



Fostering Collaboration Between Security and Radiotherapy-Focused Organizations

Inaugural Roundtable – Opening Session
24 October 2023

The Case for Collaboration between Health and Security Lessons from COVID-19 and the International Cancer Expert Corps (ICEC)

Monique K. Mansoura, PhD, MBA
International Cancer Expert Corps (ICEC), Board
The MITRE Corporation, Executive Director, Global Health Security & Biotechnology



The Case for Collaboration - The Bottom Line

- > THESIS: A Safe and resilient Health Care Systems (space, staff, stuff) is critical infrastructure for health, economic and national security
- Combination of Complexity and Scarcity demands a more efficient and importantly, effective approach to global challenges
 - a. Health Cancer/NCD and COVID/ID
 - b. Security Nuclear Security and Biosecurity/Biodefense
- Worlds in Collision and collaboration reveal keen insights and drive innovative partner and approaches
 - a. History April 2000, AIDS declared a national and global security threat
 - b. 2001 9/11 and the anthrax attacks HHS embeds a security-focused mission in its organization
 - Pre-positioned for COVID-19 response
 - c. ICEC a systems approach across health and security
- Challenges and Opportunities we can do this!

The whole is greater than the sum of its parts.

Aristotle



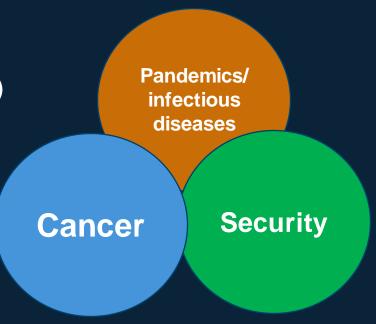


Cancer & Pandemics – safe, resilient communities

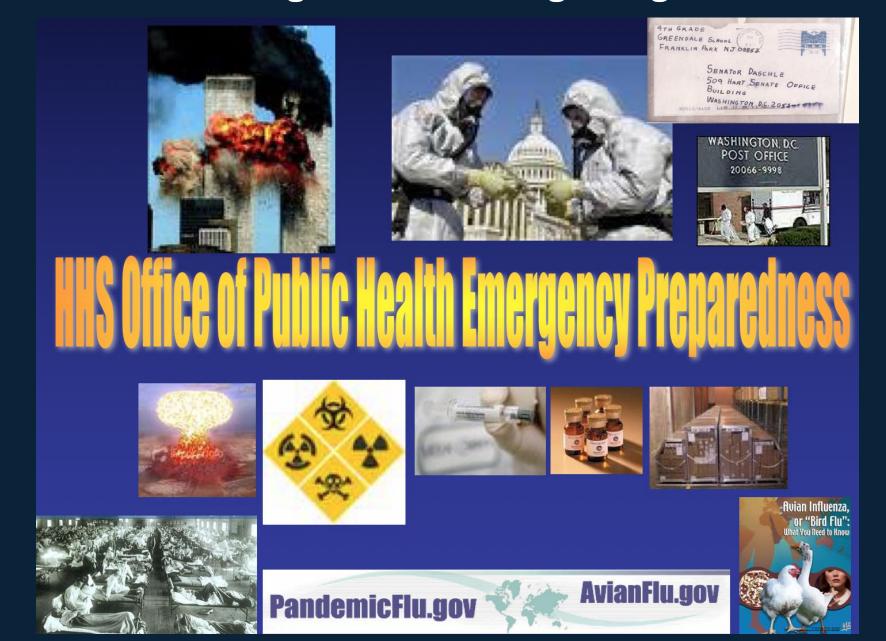
OVERVIEW

Leverage Synergies – Cancer and COVID and Security (1+1+1 = 6)

- Molecular to the Macro
- Space, Staff and Stuff across the Systems
- Benefits to cost, capacities and capabilities
- Ensure Meaningful Measures and Accountabilities that are crosscutting and challenge false dichotomies
 - Build credibility with donors and investors
 - Incentivize and reward innovation in flex competence
- Sustained Commitment Leadership, Governance, Investment
 - Healthy communities are a Security Asset



