



Public Meeting of the
President's Council of Advisors on Science and Technology (PCAST)

September 28 - 29, 2021

Meeting Minutes

LOCATION: Virtual Meeting via Zoom.gov

MEETING PARTICIPANTS

PCAST MEMBERS

- | | | |
|-----------------------------|--------------------------|-----------------------|
| 1. Frances Arnold, Co-Chair | 11. William Dally | 21. Saul Perlmutter |
| 2. Eric Lander, Co-Chair | 12. Sue Desmond-Hellmann | 22. William Press |
| 3. Maria T. Zuber, Co-Chair | 13. Inez Fung | 23. Penny Pritzker |
| 4. Marvin Adams | 14. Andrea Goldsmith | 24. Jennifer Richeson |
| 5. Dan E. Arvizu | 15. Laura H. Greene | 25. Vicki Sato |
| 6. John Banovetz | 16. Paula Hammond | 26. Lisa Su |
| 7. Ash Carter | 17. Eric Horvitz | 27. Kathryn Sullivan |
| 8. Frances Colón | 18. Joe Kiani | 28. Terence Tao |
| 9. Lisa A. Cooper | 19. Jon Levin | 29. Phil Venable |
| 10. John O. Dabiri | 20. Steve Pacala | 30. Catherine Woteki |

PCAST STAFF

1. Anne-Marie Mazza, Executive Director
2. Ambika Bumb, Deputy Executive Director
3. Sarah Domnitz, Deputy Executive Director and PCAST Designated Federal Officer

INVITED SPEAKERS, SESSION I (SEPTEMBER 28, 2021)

1. Richard Danzig, Secretary of the Navy (ret.)
2. Jonathan Gruber, Ford Professor of Economics, Massachusetts Institute of Technology (MIT)
3. Maryann Feldman, Heninger Distinguished Professor, University of North Carolina
4. Bill Bonvillian, Lecturer, MIT
5. Bindu Nair, Director of Basic Research, Department of Defense (DOD)
6. Don Graves, Deputy Secretary, Department of Commerce
7. Sethuraman Panchanathan, Director, National Science Foundation

INVITED SPEAKERS, SESSION II (SEPTEMBER 29, 2021)

1. Elizabeth Cameron, Sr. Director, Global health Security and Biodefense, National Security Council
2. Georges Benjamin, Executive Director, American Public Health Association
3. Scott Gottlieb, Senior Fellow, American Enterprise Institute
4. Anne Schuchat, Principal Deputy Director, Centers for Disease Control and Prevention (ret.)
5. Terry Adirim, Acting Assistant Secretary of Defense for Health Affairs, DOD
6. Andy Slavitt, Founding Director, Town Hall Ventures
7. Mandy Cohen, Secretary, Department of Health and Human Services, North Carolina
8. Charity Dean, CEO, The Public Health Company
9. Joshua Sharfstein, Vice Dean for Public Health Practice and Community Engagement, Professor Practice, Johns Hopkins University
10. Stéphane Bancel, CEO, Moderna
11. Karen DeSalvo, Chief Health Officer, Google

MEETING START DATE AND TIME: Tuesday, September 28, 2021, 10:00 a.m. Eastern Time

WELCOME AND INTRODUCTION OF PCAST MEMBERS**PCAST Co-Chairs: Frances Arnold, Eric Lander, Maria Zuber**

The PCAST co-chairs called the first meeting to order – Frances Arnold, California Institute of Technology; Eric Lander, Science Advisor to President Biden and Director of the White House Office of Science and Technology Policy; and Maria Zuber, Massachusetts Institute of Technology. Zuber noted that President Biden had sent a letter to Lander asking questions about what the nation had learned from the COVID-19 pandemic that could be applied more broadly to overall public health, how breakthroughs in science and technology could help the nation address challenges such as climate change, and how the nation could maintain its leadership.

After the PCAST members and staff introduced themselves with their name and affiliation, Lander noted that President Roosevelt had written a similar letter in 1944 to his science advisor, Vannevar Bush, asking what would the nation need to do in order to meet the challenges facing its citizens after the war. Bush responded to that letter in his report, “Science—The Endless Frontier,” which provided the architecture for the federal government’s science and technology strategy for the next 75 years. In his letter, President Biden said it is time to refresh and reinvigorate the structures and principles that should guide science

policy in the United States. Lander provided the five broad questions that were posed in President Biden's letter:

1. What can we learn from the pandemic about what is possible or what ought to be possible to address the widest range of needs related to our public health?
2. How can breakthroughs in science and technology create powerful solutions to address climate change?
3. How can the United States ensure that it is the world leader in the technologies and industries of the future that will be critical to our economic prosperity, national security, and international competition?
4. How we can guarantee that the fruits of science and technology are fully shared across all Americans and all of America?
5. How can we ensure the long-term health of science and technology itself in our nation?

Lander commented on the extraordinary achievements and extensive experience of the thirty members of the PCAST, adding that no one who was asked to serve declined the opportunity.

SESSION I: STRENGTHENING U.S. SCIENCE & TECHNOLOGY GLOBAL LEADERSHIP FOR THE 21ST CENTURY

MODERATOR: MARIA T. ZUBER

Zuber reviewed how the world has changed since Bush's "Science—The Endless Frontier" was formulated. In 1945, when the United States was the only world power, Europe was devastated by World War II, Russia was an agrarian state, and China was not considered a global power. In the following decades, the United States had the highest standard of living in the world, was the undisputed leader in science and technology, and offered the best educational opportunities. International students earned degrees in the United States and typically remained in the American work force. Today, Russia, China, and the European countries are world powers and each has made significant investments in science and technology. The purpose of this session is to look at steps that can be taken to ensure that the science and technology enterprise in the United States can maintain global leadership.

THE GLOBAL ENVIRONMENT

Richard Danzig, Secretary of the Navy (ret.)

Danzig began his presentation by saying that looking back to conditions in the 1990s, the Internet was vastly undervalued—almost ignored as a science issue—and fracking was a marginal environmental issue. Now in the present day, Danzig expressed the opinion that the United States is particularly under-invested in managing human capital and building the infrastructure to manage it. In the latter part of the 20th century, the Department of Defense (DOD) dominated technological development and was a strong research and development (R&D) enterprise. In the 1970s, the DOD was driving over 80 percent of the advanced semiconductor market. Now the proportion is about 2 percent. The emphasis is now on subsidies or economic regulation and controls.

