health, a global organization transforming community health systems. One of TIME's 100 Most Influential People in the World and TIME's 50 Most Influential People in Healthcare and twice named to the FORTUNE World's 50 Greatest Leaders list, Raj has received the TED Prize, Clinton Global Citizen Award, and World Economic Forum's Social Entrepreneur of the Year award. He trained in biochemistry, epidemiology and biostatistics, and medicine at the University of North Carolina at Chapel Hill, Johns Hopkins University, Harvard Medical School, and Massachusetts General Hospital.

JOHN C. POTTAGE, JR., M.D.

LEAD SCIENTIFIC CONSULTANT AT INTREPID ALLIANCE

John C. Pottage, Jr., M.D., served as Senior Vice President and Chief Scientific and Medical Officer of ViiV Healthcare from November 2009 to October 2019, where he oversaw research and development, regulatory, safety and medical affairs. Prior to joining ViiV Healthcare, Dr. Pottage served as Senior Vice President and Head of the Infectious Disease Medicine Development Center at GlaxoSmithKline from September 2008 to November 2009, and prior to that, from June 2007 to September 2008, as Vice President of Global Clinical Development of Antivirals at GlaxoSmithKline. From May 2002 to May 2007, Dr. Pottage served as Chief Medical Officer and Senior Vice President of Drug Development of Achillion Pharmaceuticals. Prior to Achillion Pharmaceuticals, Dr. Pottage served as Medical Director of Vertex Pharmaceuticals, and in various clinical and academic positions in the Section of Infectious Diseases at Rush University Medical Center. Since 2018, Dr. Pottage has served as a non-executive Director of Spero Therapeutics, Cambridge, MA. Additionally, he presently is the Lead Scientific Consultant for the INTREPID Alliance, Cambridge, MA and serves on the Global Safety Board for Medicines for Malaria Venture, Geneva Switzerland. He received his A.B. in Biology from Colgate University and his M.D. from Saint Louis University School of Medicine. He is board certified in Internal Medicine and Infectious Diseases by the American Board of Internal Medicine.

BRYAN SHUY

FORMER CHIEF OF STAFF TO HOUSE APPROPRIATIONS AGRICULTURE & FDA SUBCOMMITTEE CHAIRMAN, FORMER DEPUTY ASSISTANT SECRETARY & CHIEF OF STAFF TO THE ASSISTANT SECRETARY FOR PREPAREDNESS & RESPONSE; SENIOR VP AT THE CONAFAY GROUP

Bryan is a seasoned executive with over two decades of experience in policy and management across various levels of government. His expertise spans appropriations, healthcare, biodefense, emergency response, and agricultural issues. Bryan has served as Chief of Staff to a Congressional Appropriations Subcommittee Chairman and as a Deputy Assistant Secretary and Chief of Staff (a senior executive service appointment) in the Administration for Strategic Preparedness and Response that includes the Biomedical Research and Development Authority (BARDA), Strategic National Stockpile (SNS), and National Disaster Medical System. This work experience has taken him from briefing in the White House to leading delegations of scientists to allied nations to high level Congressional negotiations over government spending and had him participating in historic activities such as in the development and early execution of Operation Warp Speed. Today, Bryan provides government relations services to biomedical and related industry clients.

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