Current and Future Challenges to U.S. Biosecurity Strategy

Annotated Bibliography on Emerging Biological Threats and Responses in the Context of U.S. National Security

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This annotated bibliography is a CGSR contribution toward advancing the success of LLNL's Biosecurity mission and precedes the release of the unclassified 2022 U.S. National Biodefense Strategy. It is intended as an entry point to relevant biosecurity literature for researchers and policymakers working through the lens of U.S. national security. As such, materials germane to plant and animal health, as well as highly technical scientific content, are largely excluded.

Rising urbanization, population growth, mass migration, climate change, and diminishing biodiversity are expected to cause future pandemics to occur with increasing frequency. While some countries (e.g., South Korea and Vietnam) were able to respond to the COVID-19 pandemic quickly and effectively, most remain alarmingly underprepared for future natural and human-caused outbreaks. Policymakers must anticipate major threats to biosecurity and understand best practice responses to craft effective high-level strategic guidance that is customizable for local implementation. Universal elements of successful responses to COVID-19, including high levels of interpersonal and trust in government, as well as low levels of perceived corruption, are aspects policymakers should foster to improve social solidarity and resilience in the long term. Along with building preparedness and response capacities, policymakers must mitigate interrelated factors that may undermine their execution, such as the politicization of public health and the proliferation of misinformation via social media.

Rapid advances in the field of biotechnology, which leverages biological organisms or their component parts to develop products and services, hold promises of immense benefit to society. Conversely, the proliferation of such technology gives rise to concerns around its deliberate or accidental misuse. Synthetic biology, the application of biotechnology to modify or create entirely novel organisms, poses a particularly significant dual-use risk. Regardless, fostering development in biotechnology is critical for growing the U.S. bioeconomy, the share of the economy based on biological resources, and requires a robust regulatory regime. Re-examination and enhancement of international standards in biological research are essential to mitigating associated risks. Building on those established by the Biological Weapons Convention (BWC) is one potential starting point. Adherence to these standards can be bolstered by more closely aligning multidisciplinary stakeholders in the field, for example by instituting professional credentialling in biosecurity conferred through an organization like the American Biological Safety Association International (ABSA). Risks associated with digitization of biological information, automation in the life sciences and their convergence with other sectors (e.g.,

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agriculture, healthcare, manufacturing) give rise to numerous national security implications. Biotechnology stakeholders must ensure the appropriate confidentiality, integrity and availability of biological data and related networked systems, as part of what is commonly referred to in the literature as 'cyberbiosecurity.' Using foresight techniques which consider biotechnology's inherent cyber, economic, and geopolitical risks is crucial to managing the uncertainties they create. Policymakers can benefit especially from hosting scenario-based exercises among a broad range of experts to generate valuable insights on the potential futures of biotechnology development.

The Biden administration's 2022 U.S. National Biodefense Strategy is expected to provide an updated vision of the federal government's responsibilities and resource allocation in protecting against biological attacks and future pandemic response. As of March 2022, President Biden has requested $88.2 billion over the next five years for investment across U.S. and international public health capacity building, early warning infrastructure development, basic biological research and development, and regulatory modernization, among other efforts. The 2022 U.S. National Biodefense Strategy is expected to build on these investments, with an unclassified version to be released later in 2022. This will supersede the 2018 U.S. National Biodefense Strategy which sought to strengthen biodefense through a layered approach to risk awareness, detection, management, and incident recovery. The 2018 strategy draws extensively on lessons from recent biological incidents, including the 2001 anthrax attacks, the 2002 Severe Acute Respiratory Syndrome (SARS) outbreak, the 2009 influenza pandemic, the 2014 West Africa Ebola epidemic and Zika virus outbreak. Naturally, the 2022 strategy is expected to heavily integrate lessons from the ongoing COVID-19 pandemic.

To fully implement the forthcoming 2022 U.S. National Biodefense Strategy, the U.S. must continue to improve interagency biodefense preparedness by strengthening the implementing powers of the Department of Homeland Security (DHS) National Biosurveillance Integration Center (NBIC). The level of funding sustained improvements will require can be weighed against the potential $1 trillion cost of a bioterror event and be expected to realize tangential socioeconomic benefits. Shortcomings in the response to COVID-19 by international institutions, including NATO, underscore the need to improve biosecurity at the global level. Modernization of early warning systems and expansion of access to diagnostics and therapeutics are crucial to mitigating biological threats, irrespective of their origin.

Though the norm against the use of biological weapons has largely held since the BWC entered into force in 1975, policymakers must periodically re-evaluate the established regime considering advances in biotechnology to maintain its sustainable development. Again, the dual-use potential of biotechnology (e.g., engineering precision and novel biological agents) precludes a "one size fits all" governance structure that balances innovation and risk management in an era of multipolarity. While the history of biological warfare stretches back to antiquity, only recently have biodefense planners had to simultaneously grapple with multidomain deterrence, the return to great-power competition, and enduring threats posed by non-state actors. Accelerating technological advances and shifting geopolitical realities will demand that policymakers engage with a wider array of stakeholders when formulating

decisions on routine and existential matters alike. Ethical evaluations in the context of biological warfare and bioterrorism should be made by a multidisciplinary collective of international experts. Actors at the forefront of the life sciences should not be judged on the extent of their works' intended effects, but on the extent of its foreseen effects and how far they go to predict and prevent misuse. In all, greater attention should be paid to developing beneficial ethical forethought on the use of biological weapons, the deterrence thereof, and handling the aftermath of a potential biological attack.

This document complements CGSR's other recent content on biosecurity including:

- *"The Future of BioSecurity: a DoD Perspective" by Dr. Brandi C. Vann, CGSR-sponsored event*, June 2022
- *Rethinking U.S. Biosecurity Strategy for the Decade Ahead Workshop Summary*, October 2020
    - *Annotated Bibliography on Rethinking U.S. Biosecurity Strategy for the Decade Ahead*, October 2020
- *Annotated Bibliography on Current and Future Challenges to the Viability of International Agreements on Biological Weapons*, January 2019
- *Maintaining Innovation and Security in Biotechnology: Lessons Learned from Nuclear, Chemical, and Information Technologies Workshop Summary*, August 2017
    - *Annotated Bibliography on Maintaining Innovation and Security in Biotechnology: Lessons Learned from Nuclear, Chemical, and Information Technologies*, August 2017
- *Independent Biotechnology: The Innovation-Regulation Dilemma Workshop Summary*, August 2016
- *Dogs that Haven't Barked: Towards an Understanding of the Absence of Expected Technological Threats Workshop Summary*, July 2016
    - *Annotated Bibliography on Dogs that Haven't Barked: Towards an Understanding of the Absence of Expected Technological Threats*, July 2016