Danzig said influencing the evolution of the semiconductor industry or any other area of the economy will require working with private enterprise and the judicious use of federal funding and government controls. It will require a robust federal workforce to analyze problems and develop solutions, but the demands outstrip the supply of human capital. Danzig opined that government technologists are not expected to be as sophisticated scientifically as the heads of R&D working at, for example, semiconductor companies—rather, we expect government technologists to comprehend the problems and dialog with non-government experts. He also suggested that many working in the federal government were not proficient in managing human capital. Furthermore, he said it is not easy for the Bureau of Industry and Security in the Department of Commerce (DOC) to obtain data from semiconductor companies about supply chains and future plans because those companies are resistant to providing that information, although the Defense Production Act can require disclosure. As an example of a possible solution, when the Federal Aviation Administration (FAA) began collecting data on aircraft accidents, the FAA easily collected data on accidents but not on near misses. By establishing a federally funded research and development center (FFRDC), a private entity was able to collect and anonymize the near miss data, thereby assuring the aircraft companies' privacy.

Danzig commented on the importance of considering “assimilation”—not just R&D—as key to maintaining American global leadership in technology. Danzig offered a few examples to explain what he meant by “assimilation” in this context. The German Blitzkrieg during World War II, for example, relied on new, widely available technologies (combustion engine, radio, aircraft, and others) to create a new form of warfare. In contrast, the French had the same technologies available to them but created the Maginot Line. A more current example of R&D investment versus assimilation is the CHIPS Act, which will invest in the semiconductor industry. If this Act results in the creation of new fabrication facilities (“fabs”) in the United States, the positive impacts expected will not be realized until the 2030s. In the nearer-term, assimilation is the way to move forward, Danzig said. The Defense Advanced Research Projects Agency (DARPA), which has made invaluable contributions to American life and security, is a very successful R&D enterprise, but it has had problems with transition from successful research to actual productivity.

Finally, Danzig emphasized the importance of human capital in the context of competition with China. He noted that China has four times the U.S. population—20 percent of the world's population versus the U.S. share of 5 percent, which is an “asymmetric disadvantage” for the United States in the national security sector. He said the United States is losing ground with regard to the education of its citizens: In 2000, the United States generated twice as many STEM graduates as did China; in 2007, the two countries were about even; and now China generates twice as many STEM graduates as the United States. Also many STEM graduates in the United States are not U.S. citizens.

Danzig said interest in the quality of the U.S. workforce should start with birth and continue to the end of the education experience. He noted that 64 percent of China's population is located in rural areas and education suffers there for a variety of reasons, but China is aware of this and is investing in both schools and teachers. Many children living in rural China also suffer from at least one of three health deficits that can affect their education: anemia, intestinal parasites, and near-sightedness. Danzig said some people think preschool children should not be the focus, but rather the focus should be on older students. In contrast, Russia determined some years ago that generating chess grand masters could best be done by investing in teaching chess everywhere, beginning in kindergarten. They explained it as the height of the

pyramid is proportional to its base—in other words, a broader base generates a greater height. Danzig said he thinks the United States needs a broader base.

Danzig noted a need to improve the global integration of allies into the U.S. technology enterprise, which would involve altering the U.S. policy of restricting immigration (for example, by providing green cards to foreign students who graduate from U.S. educational institutions). He closed his remarks by underlining the three underdeveloped areas he thinks are important: 1) how the federal government functions and operates; 2) how the United States develops human capital; and 3) how well the United States assimilates technologies.

Zuber moderated the Q&A and discussion between PCAST Members and Danzig.

BENEFITS OF INVESTMENTS IN S&T AND MODELS AND MECHANISMS FOR FUTURE U.S. ECONOMIC DEVELOPMENT AND GROWTH

Jonathan Gruber, Ford Professor of Economics, Massachusetts Institute of Technology (MIT)
Maryann Feldman, Heninger Distinguished Professor, University of North Carolina
Bill Bonvillian, Lecturer, MIT

Jonathan Gruber stated that his comments would be based on a book he wrote in collaboration with Simon Johnson, titled *Jumpstarting America*. He mentioned two facts presented in the book. First, the United States has ceded leadership in public financing of R&D as a proportion of gross domestic product (GDP), dropping from 2 percent of U.S. GDP (\$1.00 out of every \$50.00) in 1963, to 0.6 percent, which is currently 14th in the world. Second, the U.S. economy has become fractured. In the last 15 years, 90 percent of jobs created were concentrated in five cities; similarly, 75 percent of venture capital spending is contained in five cities. But those top cities are unaffordable in that housing costs are 300 percent higher than in the average American city. *Jumpstarting America* expresses the need for a strategy that can address both the failing leadership in public R&D in America and the geographic fracturing of the economy.

Gruber claimed that public R&D spending is essential for two reasons. The first is “spillover.” Private firms underinvest in R&D because they do not want spillover to benefit other companies. Investment is done in a profit-maximizing way that benefits the company’s bottom line. This is revealed in the declining rate of publications by corporate scientists, who at one time were the most published and accomplished in the United States. Publications from industry scientists are down 60 percent in the last several decades in part because corporations shifted rewards from publications to patents. Gruber said there are examples from flat screen TVs to synthetic biology where a product was started in the United States with largely public funding but the manufacturing was offshored. U.S. developers neglected R&D follow-up.

Gruber said the second reason public R&D is essential is financing. Sixty percent of the Dow Jones portfolio comes from companies started with venture capital. Those successes are limited mainly to software and IT companies, however, because venture capital relies on a “spray and pray” business model in which limited funds (albeit millions of dollars) are invested in a large number of new ventures and then investors can rapidly follow up with more substantial investments in the most promising ventures. This model does not work well for investments that are capital intensive and have a long lead time, like green energy

investments, leading to the problem known as “the Valley of Death,” a situation in which startups have a difficult time covering expenses in the early stages before their new product is generating revenue.

