Statement Before the Subcommittee on Health, House Committee on Energy and Commerce,

United States Congress

A Hearing on "Preparing for and Responding to Future Public Health Security Threats"

May 11, 2023

Statement by

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The Manhattan Institute for Policy Research does not take institutional positions on legislation, rules, or regulations. Although my comments draw upon my research and writing as an Institute scholar, my statement to the Subcommittee is solely my own, and not that of the Manhattan Institute.

Good afternoon. To Chair Guthrie and members of the subcommittee, thank you for inviting me to testify here today. I am honored to have the opportunity to share with you my perspectives and insights on how to best prepare for and respond to future public health security threats. The federal Department of Health and Human Services declared on February 9 that it was planning for the federal public health emergency for COVID-19 to expire at the end of the day today, May 11, 2023. So it is fitting that this subcommittee now consider how to improve preparedness and response regarding threats like COVID-19, which has caused so much death, illness and hardship in America.

I will make three primary points about emergency preparedness and response. All are related ultimately to enhancing private sector involvement in biodefense and maybe useful to consider in reauthorization of PAHPA.

First, there needs to be more actionable information and financial incentives for effective emergency preparedness and response. Second, to improve public confidence in public health messaging there should be more public involvement in risk communication by the federal Centers for Disease Control and Prevention. Third, to increase trust in science-based policy-making there should be greater transparency in federally supported scientific research about public health and communicable diseases.

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<sup>&</sup>lt;sup>1</sup> Department of Health and Human Services, February 6, 2023, Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap, <a href="https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html">https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html</a>.

In October 2022 the Biden Administration issued the National Biodefense Strategy and Implementation Plan (NBSIP), which updated the 2018 National Biodefense Strategy and is intended to greatly strengthen biodefense. It defines biodefense as "actions to counter biological threats, reduce biological risks, and prepare for, respond to, and recover from biological incidents, whether naturally occurring, accidental, or deliberate in origin and whether impacting human, animal, plant, or environmental health." The NBSIP describes five goals and objectives.

- enable risk awareness and detection to inform decision-making across the biodefense enterprise
- 2) ensure biodefense enterprise defense capabilities to prevent bioincidents
- 3) ensure biodefense enterprise preparedness to reduce impacts of bioincidents
- 4) rapidly respond to limit the impacts of bioincidents
- 5) facilitate recovery to restore the community, the economy and the environment after a bioincident.

The NBSIP defines the biodefense enterprise as "Stakeholders with a role in the prevention, preparedness, detection, response, and recovery from bioincidents (e.g., Federal and SLTT governments, nongovernmental and private sector entities, and international partners)." It defines a bioincident as including "any natural or accidental occurrence in which a biothreat harms humans, animals, plants or the environment." These broad definitions suggest that biodefense involves essentially everyone. Indeed, the NBSIP purports to be "broader than a Federal Government strategy; it is a call to action for state, local, tribal, and territorial (SLTT) entities, practitioners, physicians, scientists, educators, industry, and the international community to work together to elevate biological preparedness and response." Notwithstanding this broad scope, the NBSIP does not distinguish clearly between private sector and federal components. In

that sense it misses an opportunity to employ fully the resources and initiative of private enterprise in biodefense.

In 2019, before COVID-19 hit, it was widely known that we should expect a pandemic. Bill Gates, a major supporter of global public health initiatives through the Bill and Melinda Gates Foundation—and a widely respected voice—gave a 2015 TED Talk noting that the country was not ready for an outbreak. A 2018 Washington Post story reported that Gates had urged President Trump to prepare for a pandemic that could kill tens of millions. Later that year, Lisa Monaco and Vin Gupta published an essay in Foreign Policy, "The Next Pandemic Will Be Arriving Shortly." Hollywood, for its part, pumped out a steady stream of movies like Outbreak (1995), I Am Legend (2007), and Contagion (2011) about apocalyptic pandemics. In September 2019, Laurie Garrett, a former senior fellow for the Council on Foreign Relations, published "The World Knows an Apocalyptic Pandemic Is Coming: But Nobody Is Interested in Doing Anything About It."

Many organizations were working to help identify and limit risks of a pandemic before COVID-19 hit; USAID's Emerging Pandemic Threats program received \$200 million, up until 2019, for surveillance and detection. A related project, PREDICT, based at UC Davis, worked to strengthen global capacity for detection of viruses with pandemic potential that can move between animals and people. The World Health Organization and the OIE, an international organization fighting infectious animal diseases, had programs for surveillance of new and emerging diseases prior to the COVID-19 pandemic.