Additional publications, workshops, and information are available at: https://cgsr.llnl.gov/

1.0 Public Health: The Ongoing COVID-19 Pandemic and Potential Future Outbreaks

1.1 Anticipating Emerging Threats

Bell, Jessica A., Jennifer B. Nuzzo, et al. "2021 Global Health Security Index: Advancing Collective Action and Accountability Amid Global Crisis." Nuclear Threat Initiative (NTI) and Johns Hopkins, Bloomberg School of Public Health, Center for Health Security. December 2021. https://www.ghsindex.org/wp-content/uploads/2021/12/2021_GHSindexFullReport_Final.pdf

> The Global Health Security Index (GHS) serves as a comprehensive assessment and benchmarking of health security and related capabilities across 195 states parties to the World Health Organization (WHO) International Health Regulations (IHR). The 2021 iteration finds that while many countries were able to quickly respond to COVID-19, the global community remains dangerously underprepared for future outbreaks. Factors like rising international travel, urbanization, climate change, population growth and migration, advances in biotechnology, and the threat of deliberately used bioweapons increase the probability of more frequent pandemics. The Index considers each country's ability to prevent, detect, and respond to outbreaks, health system capacity, as well as broader national and international political risks to health security.

Leiser, Owen P., Errett C. Hobbs, Amy C. Sims. "Beyond the List: Bioagent-Agnostic Signatures Could Enable a More Flexible and Resilient Biodefense Posture Than an Approach Based on Priority Agent Lists Alone." Pathogens. 17 November 2021. https://doi.org/10.3390/pathogens10111497

> The authors argue that the U.S. approach to biosecurity policy, one centered around mitigating a list of known bioagents, should be augmented to include monitoring for host responses common to groups of pathogens, known as Bioagent-Agnostic Signatures (BAS). In theory, any health authority integrating a BAS model would not need prior knowledge of a bioagent to effectively identify an outbreak, and thus be better prepared for threats posed by both known and novel pathogens.

Cummings, Christopher L., Kaitlin M. Volk, Anna A. Ulanova, et al. "Chapter 2: Emerging Biosecurity Threats and Responses: A Review of Published and Gray Literature." In Emerging Threats of Synthetic Biology and Biotechnology. NATO. 2021. https://library.oapen.org/bitstream/handle/20.500.12657/50742/978-94-024-2086-9.pdf?sequence=1#page=26

The authors synthesize over one hundred peer-reviewed documents from twenty-six countries to identify key biosecurity threats and responses. While significant positive societal and public health impact is expected from advances in biotechnology and its proliferation, concern remains for its potential deliberate or accidental misuse. The most prevalent threats cited include: 1) dual use of research; 2) biological weapons; and 3) the ecological effects of advanced biotechnology products. Best practice responses include 1) regulation and oversight of the biotechnology field; 2) risk assessment and management; 3) effective communication between researchers, government, industry, and other key stakeholders; and 4) strong adherence to ethical standards and self-governance.

U.S. Department of Health & Human Services (HHS). "Vaccines: National Strategic Plan for the United States." HHS. 2021. https://www.phe.gov/Preparedness/planning/nivms/Documents/nivms-2020-2030.pdf

The Vaccines National Strategic Plan presents a five-year vision for the promotion of vaccines and vaccination in the areas of R&D, safety monitoring, public trust, access and use across, and global cooperation. Five high level goals, each accompanied with key performance indicators, are laid out: 1) Promote innovation in vaccine and related technology; 2) maintain highest levels of vaccine safety; 3) raise awareness and confidence around routinely recommended vaccines; 4) increase access to and uptake of routine vaccines; and 5) protect U.S. public health by supporting the international immunization effort. Critically, stakeholders are encouraged to tailor their implementation plans to their communities.

Schoch-Spana, Monica, Anita Cicero, Amesh Adalja, et al. "Global Catastrophic Biological Risks: Toward a Working Definition." Health Security. 2017. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5576209/pdf/hs.2017.0038.pdf

The authors present their working definition of global catastrophic biological risks (GCBRs), which they see as a subset of global catastrophic risks. They enumerate several defining characteristics and elements of GCBRs and apply them to past and future biological risk scenarios. The authors conclude that while GCBRs represent a small portion of biological threats in the world and should not distract from work to prevent and respond to other vital disease priorities, GCBRs pose such extraordinary potential consequences for humanity that they deserve their own high-level attention, risk assessment, resources, and strategic planning.

1.2 Responding to Emerging Threats

Bollyky, Thomas J., Erin N. Hulland, Ryan M. Barber, et al. "Pandemic preparedness and COVID-19: an exploratory analysis of infection and fatality rates, and contextual factors associated with preparedness in 177 countries, from Jan 1, 2020, to Sept 30, 2021." The Lancet. 1 February 2022. https://doi.org/10.1016/S0140-6736(22)00172-6

> This expansive study attempts to understand and describe conditions associated with the dramatic cross-country variation in rates of COVID-19 infection and fatality to guide more effective future pandemic responses. The analysis suggests that existing public health indices (e.g., JEE, GHS, UHC) fail to account for poor national leadership and political environments – Countries like Burundi, the Philippines, and the Dominican Republic, which rank low on such indices, had so far maintained low standardized infection rates and infection-fatality ratios. Instead, higher levels of government and interpersonal trusts were associated with lower infection rates, while lower levels of government corruption were associated with higher vaccine uptake in middle- and high-income countries. In sum, future pandemic preparedness and response should investment more in risk communication and community engagement to boost individual's confidence in public health guidance.

Osewe, Patrick L. "Pandemic Preparedness and Response Strategies: COVID-19 Lessons from The Republic of Korea, Thailand, and Vietnam." Asian Development Bank. October 2021. https://www.adb.org/publications/pandemic-preparedness-covid-19-lessons

> Osewe identifies and describes lessons learned in crisis planning, management, and coordination, as well as best practices in whole-of-government and whole-of-society approaches to pandemic response. While Asian and Pacific countries have varied widely in their COVID-19 responses, several have well adapted and implemented mitigation measures to their contexts. For example, the Republic of Korea's success with testing and digital contact tracing, Thailand's network of over one million community workers supporting case prevention, detection, and reporting. Similarly, Vietnam's focus on prevention, significant investment in public health infrastructure, and public solidarity enabled the country of 100 million to register under 2,000 cases between December 2019 and December 2020.