Gruber described how the company, Boston Power, developed lithium-ion batteries, a critical technology, and wanted to expand to build a plant in western Massachusetts that would have employed 500 people in an area that needed jobs. The company needed investment of about \$200 million. U.S. venture capitalists would not invest in the project because it was too much money and would take too long to show a return. Chinese venture capitalists, backed by the Chinese government, were willing to finance the venture if the plant was built in China, so it was, thereby generating jobs and investments in China rather than in Massachusetts.

Gruber stated that there is clear evidence of the benefit of public R&D, growing from a negligible amount to 2 percent of GDP in the decade after World War II, and leading to major technological innovation in the last 70 years.

Gruber noted that the Human Genome Project, which was originally proposed as a private venture, failed to secure the relatively nominal initial investment of \$10 million from venture capital because the project was viewed as taking too long to complete and the resulting code would be available in the public domain. One of the scientists who developed gene sequencing was instrumental in convincing the U.S. Congress to invest \$3 billion over a 13-year period, and the result was genomics and the map of the human genome. There were many benefits, including the development of mRNA vaccines that are the basis of the COVID-19 vaccines, and the genomic sector in America today that employs 270,000 people and paid about \$6 billion in taxes in one year, twice the original project investment.

Gruber said there is an issue with both public and private R&D in the United States: The innovation, resources, and people are concentrated in a few superstar cities on the East Coast and West Coast, a result of agglomeration, which means that talented people want to live and work with other talented people. But a drawback is that most cities don't support agglomeration, which requires affordable housing, reasonable metropolitan amenities, and minimal restrictive housing policies. Gruber suggested it does not have to happen this way. In his book, he identified over a hundred widely dispersed cities with a population of at least 100,000 residents, 25 percent of whom are college educated, with housing averaging \$250,000 or less. The challenge is overcoming the agglomeration hurdle, but this can be accomplished.

Maryann Feldman introduced her presentation by saying she felt that universities are necessary but not sufficient for technology-based economic development—there are many places with strong research universities that have not been able to create new businesses and jobs in their nearby areas. Looking at the industrial genesis of the Research Triangle Park in North Carolina, it is inherently a local process that took a long time, which does not fit well in the traditional patterns of investment. A new financing model is needed. In the 1980s the passage of the Bayh-Dole Act demonstrated the potential of science to be commercialized and to create economic growth. An early example was the growth of Genentech. It also demonstrated that technology originating in universities could be commercialized leading to new companies and jobs. But data indicate that this result is typically focused in a few urban areas, mainly on the coasts, with universities deliberately engaged with the local communities in pursuing economic development. There are high rates of indirect costs, however.

Feldman said the process for transferring technologies is often housed in a university's office of technology transfer, but most technology transfer offices do not break even and few turn a profit. Rather than using the Bayh-Dole Act to transfer publicly-funded science to the public domain, there are increasing assertions of intellectual property rights and increasing demands that put faculty at odds with university administration, an untenable situation. Areas of technology have been identified that are able to create vibrant ecosystems in which small firms can reside and grow, but the process of creating those vibrant ecosystems takes a long time. The DOC's Economic Development Administration has worked with local communities to build these ecosystems, with entrepreneurs contributing to the development of local ecosystems as they create their businesses. These investments are important because in most cases they are made where the investors live. The growth is driven by local champions who often are entrepreneurs, foundations, and elected officials.

In closing, Feldman commented that venture capital is not really effective in nurturing place-based economic development because it is predicated on the model of building a company and then selling it (usually in seven years), which means that the businesses are taken away from the places that initially nurtured them, leaving limited long-term benefits for the community.

Bill Bonvillian provided the last presentation of the panel. He noted that, while not explicitly stated, industrial policy has a long history in the United States beginning with Alexander Hamilton's effort to stimulate the American manufacturing sector and his reliance on protectionist trade policies. For example, Hamilton approached the State of New Jersey to sponsor a major waterpower development project on the Passaic River, which over time led to the establishment of a number of factories in the Paterson, New Jersey area.

Bonvillian stated that industrial policy can be defined as federal government intervention to achieve technology advancement from research to development to testing and financing initial market creation. There have been several periods of American industrial policy development: The Cold War, the post-war competition with Japan and the ensuing R&D tax credit, SEMATECH, the Manufacturing Extension Partnership, the Bayh-Dole Act, energy technology initiatives in the 2000s, and advanced manufacturing initiatives in 2012. Currently, major industrial policy programs are evolving on an unprecedented scale, enhanced by a few important drivers: China's technology advances, technology needed to address climate change, and the COVID-19 pandemic.

Bonvillian listed current legislative action: The CHIPS Act with \$53 billion for microchip fabs and foundries; the Innovation and Competition Act (formerly the Endless Frontier Act) that would create an applied science directorate at the National Science Foundation (NSF) that would establish university technical research centers likely to be integrated with industry, testing and demonstration capabilities, and regional technology hubs; and the infrastructure bill, which includes about \$50 billion for demonstration projects in climate-related clean energy programs, electric vehicles, carbon capture and sequestration, advanced nuclear energy, and batteries. Concerning secure supply chains, the White House released a report in June 2021 focusing on four areas where there were serious problems: pharmaceuticals, semiconductors, critical minerals and materials, and advanced batteries. The U.S. House of Representatives' Reconciliation Bill has a suite of applied programs in energy, health, space and at the National Institute for Standards and Technology.

Bonvillain suggested an innovation framework that includes three aspects – the processes, gaps in the current innovation framework, and basic research across the agencies. Consideration could also be given to the current strong higher education system for engineering and science, versus the weak technology workforce training opportunities. Venture capital is not readily available for the hard technologies and the manufacturing sector. He highlighted working on gaps in scale-up support and capability, demand/market creation, supply chain connectivity, and manufacturing technology leadership. Bonvillain stated he thinks the United States needs a new kind of infrastructure to manage the billions of dollars of new investment.