Origins of US civilian organization integrating Health & Security



A Systems View of Global Health Security



Threat Assessment



Surveillance and Situational Awareness



Industrial Base and Supply Chain Resilience



Health System Resilience



Community and Business Resilience

Policy, Execution, Equity, Measures, Business Model, Advocacy



Partnering to transform global cancer care

HIV AND NATIONAL SECURITY: WHERE ARE THE LINKS? A COUNCIL ON FOREIGN RELATIONS. REPORT BY LAURIE GARRETT

Health & Security – 25 years of history

United States Senate Committee On
HOMELAND SECURITY
& GOVERNMENTAL AFFAIRS
Chairman Gary Peters

SHORT SUPPLY
The Health and National Security

Risks of Drug Shortages

HSGAC Majority Staff Report

March 2023

10-POINT ACTION PLAN: SUSTAINING A BIOPHARMA INDUSTRIAL BASE FOR A MORE SECURE NATION

High-impact events, including pandemics, extreme weather events, and trade disputes, put U.S. national security and long-term economic competitiveness at risk.¹

A lack of a sustainable biopharma industrial base, including critical infrastructure and a trained workforce, to ensure adequate supply of medical countermeasures, essential medicines, and medical supplies at sufficient scale and speed, warrants urgent action. We propose this 10-point action plan to mitigate risks from these high-consequence events, while fostering a stronger bioeconomy and a safer world.²

Context

Over the past two decades, the U.S. Government (USG) has made strides in bolstering our capacity to respond to biological threats from natural, accidental, or intentional causes. ³ The USG has, for example, instituted new agencies, programs, and funding sources dedicated to the nation's biosecurity. ⁴ Despite these actions, our preparedness and response to biological threats remain reactive and transactional as opposed to proactive and strategic. ⁵ This has resulted in several systemic consequences for U.S. security.



MITRE, a non-profit public interest organization, operating six

federally funded research and development centers in support

10-Point Action Plan

DRUG SHORTAGES
VOICE THAT COMMENTS

COLD MEDICINE

COLD MEDICINE

COLD MEDICINE

COLD MEDICINE

Watch >

Drug shortages rise to the level of

national security concern

Uploaded: Mar 22, 2023

10-POINT ACTION PLAN: SUSTAINING A BIOPHARMA INDUSTRIAL BASE FOR A MORE SECURE NATION

High-impact events, including pandemics, extreme weather events, and trade disputes, put U.S. national security and long-term economic competitiveness at risk.1

A lack of a sustainable biopharma industrial base, including critical infrastructure and a trained workforce, to ensure adequate supply of medical countermeasures, essential medicines, and medical supplies at sufficient scale and speed, warrants urgent action. We propose this 10-point action plan to mitigate risks from these high-consequence events, while fostering a stronger bioeconomy and a safer world.2

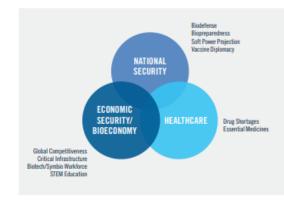
Context

Over the past two decades, the U.S. Government (USG) has made strides in bolstering our capacity to respond to biological threats from natural, accidental, or intentional causes.3 The USG has, for example, instituted new agencies, programs, and funding sources dedicated to the nation's biosecurity.4 Despite these actions, our preparedness and response to biological threats remain reactive and transactional as opposed to proactive and strategic.5 This has resulted in several systemic consequences for U.S. security.

Vision

The USG creates industrial policy to sustain a world-class industrial base, responsive to national, economic, and health security needs. We propose three primary objectives by which to accomplish this:

- Protection of the United States population from future pandemics and other biological threats (naturally occurring, accidental, and intentional), as aligned with core global health security principles:
- Development of supply chain resilience that absorbs supply and demand shocks and scales to meet national needs; and
- Leadership of the bioeconomy to meet domestic needs as well as global export requirements both during crises and intercrisis.