Currie, Chris P. “After-Action Findings and COVID-19 Response Revealed Opportunities to Strengthen Preparedness.” Government Accountability Office (GAO). August 2021. https://www.gao.gov/assets/gao-21-513.pdf

> The report examines 74 interagency biological incident exercises and real-world incidents from 2009 to 2019, as well as the COVID-19 response, identifying process deficiencies in biodefense preparation, assessment, and communication. GAO recommends action by the Secretaries of Homeland Security, Defense, Health and Human Services, and Agriculture to better coordinate responses to nationally significant biological incidents through the Biodefense Steering Committee, evaluate lessons learned across government, as well as identify and address root causes or systemic challenges. Deeper engagement with the broader biodefense enterprise (e.g., non-federal, non-governmental, and international partners) is critical in the coordination and management of biodefense activities.

Rahman-Shepherd, Afifah, Charles Clift, Emma Ross, et al. “Solidarity in response to the COVID-19 pandemic.” Chatham House. July 2021. https://www.chathamhouse.org/2021/07/solidarity-response-covid-19-pandemic/06-solidarity-within-countries

> This report examines the global response to the WHO’s calls for solidarity in the face of the COVID-19 pandemic at the international, regional, and country levels. While solidarity at all levels has been weak and fragile, the authors call out several regional (e.g., Africa, the Caribbean, Asia-Pacific) and country (e.g., Bhutan, Finland, New Zealand) examples where cooperative and coordinated action was successfully implemented. Recommendations are offered around addressing social and economic inequalities, as well as the development of national solidarity plans to maximize protection for vulnerable populations through financial, social, and healthcare means in future crises.

Vaughan, Elly, Marcela Casaca, Keven Sew. “A Country-level Pandemic Response Toolkit.” Economist Impact. October 2021. https://impact.economist.com/perspectives/sites/default/files/eiu_country-levelpandemictoolkit_oct2021.pdf

> The authors provide a toolkit for improved future pandemic response based on measures implemented in twelve selected countries. The report confirms the value of leveraging existing healthcare capacity, employing a visibly science-led approach, and building public trust. Areas for future

improvement include strengthening the role of international institutions and mitigating issues around equitable access to diagnostics, treatment, and vaccination. Responses must be tailored to a country's unique conditions. However, universal success factors include long-term investments in public health, overall resilience of healthcare systems, ability to effectively mobilize response infrastructure, and political competence.

Haldane, Victoria, Anne-Sophie Jung, Rachel Neill, et al. "From Response to Transformation: How Countries can Strengthen National Pandemic Preparedness and Response Systems." BMJ. November 2021. https://doi.org/10.1136/bmj-2021-067507

The authors explore 28 national responses to COVID-19 in the first year of the pandemic and offer 15 recommendations for navigating current and future public health threats. In sum, early and decisive implementation of preventative measures is dependent on well-functioning public health infrastructure. The article provides a roadmap for policymakers which emphasizes a whole-of-society approach —supported by effective political leadership— to ensure public health sustainability, enable widespread adherence, and protect economic security.

Trump, Benjamin D., Jeffrey M. Keisler, Kaitlin M. Volk, Igor Linkov. "Biosecurity Demands Resilience." Environmental Science and Technology. 30 March 2020. https://doi.org/10.1021/acs.est.0c00607

The authors argue that existing chemical, biological, radiological, nuclear, and explosive hazards (CBRNE) risk management frameworks are insufficient against threats posed by advances in synthetic biology. They recommend that aspects of resilience and recovery be integrated into next-generation biosecurity strategies. Such strategies require: 1) active and passive early detection capabilities; 2) rapid diagnostic tools to absorb detected threats; and 3) effective intervention mechanisms (e.g., physical barriers, chemical remediation) to contain the release of engineered biological systems.

Ghilarducci, Mark. "Reviewing Federal and State Pandemic Supply Preparedness and Response." Testimony before the U.S. House of Representatives Committee on Homeland Security, Subcommittee on Oversight, Management, and Accountability, Subcommittee on Emergency Preparedness, Response, and Recovery, July 2020, https://homeland.house.gov/download/ghilarducci-testimony-oma-71420

Ghilarducci, the Director of California Governor's Office of Emergency Services, testifies on the federal government's procurement and distribution of personal protective equipment and testing supplies during

the COVID-19 pandemic. He charts California's response to several emerging state crises in the spring of 2020, noting interactions between the state and federal government during this time. He summarizes efforts made by the state of California to develop its own response and address deficiencies in federal support. He concludes with recommendations for the U.S. government to improve its current and future pandemic response strategy, including increased broader invocation of the Defense Production Act, improved coordination at the federal level, among others.

1.3 Key Public Health Risks and Opportunities

Bipartisan Commission on Biodefense. "The Athena Agenda: Advancing the Apollo Program for Biodefense." Bipartisan Commission on Biodefense. April 2022. https://biodefensecommission.org/reports/the-athena-agenda-advancing-the-apollo-program-for-biodefense/

The report provides governance and technological recommendations for a 10-year $100 billion Apollo Program for Biodefense to deter against future natural and man-made biological threats. At the time of publication approximately 1 million (i.e., 1 in 334) Americans had died of COVID-19. Comparable once-in-a-century pandemics are widely expected to occur with greater frequency due to wildlife habitat destruction, diminishing biodiversity, and other environmental factors. Further, promising advances in biological science pose a dual-use threat through accidental, unintended, and deliberate misuse. Appendix B summarizes key success factors behind U.S. grand programs from the Panama Canal to Operation Warp Speed.

Botti-Lodovico, Yolanda, Pardis Sabeti. "Chapter 2: Breakthrough Technologies for Pandemic Preparedness." in Breakthrough: The Promise of Frontier Technologies for Sustainable Development, Brookings Institution. 2022. https://www.brookings.edu/wp-content/uploads/2021/12/Chapter-Two_Breakthrough.pdf

The authors argue that while as recently as 2019 no single country had built a strong enough pandemic preparedness system (per the GHS), universal resilience may be attainable by 2030. They detail two main pillars of development required to meet this objective: 1) biomedical advances in pathogen detection and countermeasures; and 2) information technology for real-time public health surveillance, data sharing, and health system integration. Most of the technologies described are readily available in advanced economies, the authors describe requisite elements (i.e., coordinated public health infrastructure, community empowerment, sustainable financing) for their effective transfer to low- and middle-income countries.