He provided a series of elements that should be considered:

- Recruitment of
 - Talent that is fluent in applied development, demonstration, and scale-up. Currently, this talent really only exists in DOD.
 - Change agents.
- Research that can be linked more closely to the development and scale-up phases.
- Overhauling manufacturing to move ahead in advanced manufacturing and address stagnation of industrial productivity.
- Underfunding of advanced manufacturing programs.
- Improved mapping of supply chains to identify and fill gaps.
- Development of capability for technology testing and demonstration.
- Getting agencies, industry, and academia to work together.
- Development of a good system for technology certification and validation, which could speed up technology implementation.
- Flexible contracting mechanisms, similar to the Defense Production Act and Operation Warp Speed.
- Lowering the cost of scale-up of production.
- Using federal government procurement more efficiently to address the demand, the initial market creation side.

Zuber moderated a Q&A and discussion between PCAST Members and Gruber, Feldman, and Bonvillain.

AGENCY APPROACHES TO NEW RESOURCES, INNOVATION, WORKFORCE, AND COMPETITION

Bindu Nair, Director of Basic Research, Department of Defense

Don Graves, Deputy Secretary, Department of Commerce

Sethuraman Panchanathan, Director, National Science Foundation

Bindu Nair introduced the concept of the global scientific commons as a wealth of scientific knowledge drawn from the entire research enterprise, found in scholarly publications and contributions to scientific knowledge available on the worldwide web. She stated that the United States has been a dominant leader in science and technology for a century, and that much of the scientific commons was financed by American enterprise. The DOD is guided by a national defense strategy that focuses on power competition, which includes science and engineering, although she said that many in the scientific community and the federal government may not be fully embrace that strategy. Although the United

States has been the dominant leader in science and technology for decades, it has recently begun to lose its edge and ability to influence the scientific commons. She expressed concern that research security has been weakened and that other nations, notably China, are exploiting U.S. investment in the scientific commons in perhaps unfair ways. She said the director of the Federal Bureau of Investigation, Christopher Wray, stated in June 2020 that “American taxpayers are effectively footing the bill for China’s own technological development.”

Nair said there is cooperation among scientists from all over the world, including China, in contributing to the scientific commons, and that it is a challenge to ensure that the process is fair and ethical. A study published in *Nature* showed that between 2015 and 2020, high-producing research countries such as Japan, South Korea, India, and Australia, increased their collaboration with China by 60 to 200 percent. In the same time period, the growth rate in collaborations between the United States and those same countries remained below 60 percent. Nair said that China has opaque national policies and inequitable data sharing practices. So if the Chinese get to define the scientific commons, it could threaten the health of the commons and the already established agreed-upon rules concerning participation in the global commons. Nair suggested there is a lack of coordination in this area across the federal government and a need for a “whole-of-government” approach to engage international partners. Initiatives must be created to coordinate strategies that would support collaborations with emerging research countries. The federal government must also alleviate the protective stance that inhibits such collaborations. The diverse American population with its strong immigration basis could enable this change.

Nair said the United States does not have an effective immigration process that will attract, support, and retain international scientists. She said the United States must keep in mind that the hundreds of thousands of immigrant scientists who have chosen to come to the United States for their doctoral and postdoctoral training are an untold source of soft power, whether they stay in the United States or return to their home countries. Nair also suggested that the United States should continue to participate in standards-setting bodies—the United States used to be a leader in this but its participation over time has decreased while China’s has increased.

In conclusion, Nair explained an obstacle to overcome is the current inadequate tech transfer from fundamental to applied research. Although software development is doing well, development of physical science hardware is inadequate. Before the instantiation of scientific ideas will be acceptable to private investors, an investment should be made in development of proof that those ideas work and can be sustained. Nair also expanded on the word “build,” which she said goes beyond creating physical objects to include intangible connections.

Don Graves stated that he would address the DOC’s plan to strengthen American economic competitiveness, which is a central component to President Biden’s Build Back Better agenda. He mentioned two areas of focus. The first area of focus is advancing innovation in critical and emerging technologies. For years the United States has underinvested in the fundamental building blocks of innovation – R&D, commercialization, and entrepreneurship. DOC is planning to spend \$10 billion to build tech hubs around the country, not just in the current “super cities.” DOC also is developing a clean technologies export competitiveness strategy. And the National Telecommunications and Information Administration, which is part of the DOC, is working to create open, interoperable networks that leverage

open radio access networks and enable 5G networks that are more trustworthy and affordable. All of these efforts are to support a vital, healthy, vibrant, and competitive economy.

Graves explained that DOC is also strengthening supply chain resilience, which includes correcting a 40-year decline in domestic manufacturing and creating funding for development of advanced manufacturing. There are also supply chain weaknesses that need support, especially in semiconductors, which are mainly produced outside the United States. The national manufacturing program should be funded to reverse that trend. DOC also is growing the domestic innovation ecosystem for microelectronics and strengthening workforce development efforts in that crucial sector. Finally, Graves stated that it is important to lead with equity, so DOC has launched new programs, like Build Back Better regional challenges and broadband infrastructure programs, that are aimed at ensuring underrepresented communities are empowered to participate.

Sethuraman Panchanathan described the mission and recent activities of the NSF. He stated that the mission has three parts: promoting the progress of science; advancing national health, prosperity, and welfare; and securing national defense. He stated that the NSF mission is exactly aligned with President Biden's agenda: advancing research; accessibility and inclusivity; global leadership; and sustaining technology, innovation, and partnerships. He said that his three major priorities are strengthening the NSF; inspiring the "missing millions"; and ensuring the success of translation, innovation, and partnerships.

Panchanathan explained that when he came to NSF, he immediately proposed establishing an umbrella directorate that would be seamlessly related to all other directorates. This integration of science and technology will provide support in two ways: first, through curiosity-driven, discovery-based explorations, and second, through use-inspired, solutions-focused innovations. Panchanathan mentioned several programs that illustrate the support: The Civic Innovation Challenge program was launched to provide an opportunity for community leaders to define problems that need to be addressed. NSF funded \$16 million in grants to support teams across the country to conduct pilot projects to address those problems. Eleven of the awards were in partnership with the Department of Homeland Security and the Department of Energy and were focused on resilience to natural disasters like floods, wildfires, and hurricanes. Other awards were partnerships with industry like Platforms for Advanced Wireless Research, which is a consortium of 35 companies investing in partnership with NSF to expand rural broadband service, and RINGS, a project to evaluate novel broadband technology, especially in rural and urban underserved areas. There are also other projects and programs involving establishing AI institutes; programs coming out of the American Rescue Plan that provides relief to individuals and businesses affected by the COVID-19 pandemic; and launching entrepreneurial fellowship programs.