Three Lenses of Biopharma Industrial Policy

10-Point Action Plan

MITRE, a non-profit public interest organization, operating six federally funded research and development centers in support of USG missions, proposes the following 10-point action plan.6 This plan was developed with guidance from leading experts with decades of public and private sector experience in this mission and ecosystem. These actions are aligned with multiple policy priorities of the Biden-Harris Administration.7. 8,9 As the biological threat landscape evolves in frequency and intensity, MITRE also recognizes the need for continuity across administrations in executing against the needs of this mission space. Several action items proposed here may be significantly advanced in a three-to-six-month timeframe, offering near-term wins that can be built upon for longer-term gains. We note that the USG leader who presides over this action plan should have expertise in each discipline pertaining to the product development lifecycle, in addition to the broader biopharmaceutical ecosystem.10

10-POINT ACTION PLAN

Creating an Industrial Base for Essential Medicines, Medical Countermeasures, and Critical Medical Supplies to Mitigate National, Economic, and Health Security Risks from Biological Threats

POLICY

We recommend the following policy and strategy actions to achi including portfolio-based management.

- 1. Define specific strategic goals of capability and capacity f set a "moonshot" goal akin to that aspired by CEPI and O within 100 days."11, 12 This goal would create a transparent countermeasure innovation while serving as the foundation agreements.
- 2. Establish an integrated portfolio strategy incorporating fun use systems approach) and assessment as well as sound investments, including elements such as:
 - Creating methodologies to assess the feasibility, cos analysis of trade-offs among options (e.g., capacity advanced biomanufacturing/synthetic/biotechnolog
 - Developing clear benchmarks, mission goals, and in transitions to next-generation products manufacturi
 - Optimizing stockpile and surge requirements for the
- Develop United States Government-led target product pro characteristics needed for both medical countermeasures use settings) products along with quantities required for p products, in sufficient quantities, when needed, as well as setting exercise for TPPs may help facilitate policy develop

PROGRAM

We recommend the following actions to reform enterprise mana and asset lifecycle management.

- 4. Attract, train, and retain a world-class workforce-nimble sectors, including biopharmaceutical R&D and biomanufa business practices.
- Promote agile program management and transparent acco practice for bio-incidents, and enhanced program manage
 - Developing meaningful metrics for products, portfo
 - Coordinating with multilateral organizations in the deto avoid duplication of effort, accelerate emergency
 - Managing assets aggressively across the lifecycle w no go" decisions and ensuring seamless transitions integrated systems approach (e.g., akin to Project A
 - Creating USG capabilities in health economics and making in portfolio management.

6. Institutionalize test, evaluation, and safety standards compatible with the speed and scale of MCMs required in a bioresponse, using both existing disease burdens and emerging threats as demonstration projects to validate capabilities.

FINANCING AND INDUSTRIAL BASE ENGAGEMENT

We recommend the following financing and industrial base engagement approach to stabilize and sustain funding to address market failures, secure the nation from high-impact threats, and ensure industrial base objectives are met during a crisis and between crises.

- 7. Facilitate innovative business models and financing strategies to secure sufficient funding commensurate to the threat environment over an extended period of time (e.g., multi-year funding).
- 8. Develop a portfolio budgeting approach that provides sufficient flexibilities to meet industrial base mission
- 9. Ensure spend plans link financial investments with accountability mechanisms, and are justified, durable, transparent, and aligned with budget.
- Institute a world-class scientific and national/economic security advisory board. This board, comprised of internationally recognized experts, would offer industry competitive intelligence for the bioeconomy and the government, providing vital information to inform sustained engagement with industry.
- 1. These events also have downstream effects on food security, while not explicitly mentioned here.
- Although not a focus of discussion here, these actions must be integrated with other critical functions in the broader system of capabilities for national security (e.g. biosurveillance and public health infrastructure), the bioeconomy (e.g., trade policies), and healthcare (resilient healthcare systems).
- 3. Alexander, L. (2020). Preparing for the Next Pandemic: A White Paper [Ebook]. Retrieved from https://www.help.senate.gov/imo/media/doc/ Preparing%20for%20the%20Next%20Pandemic.pdf
- 4 Ibid

