Public Meeting of the

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

September 21, 2022

Meeting Minutes

Meeting Participants

PCAST Members

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

PCAST Staff

1. Lara Campbell, Executive Director
2. Reba Bandyopadhyay, Deputy Executive Director
3. Sarah Domnitz, Principal Deputy Executive Director and PCAST Designated Federal Officer
4. Kevin Johnstun, Research Analyst
5. Quinn Anex-Ries, Intern

Invited Speakers (in order of presentation)

1. Sue Sheridan, Founding Member, Patients for Patient Safety US
2. Ruth Ann Dorrill, Regional Inspector General, Department of Health and Human Services
3. Christopher Hart, Founder, Hart Solutions, LLC

4. Peter Pronovost, Chief Clinical Transformation Officer, University Hospitals in Northeast Ohio; Professor in the Schools of Medicine, Nursing, and Management, Case Western Reserve University
5. Julie Morath, Leadership Coach and Consultant, Morath Consulting
6. Gina Raimondo, Secretary of Commerce, Department of Commerce
7. Erwin Gianchandani, Assistant Director for Technology, Innovation, and Partnership, National Science Foundation
8. Alejandra Castillo, Assistant Secretary of Commerce for Economic Development, Department of Commerce

START DATE AND TIME: WEDNESDAY, SEPTEMBER 21, 2022, 12:15 PM Eastern Time

LOCATION: Virtual Meeting via Zoom.gov

WELCOME

PCAST Co-chairs: Frances Arnold, Francis Collins, Maria Zuber

The PCAST co-chairs—Frances Arnold, Francis Collins, and Maria Zuber—called the meeting to order. Collins noted that in addition to being one of three PCAST co-chairs, he has also been serving as the Acting Science Advisor to the President. However, the President has nominated Arati Prabhakar for both this position and for the position of Director of the Office of Science and Technology Policy. The Senate Commerce Committee has approved her nomination, and a full Senate vote is expected soon.[1] Collins added that should the Senate confirm her nomination, she would take his position as a PCAST co-chair. He thanked his two co-chairs for their wonderful collegiality, smarts, and vision.

Collins said the meeting's public session would include a discussion about patient safety, efforts to advance the U.S. innovation ecosystem, and implementation of the CHIPS and Science Act. A question-and-answer session between the speakers and PCAST members would follow each session, and the meeting would end with a period for public comments. Collins reminded those listening that this is a public meeting and that a recording, along with information about PCAST, would be available at WhiteHouse.gov/PCAST. He noted that the first full report on semiconductors from the Biden-Harris administration's PCAST was recently released and was available on the PCAST website.

OPPORTUNITIES TO IMPROVE PATIENT SAFETY

Collins introduced the day's first session by noting that there have been various approaches over the past two decades to address patient safety and medical errors. During that time, prominent studies have suggested that as many as 100,000 patients die annually in U.S. hospitals because of medical errors. PCAST has formed a working group on patient safety that is co-led by PCAST members Joe Kiani and Eric Horvitz. The goal of the five presentations during this meeting is to suggest actions that the President has the power to implement to address this serious problem, improve health care, and save lives.

[1]The Senate confirmed Prabhakar's nomination on September 23, 2022

Sue Sheridan, Patients for Patient Safety US

Sue Sheridan shared her personal experiences with patient safety to demonstrate that patient safety is a major health care issue. Her son, Cal, was born in 1995 in a large regional hospital. Soon after his birth, errors were made in her son's care due to documentation errors, insufficient hospital policies, inadequate patient education, failure to follow evidence-based guidelines, and a culture that did not empower nurses to act based on a newborn's danger signs. Cal suffered brain damage when he was five days old due to a condition called kernicterus. Kernicterus is preventable, but the hospital never conducted a test to determine whether his bilirubin level was too high.

Sheridan said that nobody at the hospital would talk to her or her husband, Pat, or provide an explanation of what happened. There was no investigation or report to any authorities, nor was there any place where the Sheridans could report the harm their son suffered or share his data, despite many attempts to do so. Two years later, Pat also experienced a medical error when a pathology report on a malignant tumor in his neck was lost. Neither Pat nor his physician received the report, which she said was a diagnostic error. There were no safeguards in place to ensure that the life-threatening diagnosis was communicated to the doctor and patient. During the six months when he did not receive treatment, the cancer metastasized and became inoperable. Pat died when he was 45 years old, Cal was 6 years old, and their daughter was 4 years old.

Sheridan said that the silver lining to her son's story is that she and a group of mothers whose newborns also had suffered from kernicterus formed the nonprofit Kernicterus Prevention Partnership Coalition (KPPC). This group led a patient-powered coalition that included researchers, federal agencies, accreditors, guideline developers, health care systems, patient safety experts, nursing and pediatric organizations, the American Hospital Association, and others. Through their efforts, the coalition successfully changed the American Academy of Pediatrics' newborn jaundice management guidelines to include a universal bilirubin test for all babies before hospital discharge. The coalition also got the Centers for Disease Control and Prevention (CDC) to classify kernicterus as an emerging public health issue and fund the development of a national parent education campaign. In addition, the coalition's efforts prompted the Joint Commission to issue guidance that allowed nurses to conduct a bilirubin test without a doctor's order. These actions changed the standard of care for newborns in the United States and Canada.