Van der Linden, Sander. “Misinformation: susceptibility, spread, and interventions to immunize the public.” Nature Medicine. 10 March 2022. https://doi.org/10.1038/s41591-022-01713-6

> The spread of misinformation poses a significant challenge to the successful management of a pandemic, from reducing compliance with public health guidelines to undermining vaccination uptake. Van der Linden provides a summary of scholarship on why some are (more) susceptible to misinformation, how misinformation spreads online, and what interventions can boost psychological immunity. They recommend developing a more integrated misinformation susceptibility framework sensitive to the socio-political contexts and focusing on preventative approaches, combining pre- and de-bunking efforts. Future challenges include defining measurement and conceptualization of misinformation, as well as standardization to allow for better comparisons of outcomes across studies.

Nuzzo, Jennifer B., Lawrence O. Gostin. “The First 2 Years of COVID-19 Lessons to Improve Preparedness for the Next Pandemic.” Journal of the American Medical Association. 6 January 2022. https://jamanetwork.com/journals/jama/fullarticle/2787943

> The authors find that though COVID-19 and the 1918 influenza pandemics stand out in terms of morbidity and mortality, evidence suggests a rising frequency of future global public health emergencies. Critical lessons learned from COVID-19 applicable to future events outline the criticality of 1) health system surge capacities in pandemic preparedness; 2) testing capacity in detecting, characterizing, and managing crises; 3) public trust to foster risk-mitigating behaviors; and 4) redressing local and global inequality through robust and cooperative institutions.

Adalja, Amesh A. “Biosecurity for the Future: Strengthening Deterrence and Detection.” Statement before the U.S. House Foreign Affairs Subcommittee on Asia, the Pacific, Central Asia, and Nonproliferation. 8 December 2021. https://www.centerforhealthsecurity.org/our-work/testimony-briefings/pdfs/2021-12-08-Adalja-congressional%20testiomony.pdf

> Adalja’s testimony focuses, in the context of COVID-19, on the importance of implementing biosurveillance systems and strategies to detect the (re-) emergence of viruses with pandemic potential. Patient and environmental testing to pursue specific microbiologic diagnoses is critical to speeding identification and mitigation of novel pathogens. A two-fold recommendation is made on 1) enhancing existing diagnostic capacity; and 2) directing relevant agencies to view such activities as an integral part of

U.S. for biological threats preparedness, rather than exclusively as humanitarian aid to improve international healthcare infrastructure.

Chowdhury, Nashit, Ayisha Khalid, Tanvir C. Turin. “Understanding misinformation infodemic during public health emergencies due to large-scale disease outbreaks: a rapid review.” Nature Public Health Emergency Collection. May 2021. https://doi.org/10.1007%2Fs10389-021-01565-3

The authors provide a literature review on misinformation during abrupt large-scale infectious disease outbreaks since 2000. They find misinformation has pervaded every aspect of outbreaks since 2000, including prevention, treatment, risk factors, transmission, complications, and vaccines. Increased levels of anxiety, lack of scientific knowledge, and low trust in government was found to increase an individual’s consumption of misinformation, which is quickly disseminated and amplified by the unregulated media, particularly social media. A proactive, solution-oriented approach targeting each distinct stages of misinformation (defined as creation, production, distribution, and reproduction) and how each arises is discussed as essential to developing feasible strategy to overcoming it.

Kapiriri, Lydia, Alison Ross. “The Politics of Disease Epidemics: A Comparative Analysis of the SARS, Zika and Ebola Outbreaks.” Global Social Welfare. 2020. https://doi.org/10.1007/s40609-018-0123-y

The authors analyze peer-reviewed medical, social, and political articles to assess narratives surrounding three recent pandemics within different socioeconomic, geographical, and cultural contexts. Their analysis compared the 2003 SARS outbreak in Toronto, Canada, the 2014 Ebola outbreak in Liberia, and the 2015 Zika outbreak in Brazil. The authors identified four themes in their literature search: 1) socioeconomic distribution of the disease; 2) decision-making in research; 3) development, credibility of evidence that informs response pathways; and 4) attribution of infectious disease responsibility. Though poor and marginalized communities experience higher levels of vulnerability to pandemics, the authors found only a limited discussion of the role of social and economic inequality.

Hoffman, Stephen J., Sarah L. Silverberg. “Delays in Global Disease Outbreak Responses: Lessons from H1N1, Ebola, and Zika.” American Journal of Public Health. 7 February 2018. https://doi.org/10.2105/AJPH.2017.304245

The authors find that for recent pandemics—H1N1, Ebola, and Zika—delays in global responses are largely due to a lack of political mobilization by world health leaders and not initial detection of the disease. Faster global health mobilization could be observed due to disease novelty, greater ease of transmission, not spread during holiday seasons, and impact on U.S. citizens.

Severity of the disease, number of countries affected, and the number of people at risk did not lead to a faster global health response.

2.0 Biotechnology: The Rapid and Accelerating Advancements in Life Sciences

2.1 Managing Innovation Oversight versus Execution

Fedasiuk, Ryan. "Regenerate: Biotechnology and U.S. Industrial Policy." Center for New American Security. 28 July 2022. https://www.cnas.org/publications/reports/regenerate-biotechnology-and-u-s-industrial-policy/

Fedasiuk advocates for the adoption of an industrial policy to promote the U.S. bioeconomy, which they define in terms of steps involved in biological processing (e.g., sequencing, editing, discovery etc.) rather than the end products they produce. In execution such a policy must focus on measurably addressing the existential threat posed by climate change and improving the economic standing of the American middle class. They focus on improving bioeconomic drivers of growth: 1) equipment; 2) personnel; 3) information, and 4) capital to maintain advantage in the field. The report arrives at approx. 24 recommendations around the four drivers, representing a whole-of-government strategic approach to sustaining U.S. bioeconomic growth.

Gallo, Marcy E. "The Bioeconomy: A Primer." Congressional Research Service. 19 August 2021. https://crsreports.congress.gov/product/pdf/R/R46881

Gallo provides an overview of the bioeconomy, the portion of an economy based on products and services derived from biological resources, the advancement of which has the potential to drive $4 trillion of economic impact per year globally over the next 10 years. The U.S. bioeconomy accounted for more than 5% of U.S. gross domestic product ($959.2 billion) in 2016 and can be split into three primary domains: Agricultural, Biomedical, and Bioindustrial, as well as an intersectional category of tools and services that advance biotechnology R&D. The document outlines the federal government's bioeconomic activities and explores policy considerations around a national R&D strategy, workforce development, international collaboration, and sustainability among others.