@ 2021 MITRE #21-2355 8-5-2021

- 5. Ayote, K., Gerberding, J., & Morrison, S. (2019). Ending the Cycle of Crisis and Complacency in U.S. Global Health Security: A Report of the CSIS Commission on Strengthening America's Health Security (Ebook). Washington, DC: Center for Strategic & International Studies. Retrieved from https://csis-website-prod.s3.amazonaws.com/s3fs-public/ publication/191122_EndingTheCycle_GHSC_WEB_FULL_11.22.pdf
- 6. We note that we do not address a leadership model by which to execute the recommendations in this action plan, however, this leader should preside over the USG roles in the mission space, with the expertise to oversee critical decisions across the biopharma lifecycle.
- 7. National Security Memorandum on United States Global Leadership to Strengthen the International COVID-19 Response and to Advance Global Health Security and Biological Preparedness I The White House (2021). Retrieved 5 March 2021, from https://www.whitehouse.gov/ briefing-room/statements-releases/2021/01/21/national-securitydirective-united-states-global-leadership-to-strengthen-the-international covid-19-response-and-to-advance-global-health-security-andbiological-preparedness/

- 8. National Strategy for COVID-19 Response and Pandemic Preparedness (2021). [Ebook]. Retrieved from https://www.whitehouse.gov/ Response-and-Pandemic-Preparedness.pdf
- Interim National Security Strategic Guidance (2021). [Ebook]. Retrieved from https://www.white uploads/2021/03/NSC-1v2.pdf
- 10. For the purposes of this action plan; we do not address or recommend a leadership or governance model to execute the action plan, rather we relay the qualities in a leadership structure that we believe are critical to the mission.
- 11. CEPI. (2021). The Urgency of Now: Turning the Tide Against Epidemic and Pandemic Infectious Diseases (Ebook). Retrieved from https:// case_10032021.pdf
- 12. Borenstein, S. (2021). Science chief wants next pandemic vaccine ready in 100 days. Retrieved 27 July 2021, from https://www.pbs.org/ 100-days



MITRE's mission-driven teams are dedicated to solving problems for a safer world. Through our public-private partnerships and federally funded R&D centers, we work across government and in partnership with industry to tackle challenges to the safety, stability, and well-being of our nation.



International Cancer Expert Corps

Catalytic and disruptive innovation to transform global cancer care...



C. Norman Coleman, MD, FASTRO

ICEC Programs

- Promote expert mentoring through partnership program and matched funding to support participants
- Transform cancer care by partnering with local communities to build sustainable infrastructure and programs
- Serve as a convener to engage stakeholders to promote innovation in new technologies, such as radiation therapy equipment design

The State of Things...

- Underserved populations lack access to cancer care experts
- Surge of interest in developed world to deliver high quality cancer care
- Current environment encourages depletion of talent, brain drain in lowand middle-income countries (LMICs)
- Radioactive Cobalt-60 machines present possible environmental and security risks and lack sophistication needed for modern radiotherapy
- No practical, accessible and affordable technology resources currently exist



Innovation
New Equipment Design

...reduces mortality and improves quality of life for people with cancer in LMICs and underserved regions worldwide

Achieving Flexible Competence: Bridging the investment dichotomy between infectious diseases and cancer

Global initiatives that independently address Infectious Diseases (IDs) and non-communicable diseases (NCDs) miss the opportunity to enhance capabilities for both missions.