Regarding NSF's relationship to PCAST, Panchanathan suggested that sharing ideas and perspectives would be helpful, as would energizing relationships and networks, breaking down barriers, empowering people in the research and education systems, and engaging communities, cities, and regions.

Zuber moderated Q&A and discussions between PCAST Members and Nair, Graves, and Panchathan.

DAY 1, MEETING ADJOURNED: 3:15 p.m. Eastern Time

DAY 2, START DATE AND TIME: Wednesday, September 29, 2021, 10:00 a.m. Eastern Time

SESSION II: THE STATE OF U.S. PREPAREDNESS AND PUBLIC HEALTH AS REVEALED BY THE PANDEMIC

MODERATOR: FRANCES ARNOLD

ASSESSMENT OF GLOBAL PREPAREDNESS IN LATE 2019

Elizabeth Cameron, Senior Director, Global Health Security and Biodefense, National Security Council

Beth Cameron observed that the COVID-19 pandemic highlighted vulnerabilities in U.S. and global preparedness in the face of a global pandemic. No country was fully prepared; biodefense was typically underfunded. Past biological incidents motivated the United States to develop strategies and plans to respond to threats – for example, biological weapons real and imagined, the anthrax attacks, SARS, pandemic influenza, Ebola and others. The U.S. federal government developed a global health security agenda, made plans for achieving sustainable financing for health security, worked on biosurveillance, and identified ambitious countermeasure targets, some of which were discussed in a 2016 PCAST report. But enduring political will to commit sufficient resources to support a sustained and effective response has been lacking.

Cameron suggested that the government should set a decades-long agenda that includes ending the current pandemic and preparing for future events. It will require close monitoring of progress, being nimble in adapting programs that may not be working well, and creating a frank and honest dialog with the scientific community and policy makers that will keep the focus on the risk to public health and security.

From his first day in office, President Biden reestablished the Office of Global Health Security and Biodefense within the National Security Council, putting an emphasis on biological defense. The President re-engaged with the World Health Organization and signed a national security memorandum focused on a global response and on rebuilding a more effective response for this pandemic and the next one. He also issued an executive order to create a whole-of-government response to the COVID-19 pandemic, and he reaffirmed existing executive orders related to global health security. In September 2021, the administration also released a pandemic plan titled *American Pandemic Preparedness: Transforming our Capabilities*.

Cameron pointed out that there has been progress in the U.S. response to the COVID-19 pandemic, but some significant challenges also have been revealed. Key lessons have been learned. First, the importance of a very rapid response, which did not happen in the United States at the initial outbreak. Second, the need to invest in an early warning system and a plan to handle surge capacity (for example, plans to ensure personal protective equipment [PPE] for health care workers). An example is the Centers for Disease Control and Prevention's (CDC's) new Center for Epidemic Forecasting and Outbreak Analytics. Third, the need to establish sustainable health security financing for access to funding before a crisis develops. Hesitation costs lives and acting fast, although it risks being seen as over-reaction, must be addressed,

perhaps by a group of global leaders with the responsibility to monitor events and sound timely warnings. Finally, preparedness financing is underfunded in the United States and nearly everywhere else on the globe. One reason for this is that health ministers are not as politically influential as finance ministers or heads of state.

Cameron stated that the American Pandemic Preparedness plan will cost about \$65 billion over seven to ten years. It has five pillars – transforming medical defenses including improving situational awareness; strengthening public health systems in the United States and globally; building core capabilities like PPE stockpiles and supply chains; managing the mission with accountability from the top; and increased biosafety and biosecurity. Cameron underscored the importance of the latter because the next pandemic threat could originate from a malevolent source or from a laboratory.

THE U.S. PUBLIC HEALTH SYSTEM'S RESPONSE

Georges Benjamin, Executive Director, American Public Health Association

Georges Benjamin explained that public health is a complex partnership, between federal, state, and local governments plus non-governmental entities, that evolved piecemeal over time into a patchwork of programs, funding mechanisms, and functions. There has never been a strategic review of the whole public health system. Emergency preparedness functions have followed the same pattern. The process is reactive, in which some urgent issue, like the anthrax incident that occurred in September 2001, emerges that focuses national attention on preparedness funding and activity but then gets diluted over time as the urgency of the incident fades.

Benjamin stated that before the current pandemic, studies had indicated that a serious pandemic could happen, most likely due to influenza. When it did actually happen, it did not appear as the predicted flu pandemic but rather as an outbreak of pneumonia in Wuhan, China which ultimately turned out to be a coronavirus. He felt that this incident was not a fundamental failure of science and technology but a major failure of resources, capacity building in advance, and deployment of resources. And there were specific failures, like inadequate testing and the inability of the CDC to scale up because it did not have the capability to manufacture the tests.

Benjamin offered several examples of weak points in the system. There are many disease-reporting systems, but most are siloed and do not talk to each other. Genomic sequencing—important to identifying pandemic patterns—was not adequately deployed, and the modeling capability was limited. Supply chains were fragile. There was a general failure of communications in part because the equipment available was outdated. Nonetheless, with this pandemic—and for the first time—the public had access to extensive health information.

Benjamin noted that many of the social determinants on health drove COVID-19 inequities primarily because of exposure and susceptibility. Although some Americans can work from home, many like bus drivers, grocery store employees, and sanitary workers cannot. At the core of these inequities, there are disparities related to age and ethnicity; societal conditions like poverty, lack of housing, and lack of paid sick leave; and structural racism. The early H1N1 influenza epidemic had similar issues. This is seen each time a new significant disease enters a community.

Benjamin offered several recommendations: establish a National COVID-19 Commission (similar to the 9/11 Commission), to assess what happened throughout the system; build a public health infrastructure with next-generation tools to rapidly track disease; construct a forecast system; identify the leaders needed for this effort; build trust in government; and operationalize the necessary health equity systems.

Arnold moderated a Q&A and discussion between PCAST Members and Cameron and Benjamin.