### **Actionable Information and Financial Incentives**

A key reason that pre-COVID warnings about a coming pandemic now seem so ineffective at prompting reasonable measures to improve preparedness is that they did not provide actionable information. I know of no pre-COVID claim that a pandemic of given severity would arrive by a given date with probability X. Yet information on probability and severity is necessary to calculate the merit of costly additional control and mitigation measures. For example, the head of operations at a retirement facility that also provides assisted living services, or the head of operations for a large school district might in 2019 have contemplated improved ventilation systems—more powerful fans, better filtration, bigger air ducts, or ductwork with ultraviolet lighting to kill viruses and bacteria, or even mobile medical-quality air filters. But a key step in deciding to invest in such costly preventive measures is an evaluation of their cost-effectiveness in reducing illness and even death among the building occupants. That evaluation, however, requires information about the probability of a new infectious respiratory disease of given infectivity occurring by a specific date. Such information was unavailable in 2019 and is still unavailable. The lack of such information meant that such investments were not seriously contemplated before the pandemic and yet were difficult or very costly to undertake during the pandemic when they were most needed.

If a quantitative risk assessment of a pandemic were developed and published periodically, upward trends could be noted at an early stage. Such estimates could help provide an empirical basis for deliberations over congressional funding for federal pandemic preparedness.

Information about the probability of a pandemic occurring could also be useful to businesses and households for long-term financial planning.

Forecasting the occurrence of emerging new infectious diseases and pandemics is very difficult. The processes governing exposure to and movement of domestic and wild mammals and birds, as well as mutation and reassortment of viruses are intrinsically complex. A 2017 report for the World Bank noted that the introduction of a pathogen to humans—a spark—could come from domesticated animals or wildlife and be driven by the hunting and consumption of bushmeat, the use of animal-based traditional medicine, and the extraction of natural resources, e.g., logging and silviculture (Madhav et al, 2017). The risk that a spark will spread depends on genetic adaptation, the mode of transmission, the ease and extent of human movement, and the speed and effectiveness of public health and surveillance measures. The report concluded that both the spark risk and the spread risk are heavily influenced by these different human activities. The possibility of accidental release of infectious material from a poorly regulated or managed lab complicates forecasting even further.

There are several complementary approaches to pursue development of quantitative estimates of pandemic risk. The approaches differ in terms of their cost and technical feasibility, and how long they may take to implement. These approaches include periodic structured expert judgment, prediction markets, and collecting, organizing and synthesizing big data. I discuss these in turn.

# • Periodic structured expert judgment

Many technical questions involving substantial uncertainty, including power plant safety and earthquakes, have been addressed through the use of structured expert judgment studies. Bruin et al., in 2006 applied expert judgment to address pandemic influenza risks from the bird flu known as H5N1. They concluded that there was a 15% chance of efficient human-to-human

transmission in the next three years. Such explicit and easy-to-interpret estimates are not found in reports on pandemic preparedness by federal or international public health agencies.

### • Prediction markets

Prominent economists, including Nobel Prize winners Kenneth Arrow, Thomas Schelling, Robert Schiller, and Vernon Smith, argued for the creation of prediction markets (aka event markets) to aggregate information from large numbers of people about the likelihood that uncertain events will actually occur. They recommended that the Commodity Futures Trading Commission (CFTC) establish safe-harbor rules for selected small-stakes markets and that Congress should support the Commission's efforts.

A prediction market would allow interested parties to make a bet—say, five cents—that a pandemic of a specific severity or worse will occur by a target date—say, December 31, 2024. Each such bet requires a willing party to take the opposite bet, 95 cents, that no such pandemic occurs by that date. The broker, who solicits and matches such bets, holds payments for both bets until the target date or the event, whichever is first, and pays the winner the sum of both payments— one dollar—once the outcome is clear. Such information is credible because it can elicit participation from large numbers of people with access to both public and private information.

A 2016 study of prediction markets created in Taiwan for a period of 31 weeks considered five disease indicators (confirmed cases of dengue, severe and complicated influenza, the rate of influenza-like illnesses, confirmed cases of severe and complicated enterovirus infection, and the rate of enterovirus infections) (Eldon et al., 2016). The markets predicted the trends of three out

of five disease indicators more accurately than the preexisting system. Markets that allowed more participants and persisted for longer periods might lead to more precise estimates.