Analyeis

BMJ Global Heal

Achieving flexible competence: bridging the investment dichotomy between infectious diseases and cancer

C Norman Coleman ¹ O, Monique K Mansoura, Maria Julia Marinissen, Surbhi Grover, ^{2,4} Manjit Dosanjh ¹ O, ^{2,5} Harmar D Brereton, Lawrence Roth, Eugenia Wendling, David A Pistenmaa, Donna M O'Brien ²

To cite: Coleman CN, Mansoura MK, Marinissen MJ, et al. Achieving flexible competence: bridging the investment dichotomy between infectious diseases infectious diseases cancer. BMJ Global Health 2020;5:e003252. doi:10.1136/

Handling editor Seye Abimbola

Received 25 June 2020 Revised 7 October 2020 Accepted 9 October 2020



Author(s) (or their employer(s)) 2020. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by

STRACT

Today's global health challenges in underserved

communities include the growing burden of cancer and

other non-communicable diseases (NCDs); infectious

diseases (IDs) with epidemic and pandemic potential

'all hazards' disasters including natural, industrial or

such as COVID-19: and health effects from catastrophic

terrorist incidents. Healthcare disparities in low-income and middle-income countries and in some rural areas in developed countries make it a challenge to mitigate

these health, socioeconomic and political consequences

rapid intervention and its effective medical management

on our globalised society. As with IDs, cancer requires

and prevention encompasses the other major NCDs.

Furthermore, the technology and clinical capability for cancer care enables management of NCDs and IDs. Global

health initiatives that call for action to address IDs and

government policy and healthcare systems we have

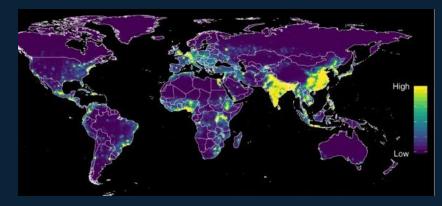
cancer, NCDs and disaster preparedness to improve

overall healthcare for the local community. This approach builds on trusted partnerships, multi-level strategies and

cancer often focus on each problem separately, or consider cancer care only a downstream investment to primary care, missing opportunities to leverage investments that could support broader capacity-building. From our

- ► In low-income and middle-income countries continued investment is needed to address in fectious diseases (IDs) and more is needed for non-communicable diseases (NCDs), which are the leading cause of death.
- The aetiological relationship between IDs and can cer is increasingly common (eg, Human papillom virus (HPV) and cervical cancer and hepatitis C an liver cancer) with many healthcare service needs in common
- catastropnic incidents including natural disasters terrorism and pandemics, such as COVID-19, require sustainable healthcare infrastructure to meet sudden surge capacity.
- Global initiatives that address IDs, NCDs and disaster preparedness separately miss the opportunity support all-hazards capacity-building.
- Cancer care is an ideal entry point to other NCDs a it requires immediate intervention like IDs and atter tion to the other NCDs and IDs.
- An approach that provides an integrated health system using the *Res-competence* model described in this paper will support routine care for NCDs, including cancer while being able to rapidly adapt to changing needs as presented by IDs and other catastroobic incidents.

- Geographic alignment in hotspots (IDs) and disease burden (NCDs)
- Both require early detection and rapid response
- Convergent, adaptable medical care capacity-building is cost-effective
- Similar etiology and systemic responses
 - Infectious agents
 - Immunology
 - Inflammation



Coleman CN, Mansoura MK, et al., BMJ Global Health 2020;5:e003252. doi:10.1136/bmjgh-2020-003252

A Dual Capacity Health System with Flex-competence

IDs and Pandemics

Population at Risk

ID Patient

Interrelationships exist between NCDs & IDs

- Infectious diseases cause some cancers (HPV, Hep C, HIV)
- Cancer patients are susceptible to infections

Cancer Patient

Patient

NCD

NCDs

Population-level
Assessment
(Pandemics)

Rapid Assessment

Ongoing Prevention & Chronic Treatment

Common Healthcare Capability Needed

Physical Exam

Lab, molecular diagnostics

Diagnostic Imaging Treatment & Prevention of Recurrence

Immune
Response &
Inflammation
Modulation

Integrated Healthcare
System
for IDs, NCDs,
Pandemics, Disasters

Prevention of IDs, Immunizations

Population Surveillance

Prevention of NCDs (screening, lifestyle, diet, no smoking)