THE FEDERAL RESPONSE

Scott Gottlieb, Senior Fellow, American Enterprise Institute

Anne Schuchat, Principal Deputy Director, Centers for Disease Control and Prevention (ret.)

Terry Adirim, Acting Assistant Secretary of Defense for Health Affairs, Department of Defense

Andy Slavitt, Founding Director, Town Hall Ventures

Scott Gottlieb discussed the weak COVID-19 pandemic response in three areas. First, the United States' inability to collect information needed to respond in a timely way, to analyze the data in real time, and to be able to provide guidance to the health community and the public about measures to take to reduce risks. Second, the challenge of needing to ramp up significant development and distribution of essential materials required to respond to a widespread infection, such as scaled development and distribution of diagnostic tests and monoclonal antibodies to treat the disease. Third, recognizing the importance of public health preparedness through a lens that includes national security, which emphasizes global risks and emerging infections abroad.

Gottlieb said that in the first domain—the ability to collect and analyze data in real time—the United States did not do a good job. CDC, which he said should have been the lead agency in the effort, has not been effective historically in rapid data collection and analysis, which was the kind of response that was needed. CDC usually responds by using data to develop definitive answers to specific scientific questions, which takes time and is usually published in the Morbidity and Mortality Weekly Report (MMWR). The effects of the pandemic were dispersed, as was data collection. For example, there was data collection on only 1,000 hospitals out of more than 6,000 in the nation. Large parts of the country were not included, like the northern half of California. Gottlieb suggested that this approach should be revised to deal with future crises. He also commented that constantly changing public health guidance engenders public distrust.

In the second domain—the development and distribution of public health tools and countermeasures—Gottlieb suggested there was a misguided belief that health officials could stockpile what was needed. In fact, when the crisis affects the supply chain, most nations begin to make demands that result in severe shortages, and some nations even hoard supplies. Products that have the lowest profit margins, often manufactured overseas (like gloves, reagents, and nasal swabs to collect samples) are the first to become scarce. Gottlieb suggested that the United States must be prepared in advance to ramp up facilities and production to meet increased demand. This may require government subsidies to manufacturers to encourage them to overbuild their capacity and operate at less than 100 percent capacity. In return, the government would have the right to demand delivery of the product in a pre-planned way. In the recent crisis, the CDC was expected to provide that service, but the CDC does not, for example, develop and distribute diagnostic tests; private manufacturers do that.

In the third domain—the global public health response—Gottlieb said he felt that the United States could not rely on some foreign nations to openly provide needed information in a timely fashion, if ever. The COVID-19 pandemic has shown that a government that is host to an emerging pathogen may have travel, trade, and other restrictions unilaterally imposed on it. Going forward, Gottlieb stated that the U.S. national security apparatus will have to be more engaged in the U.S. global public health mission, including in surveillance. Public health and national security will need to find a way to co-exist.

Anne Schuchat observed that the most important problem in the current pandemic is public trust. She said that the best R&D and the best interventions rely on the trust and credibility of the public health system. She observed that the trust had been damaged in the past, and that the restoration of trust is a continuing process that depends mainly on community and individual acceptance. That restoration is manifested by successfully dealing with challenges to public health and emergency response.

Schuchat commented on several other elements of the pandemic response. She said that behavioral interventions are the first response available while waiting for a vaccine to be developed and for diagnostics and treatments to become available. Schuchat also said that the public health system could not scale to the demands of the pandemic. Furthermore, data sharing is incredibly difficult, requiring use agreements between state and local health agencies and the CDC, imposing constraints on what data the federal government can share with researchers and others. Another area of concern is public-private partnerships, which highlighted a degree of distrust of industry in some parts of the country and some areas in the public health system. Schuchat said another area of concern is data analytics and modeling, which involves both resources and access to business management experience. How can people who have such skills work in a federal system where they cannot obtain the level of pay available in the private sector? The public health system at all levels does not have the workforce, investment, and pipeline retention needed.

Terry Adirim described the DOD's large integrated Military Health System (MHS), which includes 50 hospitals worldwide, several hundred outpatient clinics, dental clinics, and almost 140,000 health care personnel who serve 9.6 million active-duty servicemembers, retired military personnel, and their families. The MHS also has its own health sciences university and medical school, which supports \$2 billion in medical R&D. When the pandemic emerged, the then-Secretary of Defense immediately identified the pandemic as the greatest threat to the nation's security at that time. Adirim stated that the first DOD Force Protection Guidance was released in January 2020 and included mandated masking, social distancing and quarantine measures, which eventually included a mandate for vaccination of all military personnel. A COVID-19 registry was also established to develop practice management guidelines. Early on DOD established a program to provide screening, surveillance, and diagnostic testing.

The supply chain challenges existed at the outset of the pandemic, but partly because of DOD's extensive procurement capabilities that were already in place, DOD contributed to supporting the Department of Health and Human Services' (HHS') critical medical supply chain needs. It was supported by a joint acquisition task force that helped reconstitute the national stockpile. Since then, HHS has been using DOD's contracting capabilities to support supply chains. In summer 2020, DOD entered into a memorandum of agreement with HHS to accelerate the development and manufacturing of resources such as therapeutics and vaccines, and to distribute these resources. As of summer 2021, the relationship is in the process of transitioning so HHS will have this capability on its own. On January 21, 2021 President

Biden signed an executive order that directed all departments to focus on supply chain resiliency. Adirim noted that the DOD experience and capabilities would be helpful to that effort.

Adirim closed with several points, among them: the importance of using public health data to create standards that would enable cooperation between agencies; the awareness that because DOD had developed a disease surveillance system (Global Emerging Infections Surveillance) in 1997, it has the ability to identify emerging infections and support whole genome sequencing—there is the potential to improve on this system and find more uses for it; and the importance of anticipating legal and regulatory changes that might be needed to support future government responses during pandemics, such as supporting health care practitioner reciprocity across state lines.