## • Big data solutions

A third approach to estimating the risk of a pandemic would rely on the collection, organizing and synthesis of big data. This approach would upgrade and update the USAID's now-defunct PREDICT program, including surveillance and testing of livestock, poultry, and wildlife of special concern for the presence of viruses either novel or of special interest. PREDICT sought to identify where pathogens are most likely to spill over to humans, where they will amplify, and who is at risk. It also sought to provide information on which pathogens are most likely to become pandemic and which control strategies can be most effective. This approach would likely be time-consuming; it would require a major investment and renewed international cooperation in the collection and analysis of specimens outside the United States. It would also require novel systems for data integration and synthesis. Unlike similar work described in the NBSIP, however, this big data solution would and should have as an explicit goal a quantitative estimate of the risk of that a pandemic of given severity occurs prior to a specific time horizon.

Congress should support all three approaches to quantitative estimates of pandemic risk—structured expert judgment, prediction markets, and big data solutions.

The lack of quantitative information about the risk of a pandemic may not be the only explanation for why pandemics were expected in 2019, but no one was doing anything, as Laurie Garrett lamented. There are apparently no private-sector financial instruments to signal changes in risk. An active prediction market for pandemic risk would serve as one such signal. Another

might be catastrophe bonds, modeled in part on the specialized pandemic catastrophe bonds developed and marketed through the World Bank and benefiting from Bank-related subsidies. Some academics have suggested that pandemic catastrophe bonds for unintentional pandemics could be feasible (Medder and Schwarcz, 2022).

Pandemic-related financial instruments such as catastrophe bonds could allow firms and households to protect against the financial risks of pandemics, and thereby help to achieve goals of the NBSIP. Service industries—including airlines (and aircraft manufacturers), hotels, restaurant chains, cruise lines, and the travel industry generally—were very hard hit by the pandemic. So, too, were manufacturers and distributors of business apparel for men and women. At the same time, the pandemic made winners of private enterprises making goods or services that could aid people and businesses. Apart from vaccine developers and makers of personal protective equipment, such winners included the tech giants offering telecommunications hardware and software including Apple, Google, and Microsoft. Other winners included makers of UV lighting systems capable of zapping coronaviruses, medical-grade indoor air-filtration systems, and lumber mills trying to meet unanticipated growth in demand for residential construction.

Financial instruments that provide information to policymakers and business leaders about how markets view pandemic risks would facilitate business planning decisions that promote preparedness, such as whether to develop or expand contingency plans for telework, for example, or to improve ventilation.

Congress should ensure that no legislative or regulatory obstacles inappropriately hinder the development of such financial instruments.

## **Improving Risk Communications**

The NBSIP recognizes the importance of effective communication and discusses "strategic risk communications", and "transparency in communications". A component of Goal 3 is to "Promote Evidence-Based Health Communication to the Public". Its Goal 4, Rapidly Respond to Limit the Impacts of Bioincidents, includes as Objective 4, "Execute risk-informed, accurate, timely, and actionable science-driven risk communications and community engagement." The report does not, however, say how it will ensure transparency in communications or ensure that risk communications are "risk-informed, accurate, timely and actionable as well as science-driven.

In fact, there was substantial dissatisfaction with federal communication about COVID-19 risks during the pandemic. Veteran public health experts described as CDC's failures as "notable". They include knowingly releasing flawed diagnostic tests,[1] neglecting CDC's own best practices in risk communications,[2] issuing recommendations for temperature screening methods that "do not work,"[3]] and CDC guidance for schools was so flawed that its 2021 recommendations drew a public rebuke from the very scientists it cited. CDC's earlier recommendations for preemptive coordinated school closures likely contributed to the large and discouraging decline in students' academic performance since 2020, including a growing gap in test scores between low and high poverty elementary schools, as well as declines in kids' mental health, and adverse effects on parents' jobs and wages.[5]

CDC could do better. FDA's good guidance practice regulation—which was issued in the fall of 2000, following efforts by major industry associations to have Congress require FDA to do so—could be a guide. The regulation has helped prevent FDA from issuing guidance documents that were really regulations and from offering so-called podium policy—in which officials make off-the-cuff recommendations from behind a podium. Instead, FDA has adopted a standardized and regularized process that controls nearly all formal use of statements about what regulated entities "should" or "ought to" do. That process explicitly allows regulated entities not to follow FDA recommendations, provided that they comply with existing statutory and regulatory requirements as stated in relevant statutes and regulations.

Importantly, FDA's process requires it to open a public docket to formally accept public comment on all guidance that it issues. The open docket can be seen as a formal and general acknowledgement that it needs public input to make sound decisions about recommendations that it makes. It maintains such dockets even in instances where it determines that it must issue guidance without prior public comment because it is not necessary or appropriate to seek public comment in advance.