Sharma, Shruti. "How Should Countries Study Viruses Safely?" Carnegie Endowment for International Peace. 14 July 2021. https://carnegieendowment.org/2021/07/14/how-should-countries-study-viruses-safely-pub-84962

Sharma calls for enhanced biotechnology regulation particularly in gain of function (GOF) research, experimentation that enhances the potency of a virus to understand its virulence and/or transmissibility. Three potential approaches are described: 1) establishment of a national agency for

transparent review of all GOF experiments prior to their initiation; 2) opening of negotiations on an international treaty under the WHO to regulate GOF research; and 3) expansion of mandated reporting of naturally occurring disease outbreaks to the WHO to include lab-acquired infections.

Langer, Ronit, Shruti Sharma. "The Blessing and Curse of Biotechnology: A Primer on Biosafety and Biosecurity." Carnegie Endowment for International Peace. 20 November 2020. https://carnegieendowment.org/2020/11/20/blessing-and-curse-of-biotechnology-primer-on-biosafety-and-biosecurity-pub-83252

The authors provide an overview of emerging dual-use applications and associated risks of biotechnology, for which they take the OECD's definition as "the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services." Neither current country-level guidelines and legislation nor international standards, established by the Biological Weapons Convention (BWC), are sufficient in mitigating risks from advances in the life sciences. A first step toward doing so could involve establishing liability and accountability mechanisms within the BWC, or other such binding treaty.

Trump, Benjamin D., S.E. Galaitsi, E. Appleton, et al. "Building Biosecurity for Synthetic Biology." Molecular Systems Biology. 21 July 2020. https://doi.org/10.15252%2Fmsb.20209723

The authors argue that advances in synthetic biology demand an overhaul of biosecurity policies and practices. The proliferation of genetic engineering capabilities and synthetic biology's dual-use nature requires a governance regime to balance risk mitigation with supporting innovation. Regulatory improvement include: 1) treat security as an investment in the future applicability of biotechnology; 2) engage social scientists and policy makers early in development and forecasting; and 3) necessitate coordination among global stakeholders to ensure acceptable levels of risk in research.

Moritz, Rebecca L., Kavita M. Berger, Barbara R. Owen, David R. Gillum. "Promoting Biosecurity by Professionalizing Biosecurity." Science. 21 Feb 2020. https://doi.org/10.1126/science.aba0376

The authors argue that limitations in current biosecurity policy can be addressed in part through the growth and development of a biotechnology workforce able to identify, assess, and mitigate security risks more effectively. Best practice risk management must recognize that effectively countering malicious uses of biotechnology relies on continued research, knowledge gain, and advancement in the space. The article proposes a universal biosecurity credential based on core competences, including

biosafety, program management, physical security, personnel suitability, material control and accountability, as well as cybersecurity, among others.

Gronvall, Gigi K., Lane Warmbrod, Marc Trotochaud, et al. "Summary of Recommendations on The US Bioeconomy: Maximizing Opportunities for Economic Growth and National Security with Biology." Johns Hopkins Bloomberg School of Public Health. 12 August 2019. https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2019/190716-USbioeconomy.pdf

The report summarizes a range of stakeholder inputs on policy options to strengthen the U.S. bioeconomy, encompassing parts of the energy, agriculture, medical, industrial, and defense sectors. To maintain its competitive edge in biotechnology, which greatly enhances national security, the U.S. should 1) pursue cost saving contracting mechanisms; 2) institute talent recruitment and retention programs; 3) articulate a coordinated bioeconomy vision; 4) leverage grants and/or tax credits to promote startup growth; 5) clarify regulation of synthetic biology products; and 6) explicitly state how industry can best benefit government needs.

2.2 Future Foresight and Uncertainty Analysis

Nelson, Cassidy, Ilker Adiguzel, Marie-Valentine Florin. "Chapter 12: Foresight in Synthetic Biology and Biotechnology Threats." In Emerging Threats of Synthetic Biology and Biotechnology. NATO. 2021. https://library.oapen.org/bitstream/handle/20.500.12657/50742/978-94-024-2086-9.pdf?sequence=1#page=186

The authors offer an introduction to the foresight process to promote better understanding of its potential applications in the context of synthetic biology and biotechnology, as well as strengths and limitations. Emphasis is placed on scenario-based thinking, rather than attempting to forecast one single predetermined future, to understand forces shaping possible emerging futures more fully. Recommendations on the use of foresight in the context of biotechnology include: 1) Careful consideration of the design process, and 2) Inclusion of diverse experts (e.g., from the social science, humanities, and intelligence communities) to maximize strategic insight in the context of synthetic biology.

Yassif, Jaime M., Kevin P. O'Prey, Christopher R. Isaac. "Strengthening Global Systems to Prevent and Respond to High-Consequence Biological Threats." Nuclear Threat Initiative (NTI). November 2021. https://www.nti.org/wp-content/uploads/2021/11/NTI_Paper_BIO-TTX_Final.pdf

The report summarizes the results of a March 2021 tabletop exercise on reducing high-consequence biological threats co-hosted by NTI and the

Munich Security Conference. Participants faced a fictious bioterrorist attack, ultimately resulting in three billion cases and 270 million fatalities due to persistent; 1) weakness in global pandemic detection and warning systems; 2) gaps in nation-level preparedness; 3) poor research governance; and 4) insufficient global preparedness financing. Recommendations synthesized from the discussion call for greater centralization, transparency, and agility in meeting future real-world outbreaks.

Pollett, Simon, Michael A. Johansson, Nicholas G. Reich, et al. "Recommended reporting items for epidemic forecasting and prediction research: The EPIFORGE 2020 guidelines." PLoS Medicine. 19 October 2021. https://doi.org/10.1371/journal.pmed.1003793

The authors aim to fill the gap in guidelines for reporting epidemic forecasting and prediction research based on application of the Delphi among an international panel of disease modelers and model users. The resulting EPIFORGE checklist does not advise on how to perform epidemic forecasting and prediction, but rather serves as a standard to ensure critical aspects of such studies are reported in a comparable and reproducible way.

Lewis, Stephen M. "Emerging Biosecurity Considerations at the Intersection of Biotechnology and Technology." In Applied Biosecurity: Global Health, Biodefense, and Developing Technologies. Advanced Sciences and Technologies for Security Applications. June 2021. https://doi.org/10.1007/978-3-030-69464-7_7

Lewis explores the convergence of biology with previously contrasting disciplines (e.g., computer science, mechanical engineering etc.) upon which they base a model for the "full stack biotechnologist," a multiskilled expert with new risk potentials to consider. New approaches to biological design and development, along with integration of AI therein, both accelerate and democratize advancement of dual-use applications. Further, biotechnology is picking up where silicon-based Moore's law is plateauing in the forms of novel biosensors, cell-free reactions, DNA-storage, and emerging neurotechnology use cases. These same technologies may form the basis of mitigation strategies against the threats they also pose.