Diagnostics (Lab & Imaging)

Treatment (incl. palliative care)

Patient Surveillance

IMPROVED
HEALTH
OUTCOMES &
PREPAREDNESS

Coleman CN, Mansoura MK, et al., BMJ Global Health 2020;5:e003252. doi:10.1136/bmjgh-2020-003252

Cautionary Tales – Collision of Cultures

Health and National Security: A Contemporary Collision of Cultures

Kenneth W. Bernard



- The health community must temper its tribal convictions and convince powerful defense and foreign affairs communities to embrace relevant health issues in the first tier of policy and budget concerns
- Health professionals and organizations generally have little experience in crafting messages and issues that speak to the critical power players who have foreign policy, intelligence, and defense credentials. But it is not solely their fault. The security sector is not enthusiastic about being told that issues such as pandemics should be considered "front burner" security problems

Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science Volume 11, 2013

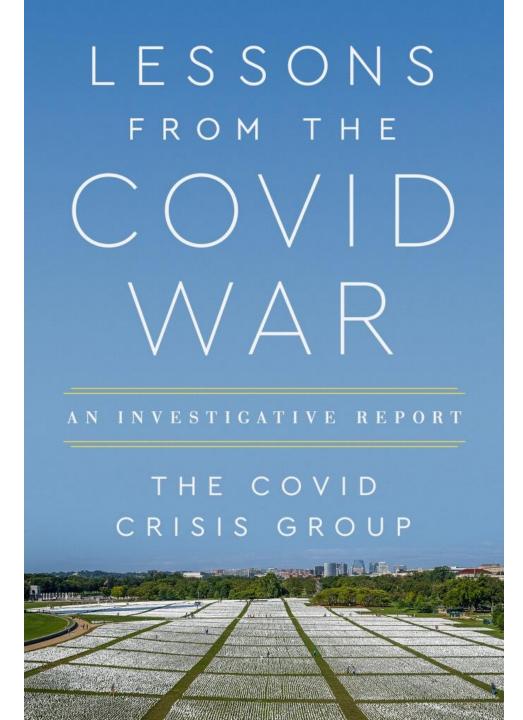
Treatment not Terror - A powerful framework

Treatment, Not Terror: Time for Unique Problem-Solving Partnerships for Cancer Care in Resource-Challenged Environments



- C. Norman Coleman, Miles A. Pomper, Neson Chao, Ferenc Dalnoki-Veress, David A. Pistenmaa, J Global Oncology, Vol 3, Issue 6, Dec 2017
- "The driving forces that bring the public health and security communities together are the real threat of dirty bombs and other forms of nuclear and radiological terrorism, and an enormous shortage of cancer care in LMICs."
- The daunting, and at times overwhelming nature of these issues provides the incentive needed to build uniquely effective global problem-solving partnerships"





"The pandemic has been one of the major mass traumas suffered by humanity during the last one hundred years.

Yet there remains a significant gap between the size of the crisis and the scale of the reforms.

None of the reforms enacted thus far would have made a difference had they been in place in 2019. This report hopes to change that."



Positive Trends

- On 1 August 2023, the U.S. State Department officially launched a new Bureau of Global Health Security and Diplomacy
- This new Bureau will seamlessly integrate global health security as a core component of U.S. national security and foreign policy, underscoring the Department of State's commitment to advancing human health worldwide.



Our Mission

The Bureau of Global Health Security and Diplomacy (GHSD) leads and coordinates the Department's work on strengthening global health security to prevent, detect, and respond to infectious diseases, including HIV/AIDS. The Bureau leads U.S. diplomatic engagement; leverages and helps coordinate U.S. foreign assistance; and promotes international cooperation at the national, regional, and multilateral levels to better protect the United States and the world from health threats. The Bureau elevates and integrates global health security as a core component of U.S. national security and foreign policy.