Andy Slavitt presented a hypothetical scenario wherein the United States misses the opportunity of containing an emerging infectious disease despite its best efforts and the virus spreads invisibly and asymptotically but is highly infectious so that the United States has an extended outbreak and extended impacts, with a high death toll. Even if the science knowledge and the vaccines were perfect, the United States would still be left with the problem of 30 percent of the public being left behind due to lack of trust in leaders from the scientific and public health communities and a distrust of information. Slavitt said this problem needs to be addressed. It is not simply a lack of scientific literacy in the public. It also reflects the lack of communication skills on the part of the scientific and public health communities. Slavitt said there is a need to study and determine how the United States can dramatically improve communication with the public, including understanding how people are thinking about, viewing, and interpreting information. He said that when the Biden administration started in January 2021, the United States was in good shape for vaccine distribution as a result of assistance from the military and partnering with pharmacies. But the administration did not truly understand how to communicate with approximately 30 percent of the population—large advertising campaigns with celebrities are not enough. He said a lot of effort should be made now so that the next time a pandemic emerges, the responsible federal officials have the necessary tools at the outset, including having people in local communities who can provide context.

Arnold moderated a Q&A and discussion between PCAST Members and Gottlieb, Schuchat, Adirim, and Slavitt.

THE VIEW FROM THE STATES

Mandy Cohen, Secretary, Department of Health and Human Services, North Carolina

Charity Dean, CEO, The Public Health Company

Joshua Sharfstein, Vice Dean for Public Health Practice and Community Engagement, Professor Practice, Johns Hopkins University

Representing the North Carolina Department of Health and Human Services, Mandy Cohen said that her state was politically purple, geographically, racially, and ethnically diverse, mainly rural, with a decentralized public health system. Her remarks included three areas: data, “last-mile execution,” and trust and communication. With respect to data in the short term, she stated that it is not acceptable not to require race and ethnicity data across the country. This information is required in North Carolina in

order to log a vaccine into the database and therefore there is a 99 percent completion rate for race and ethnicity data. Federal pharmacy data for vaccines, however, allows race and ethnicity information to be entered but does not require it. Therefore, if a resident of North Carolina obtains a vaccine at a CVS, Walgreens, or Walmart in North Carolina, race and ethnicity data may not be captured. Secondly, there should be standardization of COVID-19 data metrics. For example, although every hospital admission is recorded in North Carolina, the vaccine status of everyone hospitalized is not necessarily recorded, and variability in reporting definitions make apples-to-apples comparisons between states difficult. Thirdly, a vaccine verification system and standards that travel beyond state borders. For example, if a resident of North Carolina does not get vaccinated by one of North Carolina's vaccine providers, the state does not have access to the kind of data elements necessary to verify that person's vaccine status.

Cohen said that in the long term, one data infrastructure goal should be to develop an integrated data platform that is interoperable across the public health system and includes a master patient identifier (MPI) that would enable linking patient data across different data repositories, although this is impeded by security and privacy issues at this time. In terms of the "last mile execution", Cohen said that the most difficult impediment to overcome is the lack of people to perform tests, administer vaccines and therapies, staff ICUs, and so on. Cohen also emphasized a need in the "last mile" for rapid, inexpensive COVID-19 tests, which are in short supply everywhere.

Cohen observed that there is a lot of confusion and inconsistency to many aspects of the advice provided about the COVID-19 pandemic, from the need for masks to whether to get a booster, and the advice comes from a number of sources. There is a need for simple, clear instructions, and definition of the roles of health care leaders in an emergency. There are advantages to being decentralized, like being able to tailor responses to specific needs, but that can lead to confusion across jurisdictions. Procedures in an emergency need to be standardized and there needs to be an authority that can mandate operations, procedures, and use of resources.

With regard to trust and communication, Cohen suggested multiple approaches. One pertains to the younger population of 5 to 11-year-olds that may soon be approved for COVID-19 vaccination. She stated that focus groups and message testing confirmed that the messaging must be completely new and come from different messengers. There is also behavioral analysis now on what motivates parents in making vaccination decisions for their children. She added that her state also has a consolidated health and human services voice, absent at the federal level, to reinforce health policy recommendations.

Charity Dean emphasized the importance of containment of any new fast-moving pathogen, which is facilitated at the local level through local health departments and local health providers. She commented that the United States had failed at containment in the COVID-19 emergency because the current public health system was unable to effect containment. The United States has about 3,200 local health departments manned by outstanding health care personnel. But the infrastructure, procedures and technology are outdated – for example, the use of handwritten reports, rooms filled with paper files, and reports sent by fax machine and ordinary mail. Some areas don't even have internet or the ability to send emails.

Dean said information moves through local offices to the state and then to the CDC, which analyzes the data, prepares its report, and then makes it available to the public health community. The process can take months. Dean named five integral pieces of information in the process: data, intelligence, decisions,

actions, and outcomes. Data collection takes time; intelligence is based on individual vigilance that is prone to failure; decisions rely on layered jurisdictional authority, and outcomes are typically disconnected and siloed. Dean suggested three principles of design solution: Speed because the process must move faster than the pathogen; resilience so that political interests cannot divert the response; and a whole-of-society response that does not rely on government alone.

Dean proposed four pillars needed to formulate a systems solution: intelligence infrastructure, authority infrastructure, operational infrastructure, and the trust of the American people. An intelligence platform is needed to detect and predict front line disease threats in real time. The platform should protect privacy; be integrated across sectors, jurisdictions, and government; include electronic data exchange; and result in outcomes data released in real time. Artificial intelligence could enable pattern detection of scattered unreliable data that could provide early warning of new infections. It could also lead to aligned decision-making so that there could be one uniform containment response, something that was missing in the COVID-19 pandemic. The objective is to construct a networked real-time system in which every part—school, university, jail, etc.—is able to see intelligence from every other part.

Dean said this system only works if there is the right authority infrastructure. The disparate 50 state system needs a harmonized layered jurisdictional authority. If that could be accomplished, the next step would be to correlate the pre-determined threat levels to the right level of authority. The next piece is the operational infrastructure needed to support control and prevention. That infrastructure should be outside the political hierarchy for the protection of the health officials involved. In closing, Dean stated that, in a democracy, fast-moving pathogens can only be contained by the participation of all citizens and the restoration of institutional trust and trust in the system.

Joshua Sharfstein discussed why the United States did not have one of the best responses to the COVID-19 crisis. He suggested one reason is that public health is poorly funded (3 percent of total health spending) compared to healthcare (97 percent).