2.3 Cyberbiosecurity

Vogel, Kathleen M., Sonia Ben Ouagrham-Gormley. "China's Biomedical Data Hacking Threat: Applying Big Data Isn't as Easy as It Seems." Texas National Security Review. Summer 2022. https://tnsr.org/2022/04/chinas-biomedical-data-hacking-threat-applying-big-data-isnt-as-easy-as-it-seems/

The authors argue that the U.S. security community has failed to consider the complex socio-technical factors involved in the illicit acquisition,

integration, and use of biomedical data. While the rate at which health and biomedical institutions have been targeted by hackers has risen since 2015, the challenge of extracting knowledge from breached data remains. U.S. officials must expand their understanding of how well our adversaries can interpret, integrate, and use biomedical data for economic or military benefit in order to have a fuller picture of the risk landscape.

Adler, Aaron, Jake Beal, Mary Lancaster, Daniel Wyschogrod. "Chapter 7: Cyberbiosecurity and Public Health in the Age of COVID-19." In Emerging Threats of Synthetic Biology and Biotechnology. NATO. 2021. https://library.oapen.org/bitstream/handle/20.500.12657/50742/978-94-024-2086-9.pdf?sequence=1#page=116

The authors contend that importance of digital resources in combatting COVID-19 has elevated concern around the potential for cyberattacks by state or non-state actors on public health-related targets. The piece considers several key challenges to the confidentiality, integrity, and accessibility of data with potential to cause significant biosecurity consequences. Further, such challenges are likely to be compounded by those in related areas like supply chain integrity and/or social media manipulation. The effectiveness of public health policy depends heavily on increased attention to and investment in mitigating such intractable issues.

Mueller, Siguna. "Facing the 2020 Pandemic: What does Cyberbiosecurity Want Us to Know to Safeguard the Future?" Biosafety and Health. February 2021. https://doi.org/10.1016/j.bsheal.2020.09.007

Mueller posits that the ongoing COVID-19 pandemic, rapid advances in the life sciences over the last 10 years, along with rising digitization and automation have created opportunities for exploitation at the intersection of the life sciences and digital worlds. The piece cyberbiosecurity challenges 1) in the evolving threat landscape and determining potential risks; 2) in developing adequate, valid, and implementable safeguarding measures; and 3) in life sciences-specific critical risks and consequences. Recommendations around better understanding and mitigating emerging cyberbiosecurity challenges include: 1) aligning classic information security frameworks with the needs of bioscience; 2) develop a risk severity hierarchy; and 3) institute best practices from overall and analogous cyber-physical systems arena.

Richardson, Lauren C., Nancy D. Connell, Stephen M. Lewis, Eleonore Pauwels, Randy S. Murch. "Cyberbiosecurity: A Call for Cooperation in a New Threat Landscape." Frontiers in Bioengineering and Biotechnology. June 2019. https://doi.org/10.3389/fbioe.2019.00099

The authors describe the convergence of information technology and life

sciences as both a key driver and threat factor for the rise of biotechnology research and industrial applications. They segment the cyberbiosecurity landscape between tech driving biotechnology advances (i.e., automation, AI, synthetic biology) and subsequent digitization of traditional sectors leveraging biotech (e.g., manufacturing, biomedicine, agriculture). Relevant vulnerabilities are laid out in a seven-sector framework spanning medicine, infectious disease, systems management, and biotechnology across which more cooperation is needed to recognize and mitigate threats.

George, Asha M. "The National Security Implications of Cyberbiosecurity." Frontiers in Bioengineering and Biotechnology. March 2019. https://doi.org/10.3389/fbioe.2019.00051

George contrasts the importance of cyberbiosecurity in national security with the woeful lack of organizational and financial attention paid by private and public sector stakeholders. The piece calls for a national security policy which, 1) assesses relevant risk and incorporates deterrent and enforcement measures, 2) sets clear consequences for those that conduct cyberbiological attacks or otherwise compromise cyberbiosecurity, 3) establishes voluntary standards in partnership with the private sector, 4) identifies threats, vulnerabilities, consequences, and solutions, and 5) results from a whole-of-society approach.

3.0 Biological Warfare: The Use of Biotechnologies in Future Conflicts

3.1 Balancing Pandemic Preparedness with Biodefense

The White House. "FACT SHEET: The Biden Administration's Historic Investment in Pandemic Preparedness and Biodefense in the FY 2023 President's Budget." 28 March 2022. https://www.whitehouse.gov/briefing-room/statements-releases/2022/03/28/fact-sheet-the-biden-administrations-historic-investment-in-pandemic-preparedness-and-biodefense-in-the-fy-2023-presidents-budget/

> The release describes the Biden administration's progress in combatting COVID-19 and bolstering overall U.S. biosecurity, including an FY23 $88.2 billion request for mandatory funding for the next five years. This funding is to be invested across 1) capacity building for countermeasures, 2) early warning and public health infrastructure development, 3) basic research, 4) regulatory streamlining, 5) biosecurity innovation efforts, and 6) international biological threat preparedness. The 2022 U.S. National Biodefense Strategy is expected to build on these investments, as well as the goals enumerated in the 2021 "American Pandemic Preparedness: Transforming Our Capabilities" (see below). An unclassified version of the Biden administration's biosecurity strategy is expected later in 2022.

The White House. "American Pandemic Preparedness: Transforming Our Capabilities." 2 September 2021. https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf?page=29

> The Biden administration is engaged in a whole-of-government review of the national biosecurity strategy, seeking to integrate the lessons of COVID-19 into an updated unclassified strategy in 2022. The administration's focus is organized across five pillars: 1) transforming our medical defenses; 2) ensuring situational awareness; 3) strengthening public health systems; 4) building core capabilities; and 5) managing the mission. The document describes high level goals and funding requirements, the plan is estimated to cost $65.3 billion over 7 to 10 years.

The White House. "National Biodefense Strategy." 2018. https://trumpwhitehouse.archives.gov/wp-content/uploads/2018/09/National-Biodefense-Strategy.pdf

> To be superseded by the 2022 U.S. National Biodefense Strategy, the 2018 strategy released by the Trump administration presents the U.S.

government's purpose, risk management strategy, assumptions, and proposed governance structure for countering biological threats. Five goals are laid out: 1) enable risk awareness to inform decisionmakers; 2) ensure biosecurity incident presentation capacity; 3) ensure preparedness to reduce incident impact; 4) rapidly respond to biological incidents; and 5) facilitate holistic post-incident recovery efforts.