FDA's guidance documents cover a wide variety of topics, from drug development, drug safety, and food safety to the agency's response to Covid-19. In 2020, FDA issued dozens of guidance documents related to Covid-19, including guidance regarding its decision not to take enforcement action for the marketing of medical products for unapproved uses.

Congress should direct the CDC to adopt mandatory processes for public health advisories like those of FDA.

# **Improving Trust in Federal Health Science Research**

The pandemic has served to undermine confidence in public health policies and in the role of science in informing policy. While ensuring that policy is well-grounded in scientific research is a broad task that predates the pandemic, the pandemic may provide an opportunity. Concerns over independent reproducibility of scientific research--a cornerstone of validity—have prompted many prominent scientific journals, including *Proceedings of the National Academy of Sciences (PNAS)* and *Science*, to make the research they publish more transparent and the underlying data sets more available. The federal journals controlled by the U.S. Department of Health and Human Services (HHS), however, are exceptions to this trend toward transparency. These journals include *Emerging Infectious Diseases (EID), Environmental Health Perspectives*,[3] *Morbidity and Mortality Weekly Report (MMWR)*,

Federal and state policymakers craft laws and regulations, including for pandemic preparedness based on the findings published in these journals—yet it can sometimes be impossible for other experts to check the original work. None of these journals has adopted the research transparency policies that are now common among scientific journals. None recommends that authors share all data and computer code with other researchers who request them.

HHS or Congress should require these federally controlled and supported peer-reviewed journals to adopt modern transparency measures to promote the reproducibility and robustness of the research that they publish.

#### .References

1. Kenneth J. Arrow et al., "The Promise of Prediction Markets," *Science* 320, no. 5878 (May

- 16, 2008): 877–78.
- 2. W. Bruine De Bruin et al., "Expert Judgments of Pandemic Influenza Risks," *Global Public Health* 1, no. 2 (2006): 179–94.
- 3. Eldon Y. Li, Chen-Yuan Tung, and Shu-Hsun Chang, "The Wisdom of Crowds in Action: Forecasting Epidemic Diseases with a Web-Based Prediction Market System," *International Journal of Medical Informatics* 92 (August 2016): 35–43.
- 4. Laurie Garrett, September 20, 2019, "The World Knows an Apocalyptic Pandemic Is Coming: But Nobody Is Interested in Doing Anything About It," *Foreign Policy*
- 5. Randall Lutter, February 2023, Letter: <u>Federal Journals Need Transparency Policies</u>, *Science*, 379(6634) 766-767
- 6. Randall Lutter, February 1, 2023, Restoring Public Trust in Public Health, The Hill
- 7. Randall Lutter, January 2023, <u>Are Research Papers Published in Federal Health Journals Independently Reproducible?</u> Manhattan Institute Issue Brief
- 8. Randall Lutter, October 2022, Why Congress Should Step in and Regulate the CDC, The Hill
- 9. Randall Lutter, September 2022, <u>CDC's COVID-19 Communication Failures</u>: Reforming the Process for Public Health Recommendations, Manhattan Institute Issue Brief
- 10. Randall Lutter, September 16, 2021, <u>Pandemic Preparedness: What Role for the Private Sector?</u> Manhattan Institute Issue Brief
- 11. National Academies of Sciences, Engineering, and Medicine, 2019, *Reproducibility and Replicability in Science* (Washington, D.C.: National Academies Press).
- 12. Nita Madhav et al., "Pandemics: Risks, Impacts, and Mitigation," in Disease Control Priorities: Improving Health and Reducing Poverty, ed. Dean T. Jamison et al., 3rd ed. (Washington, DC: International Bank for Reconstruction and Development / World Bank, 2017), pp. 315–45.
- 13. L. Medders and S. Schwarcz, December 18, 2022, Securitizing Pandemic Risk Insurance, *Risk Management and Insurance Review*, Vol 25, Issue 4, pages 551-583. https://doi.org/10.1111/rmir.12229
- 14. Lisa Monaco and Vin Gupta, "The Next Pandemic Will Be Arriving Shortly," *Foreign Policy*, Sept. 28, 2018.
- 15. The White House, October 2022, National Biodefense Strategy and Implementation Plan: <a href="https://www.whitehouse.gov/wp-content/uploads/2022/10/National-Biodefense-Strategy-and-Implementation-Plan-Final.pdf">https://www.whitehouse.gov/wp-content/uploads/2022/10/National-Biodefense-Strategy-and-Implementation-Plan-Final.pdf</a>