Sharfstein said George Washington University School of Public Health prepared a case study of Missouri's response, which was determined to be poor. The study found that data quality in the state was "severely lacking" and generally of such poor quality that it hindered an effective response to the pandemic. Testing was inadequate because of lack of inventory and personnel to perform the testing. Testing sites were poorly located and failed to cover many sectors of the population, especially those who had the highest risk of a bad COVID-19 outcome. Health departments had limited contact tracing capacity and resources. Forced to install a vaccine appointment system in the middle of the crisis, the demand for vaccines could not be met. The study also found that Missouri health departments lacked an understanding of basic health and social service needs, especially for racial and ethnic minorities.

Sharfstein commented that not all experiences were as dire as Missouri's. Baltimore met the pandemic with a state-of-the-art dashboard that maintained comprehensive and accurate data. The University of Maryland and Johns Hopkins University collaborated to expand testing, manage quarantine and isolation housing, and increase the availability of vaccines. The city hired 250 community health workers to perform contact tracing and to provide resource support and vaccine education, which resulted in Baltimore being in the top 3 percent of jurisdictions in the country in vaccination coverage.

The state of Maryland installed a real-time health information exchange focused on COVID-19. Hospitals are able to share data in real time so the state of Maryland knows how many hospitalized patients there are, where they are, length of stay, and activity in intensive care units. The data are derived from medical records that include vaccination information and are linked to a universal patient identifier that Maryland creates for every person in the medical system. Race and ethnicity are part of the record too. The state is able to notify physicians of their patients who still need to be vaccinated.

Arnold moderated a Q&A and discussion between PCAST Members and Cohen, Dean, and Sharfstein.

ESSENTIAL PARTNERSHIPS: GOVERNMENT-UNIVERSITY-INDUSTRY

Stéphane Bancel, CEO, Moderna

Karen DeSalvo, Chief Health Officer, Google

Stéphane Bancel, CEO of Moderna, discussed the logistics of surge response in the pharmaceutical manufacturing industry. He suggested collectively investing in research focused on about 20 of the pathogens most likely to cause the next pandemic is critical to being prepared. He recommended speculatively initiating Phase I dosing trials on all 20 pathogens to figure out vaccine dosing now to save time later when the next pandemic happens.

On the manufacturing side, Bancel said Moderna started without a commercial product and built capacity, which is still ongoing. He commented that manufacturing capacity should be available with a few companies supporting the effort to manufacture product at only partial capacity at all times so that if quick scale-up is required during an emergency, the manufacturing capacity is available. This would require subsidization from the federal government because otherwise these companies might run their manufacturing at a financial loss since they are not operating at full capacity. Bancel also suggested building a stockpile of raw materials to be available in the event of a surge demand, using the stockpile as a source of inventory for routine manufacture and product delivery.

For lessons learned from the COVID-19 pandemic, Bancel said that Operation Warp Speed was an excellent example of collaboration between industry and government—the government having one point of contact that industry could call, rather than industry having to coordinate with different agencies separately, was particularly helpful. He added that the military sector support had been extremely valuable in facilitating the scaling of manufacture and procurement of raw materials.

Bancel explained that he became aware of the new coronavirus circulating in China in the last week of December 2019 and believed that it would be similar to the MERS and SARS experiences: a localized outbreak that would be resolved relatively quickly. When it became evident in January 2020 that it had the potential of the 1918 flu pandemic, Moderna shifted its priorities from the 24 drugs it had in development at that time to developing a COVID-19 vaccine rapidly. One of the greatest challenges was building the necessary manufacturing capacity. Bancel said that in 2019, Moderna manufactured 100,000 doses, but the requirement in the beginning of 2021 was a billion doses, a 10,000-fold increase.

Karen DeSalvo stated that billions of people around the world turn to Google to get answers on a wide variety of topics, including health. Google took several actions to respond to the challenges of the COVID-

19 pandemic. One challenge is lack of timely, accurate, granular data to make decisions. As a result, Google created COVID-19 Community Mobility Reports—a privacy-preserving tool for using data already being used for other activities, such as measuring how busy a restaurant is—to provide snapshots on how the public's movements changed in response to, for example, COVID-19 shelter-in-place orders. A second example was working with academia who were focused on public health by funding an initiative called Global Health, which is a tool to track, for example, COVID-19 variants around the world using different types of data, including geospatial data. Google also monitors its website for trends in searches for disease symptoms that can be used to support forecasting. These tools are available as open data in a cloud repository. Finally, in response to questions from some public health groups, Google is looking at a privacy-preserving digital contact tracing app that could help identify individuals who had a positive COVID-19 test. The tool would use Bluetooth low energy, not GPS tracking.

DeSalvo referred to a 2016 HHS report, Public Health 3.0, that listed 51 recommendations mostly for the federal government to improve the public health system. The National Academy of Medicine subsequently published a discussion paper in *NAM Perspectives* in April 2021 that updated many of those recommendations. DeSalvo highlighted some of the recommendations: build with public health, not for public health; ensure that standards and interoperability are an integral part of the solution; work on surveillance approaches that allow for using privacy-preserving novel signals; and infrastructure should permit disaggregation of race and ethnicity data and other sociodemographic characteristics. She suggested that there would not be a single unified public health structure, but rather one that is interoperable so that local jurisdictions can develop their own structures that are able to communicate.

DeSalvo observed that public health has been under-resourced for decades, perhaps with inappropriate and inflexible focus. There must be investment in the upstream drivers, like the social care system, also underfunded, and other components of the system that need to be strengthened.

Arnold moderated a Q&A and discussion between PCAST Members and Bancel and DeSalvo.

PUBLIC COMMENT

Wendy Naus, Consortium of Social Science Associations, provided two minutes of public comments.

CLOSING COMMENTS

Arnold expressed appreciation to all who participated and adjourned the meeting.

MEETING ADJOURNED: 3:55 p.m. Eastern Time

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

Frances Arnold, Ph.D.
Co-Chair
President's Council of Advisors on Science and Technology

Eric Lander, Ph.D.
Co-Chair
President's Council of Advisors on Science and Technology

Maria Zuber, Ph.D.
Co-Chair
President's Council of Advisors on Science and Technology