Sheridan explained that the coalition took an unconventional approach to promote action: they used their newborns' birth data and stories to put kernicterus on the radar and expedite implementation of best practices.

Sheridan said the number one threat to patient safety is the assumption among patient safety improvement experts that the health care system can fix itself. That model has not worked, she said, and health care systems have not shown any urgency to solve patient safety in the face of other competing priorities.

To address this threat, Sheridan's current organization, Patients for Patient Safety US (PFPS US), proposed several recommendations for improving patient safety. First, PFPS US recommended democratizing patient safety and called for the Department of Health and Human Services (HHS) and its agencies to engage diverse patients, families, and communities—especially those that have been marginalized—in

assessing, planning, implementing, monitoring, and evaluating patient safety. Such engagement in the design of patient safety programming would ensure equity, trustworthiness, and patient-centered practices.

Sheridan said the second threat to patient safety is that nobody is in charge, and that there is fractured federal leadership on this issue. PFPS US recommended that HHS establish greater national oversight and coordination of patient safety efforts and take the following actions:

- Establish patient safety as a priority in the HHS Secretary's national strategy and create a federal advisory committee.
- Establish an independent agency for patient safety, such as the proposed National Patient Safety Board or models from the United Kingdom and Norway, where patients can report harm.
- Create a presidential commission to oversee a patient safety moonshot.
- Reallocate resources to patient safety.
- Establish meaningful incentives and penalties.

Threat number three, said Sheridan, is that nobody knows the true magnitude of the errors occurring because the nation does not have the right data to monitor and improve patient safety. Key data is not shared because it is protected by confidentiality agreements and other mechanisms. To remedy this threat, PFPS US recommended that the nation redesign reporting and surveillance of patient harm in a way that captures patient safety event reports and related data. Toward that end, PFPS US called for the Agency for Healthcare Research and Quality (AHRQ) to coordinate the redesign of the current national patient surveys that the Centers for Medicare and Medicaid Services (CMS) uses in its payment models. PFPS US also called for CMS to expand the list of reportable serious harms to include diagnostic errors, require mandatory reporting of harms as part of the conditions for participation that health care organizations must meet to participate in the Medicare and Medicaid programs, and levy appropriate penalties if health care organizations do not report harms. In addition, PFPS US recommended that the HHS Office of the Inspector General (OIG) expand the trigger tools used to capture a wider variety of harms, including diagnostic errors and harms to newborns, and expand its surveillance beyond Medicare populations. In the same vein, the CDC should count how many people die from medical errors and collect death certificates that state medical error as a cause of death.

The fourth threat to patient safety, said Sheridan, is a lack of transparency. Obscuring the truth to patients and families and withholding patient records after a harm event have become entrenched in the U.S. health care system and accepted as normalized behavior. Addressing this threat requires standards for timely communication and disclosure to inform patients and families of a harm event, similar to the Communication and Optimal Resolution laws in the United Kingdom and Canada, or via a communication and resolution program. This should be a condition of participation in Medicare and Medicaid, with meaningful financial penalties when disclosure or learning does not occur. In addition, the Office of the National Coordinator for Health Information Technology (ONC) and CMS should review and enforce the standards set forth in the 21st Century Cures Act, with meaningful penalties that prevent blocking information and that stop practices that limit patient access to medical records and notes.

The final threat Sheridan listed was the lack of adherence to evidence-based guidelines for clinical practices. PFPS US's final recommendation is to establish meaningful incentives, monitoring, and enforcement for implementing evidence-based clinical practices. In that regard, CMS should require health care systems to implement evidence-based practices as a condition for participation, with meaningful monitoring, incentives, and penalties to ensure adherence to evidence-based practices.

In conclusion, Sheridan said that it is important to remember that patient safety affects real people. Her son is now 27 years old and a comedian and award-winning playwright. He also has cerebral palsy with impaired mobility, hearing, and speech—a lifetime of challenges from an event that should have never happened. His sister, now 25 years old, grew up in chaos and was often in her own world trying to make sense of where her father went and why her bother was so different. Today, she is an extremely compassionate and empathic person, but the toll on her emotional wellness has been significant, said Sheridan.

As a final remark, she said she was speaking to PCAST because she fears that the nation has given up on patient safety. The nation needs to do more to fight against unsafe care in the same way that it approaches climate change and biomedical research.

Ruth Ann Dorrill, HHS OIG

Ruth Ann Dorrill opened her remarks by noting that the HHS OIG has collected a number of stories that are similar to Sheridan's. She explained that as HHS's oversight agency, OIG conducts audits, investigations, and evaluations. It also generates independent data about HHS's programs, makes recommendations to support and improve those programs, and makes recommendations to CMS, AHRQ, and the CDC.