AMBASSADOR-AT-LARGE, U.S. GLOBAL AIDS COORDINATOR AND SENIOR BUREAU OFFICIAL FOR GLOBAL HEALTH SECURITY AND DIPLOMACY

Dr. John N. Nkengasong



ADDITIONAL BACKGROUND

Hybridity



Monique K. Mansoura, Ph.D., MBA, leads MITRE's work in global health security and biotechnology. An expert in biodefense and drug development and policy, Mansoura credits several man-made and natural disasters with sharpening her resolve to find ways to reimagine how the U.S. prepares for and navigates major events like the COVID-19 pandemic.

- Education: Chem/Bio-engineering, Human Genetics, Business
- US Government (1996-2011)
 - Human Genome Project
 - Biodefense/Biosecurity post-9/11 (BARDA)
 - Global Health Security Initiative
- MIT Sloan Fellow (2011-2012)
- Biopharmaceutical Industry (2012-2017)
 - Novartis Vaccines → CSL/Seqirus
 - Independent
- MIT Laboratory for Financial Engineering (2016-2018)
- Non-profits
 - MITRE (2017-)
 - Federally Funded R&D Center (FFRDC)
 - COVID-19 Healthcare Coalition
 - International Cancer Expert Corps, ICEC (2015-)

https://www.mitre.org/careers/working-at-mitre/employee-voices/biodefense-expert-national-preparedness

MITRE's Data-Driven, Evidence Based Analyses of the Biopharma/Biotechnology Industrial Base



10-POINT ACTION PLAN: SUSTAINING A BIOPHARMA INDUSTRIAL BASE FOR A MORE SECURE NATION



10-Point Action Plan

MITRE, a non-profit public interest organization, operating federally funded research and development centers in su of USG missions, proposes the following 10-point action nlan ⁶ This plan was developed with quidance from leading experts with decades of public and private sector experie in this mission and ecosystem. These actions are aligned multiple policy priorities of the Biden-Harris Administration 8.9 As the biological threat landscape evolves in freque and intensity MITRE also recognizes the need for contiacross administrations in executing against the needs of mission space. Several action items proposed here may significantly advanced in a three-to-six-month timefram offering near-term wins that can be built upon for longer gains. We note that the LISG leader who presides over this action plan should have expertise in each discipline perta to the product development lifecycle, in addition to the broader biopharmaceutical ecosystem.



MITRE | Global Health Security

Collaborating Across Sectors to Build a Biopharma Industrial Base

In an evolving threat landscape, MITRE's public service mission and trusted relationship with government has never been more important than it is today The nation will continue to grapple with the threat of biological events such as COVID-19, and MITRE stands ready to partner across sectors to mitigate the consequences of such events to the American people.

MITRE has extensively engaged leaders from industry, academia, and government to develop sustainable solutions for building a biopharma industrial base. This industrial base secures access to, and supply of medical countermeasures, essential medicines, and critical medical supplies, which MITRE understands as vital to national, economic, and health security interests.

In bringing interdisciplinary, systems thinking to the complex challenges facing government in securing and sustaining a biopharma industrial base, MITRE serves as a uniquely qualified partner to government. Our experts offer decades of experience related to the persistent challenges facing government and industry in the strengthening and sustainment of this industrial base.

In crisis or "peacetime," we lead with a driving sense of urgency to help government develop innovative business models, establish strong partnerships, and implement evidence-based recommendations to see world safer from health threats.

The loss of life and livelihood caused by COVID-19 brought in stark relief the devastating nature of novel pathogens and the critical importance of being prepared for the next threat.

Dr. Jay Schnitzer, Chief Medical and

MITRE

https://www.mitre.org/publications/technical-papers/building-a-sustainable-biopreparedness-industrial-base

https://www.mitre.org/news/press-releases/mitre-proposes-10-point-plan-to-sustain-a-biopharma-industrial-base