Sun, Tao, Jie Song, Meng Wang, Chao Zhao, Weiwen Zhang. "Challenges and Recent Progress in the Governance of Biosecurity Risks in the Era of Synthetic Biology." Journal of Biosafety and Biosecurity. June 2022. https://doi.org/10.1016/j.jobb.2022.02.002

The authors summarize the most recent technical progress in synthetic biology and accompanying risks, and overview current international treaties, soft guidance, and national regulatory measures to address its potential harm. Areas for improved governance in the Chinese context include 1) strengthening biosecurity capacity; 2) improving biosecurity regulation, and 3) promoting international cooperation in biological risk management.

Currie, Chris P. "Opportunities to Address National Strategy and Programmatic Challenges." Statement to the U.S. Senate Committee on Homeland Security and Governmental Affairs. 17 February 2022. https://www.gao.gov/assets/gao-22-105733.pdf

Currie's statement summarizes GAO's evaluations of U.S. federal biodefense efforts between December 2009 and August 2021, including challenges and areas for improvement. Recommendations include the need to 1) implement the 2018 National Biodefense Strategy with coordination from the HHS (since superseded by 2022 National Biodefense Strategy); 2) strengthen routine interagency biodefense preparedness; 3) improve the implementing powers of the Department of Homeland Security (DHS) National Biosurveillance Integration Center (NBIC); and 4) streamline DHS/NBIC acquisition of aerosolized biological attack detection tech.

Xue, Yang, Hanzhi Yu, Geng Qin. "Towards Good Governance on Dual-Use Biotechnology for Global Sustainable Development." Sustainability. December 2021. https://doi.org/10.3390/su132414056

The authors argue that traditional top-down and bottom-up governance models for dual-use biotechnology (e.g., gene editing, synthetic biology) should be avoided, instead proposing an experimentalist model. Their suggested governance structure for sustainable biotechnology development comprises four factors: 1) consensus on a broad governance framework with open-ended principles; 2) that countries act based on local conditions; 3) establish a consultation mechanism for transnational information sharing

and review; and 4) iterative renewal of the resulting global governance framework.

Cross, Glen, Lynn Klotz. “Twenty-first century perspectives on the Biological Weapon Convention: Continued relevance or toothless paper tiger.” Bulletin of Atomic Scientists. July 2020. https://doi.org/10.1080/00963402.2020.1778365

The COVID-19 pandemic has inspired new critiques of the Biological Weapons Convention and reassessments of the norm against the use of biological weapons. Drawing on the limited historical uses of biological weapons, Cross and Klotz propose that the BWC was successful in establishing a near-universal norm. The authors conclude that the COVID-19 pandemic underscores the futility of biological weapons, further strengthening the norm.

3.2 Biodefense and Offensive Use

Michalski, Aleksander, Józef Knap, Agata Bielawska-Drózd, Michał Bartoszcze. “Lessons learned from 2001–2021 – from the bioterrorism to the pandemic era.” Annals of Agricultural and Environmental Medicine. 2022. http://www.aaem.pl/pdf-146604-73226?filename=Lessons%20learned%20from.pdf

The authors provide an analysis of key literature on bioterrorism, biological weapons, and the COVID-19 pandemic – Highlighting importance of international cooperation in mitigating uncontrolled proliferation, weaponization, and use of biological agents. Attention is called to the rising potential for misuse of bioengineering to produce and propagate biological agents for maximum lethality by state and non-state actors alike. Shortcomings in the response to COVID-19 by international institutions, including NATO, demonstrate the need for increased supervision of the biotechnology industry, modernization of early warning systems, as well as improved global access to diagnostics and therapeutics to prevent and counteract biological threats irrespective of their origin.

Gisselsson, David. “Next-Generation Biowarfare: Small in Scale, Sensational in Nature?” Health Security. 22 April 2022. https://doi.org/10.1089/hs.2021.0165

Gisselsson describes major shifts in the aims of biological warfare from mass destruction to more precise disruption enabled by developments in the field of synthetic biology. The features that prevented biological warfare on the strategic level are becoming increasingly surmountable, such as the rise of discrete production facilities, increase of genetic manipulated pathogens, and contracting pace at which vaccines can be developed. To effectively meet these future risks, societies must ensure traditional means of

biodefense (i.e., biosurveillance, PPE stockpiling) are combined with counter-information warfare and medical intelligence capabilities.

Bremseth, L.R., James Giordano. “What COVID-19 and China’s Grand Strategy May Teach about the History of the Future.” in Strategic Latency Unleashed: The Role of Technology in a Revisionist Global Order and the Implications for Special Operations Forces (pp. 109-120). Lawrence Livermore Press. 2021. https://cgsr.llnl.gov/content/assets/docs/StratLatUnONLINE.pdf

The authors argue that COVID-19 has exposed vulnerabilities in US biosecurity, and other strategic threat preparedness and response, susceptible to low-cost adversarial exploitation. The potential consequences of which are illustrated through a scenario in 2049 where China has achieved international dominance by shaping the preceding years through a combination of strategic deception and various non-kinetic engagements (e.g., economic, cyber, precision biological and chemical enterprises). To counter such an outcome, the US should articulate a long-range strategic plan which employs all elements of national power to achieve national objectives. Further, a Joint Interagency Task Force should be established to supervise the execution of a whole-of-nation approach to mitigating natural and manmade national security threats, biological or otherwise.

Simon, Fabrice, Hélène Savini, Jean-Nicolas Tournier, Cécile Fickoe. “Biodefence research: what to fund now?” The Lancet Infectious Diseases. November 2021. https://doi.org/10.1016/S1473-3099(21)00622-8

The authors argue biodefense preparedness and response strategy should not be based on historical bioterror-related pathogens. Policymakers should instead anticipate unconventional threats, like easily acquired or home-grown pathogens and unknown or emerging agents, as well as specific targets (e.g., industrial and/or remote military sites). The authors call for increased funding around 1) modernized risk assessment; 2) versatile vaccine platforms; 3) early recognition of bioterror attacks; 4) syndrome-based alerts; and 5) ready-to-use case management. Finally, a strategic communications plan is needed to counter fear expected by attackers.

Long, Carrie M.; Andrea Marzi. “Biodefence research two decades on: worth the investment?” The Lancet Infectious Diseases. August 2021. https://doi.org/10.1016/S1473-3099(21)00382-0

The authors assess U.S. biodefense funding and research since 2001, though considerable advancements did not mitigate a truly global outbreak, there have been remarkable successes against discrete threats. Targeted biodefense research has bolstered protection against bioterrorism and related capabilities such as in vaccines, therapeutics, preparedness, and

infrastructure. Given rapid scientific advances, additional resources are needed for modernized research and technology, as well as improved local and global biosecurity. Compared with the estimated $1 trillion plus cost of a bioterror event, combined with tangential advancements from relevant investment, sustained biodefence funding is deemed worthwhile, both in theory and practice.

U.S. Department of the Army. "Army Biological Defense Strategy." U.S. Army Publishing Directorate. 1 March 2021. https://armypubs.army.mil/ProductMaps/PubForm/Details.aspx?PUB_ID=1022256

This document describes an integrated approach toward the routine application of biosecurity principles throughout the Army for success in strategic environments characterized by ubiquitous, ever-changing biological threats. The strategy emphasizes the need to retain and expand biological capabilities as key for competing with and deterring U.S. near-peer adversaries. To meet these requirements, it describes four lines of effort around: 1) scientific, medical, and operational biological defense knowledge; 2) biological defense situational awareness; 3) modernization of biological policy, doctrine, and force structure; and 4) planning, preparation, and training to counter biological threats and hazards.

Beaver, Bill; Lim, Yong-Bee; Parthemore, Christine; Weber, Andy, "Key U.S. Initiatives for Addressing Biological Threats Part 1: Bolstering the Chemical and Biological Defense Program," Council on Strategic Risks, 9 April 2021, https://councilonstrategicrisks.org/2021/04/09/briefer-key-u-s-initiatives-for-addressing-biological-threats-part-1/

The report describes critical activities undertaken by the DoD Chemical and Biological Defense Program (CBDP), including funding advances against biological threats, encouraging their development, and working with allies and partners. The authors advocate increasing CBDP's annual budget to approximately $7 billion as part of a 10-year $20 billion whole-of-government investment to build resilience against biological events. Recommendations are presented for the expansion of international cooperation, undertaking annual drills of rapid-response capabilities, and increasing transparency around biological threat intelligence.

Epstein, Gerald L., "Biodefense and the return to great-power competition," The Nonproliferation Review, 5 February 2021, https://doi.org/10.1080/10736700.2020.1852751

Epstein argues that while the return of great-power competition does not entirely displace concerns over terrorism, U.S. planners must seriously

consider the role bioweapons might have in adversary strategies. State-sponsored bioweapon programs differ from those of terrorists in 1) the scope and scale of potential deployment; 2) level of technological sophistication, and 3) applications that might particularly suit Russian or Chinese objectives. Further development of technical tools for detection and attribution of biological attacks will strengthen norms against their use.

Townsend-Drake, Alex; Harvin, Donell; Sellwood, Chloe, "Bioterrorism: Applying the Lens of COVID-19," Counter Terrorism Preparedness Network, 2021, https://www.london.gov.uk/sites/default/files/ctpn_bioterrorism_report_single_pages.pdf

The report outlines the threat of bioterrorism to cities in the context of COVID-19 and other relevant case studies. The authors argue that geopolitical fragility, conflict, and socioeconomic inequality will continue to provide the basis for terrorism. Further, population growth, rising migration, and urbanization will create attractive targets for attacks enabled by the bioweapons and proliferation of other emerging technologies. The report outlines high-level transferable recommendations for boosting bioterrorism preparedness and public health crisis response capacity including forming strategic and communication plans, leveraging academic and industry expertise, and enhancing healthcare system services among others.

Chakraborty, Arup, George Whitesides. "21st Century Multi-Domain Effects–Executive Summary." Department of Defense's (DoD) Defense Science Board. September 2020. https://dsb.cto.mil/reports/2020s/FINALBiologyExecutiveSummary.pdf

The report finds that major advances in life science and technology are being driven primarily by commercial and academic interests without significant input from the DoD. Military and national security stakeholders must not underestimate the opportunities and risk biotechnologies (e.g., gene editing, synthetic biology, immunology) present to the future of war. A series of recommendations are made, centering around strengthening partnerships with non-governmental players to fulfill DoD's requirements.

Berger, Kavita M., Diane DiEuliis, Corey Meyer, Venkat Rao. "Roadmap for Biosecurity and Biodefense Policy in the United States." Gryphon Scientific, National Defense University, Parsons. 2018. https://wmdcenter.ndu.edu/Portals/97/Documents/Publications/1A%20Full%20Report.pdf?ver=

The authors survey efforts in the U.S. government around biotechnology funding and policy, which are divided into two efforts around 1) biosecurity

and 2) biodefense. The authors find that a lack of assessment of both gaps in and implementation of U.S. government biotechnology policies. To address this, the authors develop a roadmap based on six cyclic actions and identify stakeholders in U.S. government agency, biological research and health fields who might be responsible for contributing to or leading the suggested actions. Special attention is given to the role of the DoD in driving biotechnology innovation and the effective application of biosecurity policy.

3.3 Ethical Considerations in Biological Warfare and Bioterrorism

Melin, Anders. "Overstatements and Understatements in the Debate on Synthetic Biology, Bioterrorism and Ethics." Frontiers in Bioengineering and Biotechnology. 15 December 2021. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8714945/

Anders argues that while some estimates on the overall risk of bioterrorism may be exaggerated, certain inherent risks, like the deliberate spread of known pathogens, must be taken seriously. Understatements are often motivated by a principle of hope (i.e., technological progress holds future benefits for humanity which may be inhibited by excess precaution), which is problematic in that the benefits of synthetic biology are likely to be unequally distributed. Instead, a principle of precaution is a better for assessing advancements in the field, given their outsized risk for misuse.

Ristanovic, Elizabeta. "Chapter 19: Ethical Aspects of Bioterrorism and Biodefence." In Defense Against Bioterrorism: Methods for Prevention and Control. NATO. 2018. http://ndl.ethernet.edu.et/bitstream/123456789/74975/1/2018_Book_DefenceAgainstBioterrorism.pdf#page=255

Ristanovic argues the dual-use nature of biotechnology and potential for bioterrorism demands the formation of an international bioethical framework which considers relevant principles established in medicine, law, politics, public health, and warfare, among other fields. The scientific community should be judged on not on the extent of the intended effects of their work, rather on the extent of its foreseen effects and how far they go to predict and prevent misuse. While scientists may be able to recognize a discovery's technical implications for use as a bioweapon, they have no special expertise in assessing the implications of biological attack. As such, ethical and policy evaluations must be made by a multidisciplinary collective of stakeholders at the international level to develop maximally beneficial forethought on issues relevant to victims of potential biological attacks.