Dorrill said that over the past 15 years, OIG has focused on conducting reviews of medical records to determine the incidence of adverse events among various populations. In 2006, the U.S. Congress directed OIG to investigate the incidence and cost of serious reportable events—sometimes called "never events"—in hospitalized Medicare patients. After receiving this mandate, OIG spoke with experts and stakeholders around the nation, including those at HHS, top academic institutions, and the founders of patient safety organizations. Dorrill and her colleagues concluded that while it is useful to have a list of some 30 "never events," these events should never happen in the first place because they are more extreme, result in serious injury or death, and are clearly preventable.

According to Dorrill, when the OIG team spoke with nurses and others on the front lines of care, they learned that "garden-variety harms" are more common than never events. These small harm events can accumulate and have great impact on someone's life span, health outcomes, and quality of life. More importantly, said Dorrill, frontline care deliverers may not recognize these "garden-variety harms" because they are not as dramatic as something like performing surgery on the wrong leg.

Dorrill said that based on these findings, OIG staff broadened their objective to include all-cause harms and examine all adverse events defined as harm in providing health care. This included looking for acts of commission, such as traditional medical errors; acts of omission, where there was misdiagnosis or inaccurate care; and cases of preventable harm. For example, an unexpected allergic reaction with no

previous history is a harm that would not be preventable, nor would be a case where a patient was in such poor health that almost any treatment could result in unintended consequences.

Dorrill explained that conducting this type of investigation requires a full medical record. To develop a review protocol to determine the incidence rate of a particular type of harm for various populations, OIG hired patient safety experts. OIG has since conducted 18 studies that identified the type of harm; its incidence, severity, preventability, and cost to the Medicare program; and any contributing factors. The medical record review consists of five steps:

1. Abstractors organize the record by components to account for the fact that every electronic health record (EHR) system uses a different format for their medical records.
2. Nurses identify triggers in the record as clues to harm.
3. Physicians conduct a full review to assess a harm for its severity and the extent to which it might have been preventable.
4. A physician panel meets to determine consensus for the physicians' findings.
5. Medical coders use CMS software to re-code claims without the event to determine the cost of a claim attributable to the adverse event.

The OIG team launched an effort to call the families of patients who had experienced an adverse event right after discharge—the team knew an event had occurred because it had reviewed the medical record—to see if the families knew the event had occurred. Of the families called, only 21 percent were aware of any harm occurring, and in those cases, the families assumed that the patient's worsening condition was due to age or other factors; they did not know that a harm event or medical error may have played a role.

Dorrill said that to determine the incidence of a given harm in various populations, OIG requested a national sample of medical records from hospitals, nursing homes, and other places that deliver care. She noted that OIG has a big advantage over other researchers because these providers receive funds from HHS and so they have to respond to a request for medical records.

Dorrill said that in November 2010, OIG released a report on adverse events in U.S. hospitals among Medicare beneficiaries based on a nationwide, representative sample of hundreds of Medicare patient records from October 2008. This review found that 27 percent of Medicare patients experienced harm during their hospital stay. Approximately half of the incidents were what the physician reviewers, as well as many other researchers, classify as temporary harm, or harm that occurred but which hospital staff ameliorated. Such harms, Dorrill said, could have been more serious but were fixed quickly. The other roughly 50 percent of harms ranged in severity from those that prolonged hospitalization, led to the patient being moved to the intensive care unit (ICU), produced permanent harm requiring life-sustaining intervention, or contributed to or resulted in the patient's death.

The most interesting finding, said Dorrill, was that the range of harms went far beyond what she and her colleagues expected to find, and included errors in medication, patient care, infection control, and surgery. Moreover, the range of harms was not always reflected in incident reporting systems or in federal provisions to incentivize better care; only 14 percent of hospitals had identified the harm in their

surveillance systems or incident reports. This study estimated that 267,000 patients nationwide experienced harm in October 2008, with the reviewers determining that 47 percent of the harms were preventable. Dorrill noted that when the OIG team interviewed nurses, physicians, and administrators to determine why harms were not reported, they found the most prominent reason was that they did not identify the event as a harm.

OIG's most recent report, said Dorrill, presents findings from an October 2018 review that examined whether the incidence of adverse events had decreased over the decade since its first report in 2008. Using the same methodology, this review of medical records found that 25 percent of Medicare patients experienced harm during their hospital stays, representing an estimated 258,323 patients. The range of harms and percentage of preventable harms were the same as in the October 2008 review. This study also found that CMS's payment incentives list only identified 5 percent of these events. The main conclusion, said Dorrill, was that there are more harms and a wider range of harms that go unnoticed, are not tracked, and are not improved by federal or state efforts than was previously recognized.

Dorrill said that OIG used an established harm level scale to determine that 74 percent of the harms resulted in a prolonged hospital stay, elevation in the level of care to the ICU, transfer to another facility, or subsequent admission, all of which add to the cost of care. Ten percent of the harms contributed to or resulted in permanent patient harm, 7 percent required life-sustaining intervention, and 10 percent contributed to or resulted in the patient's death. For clinical categories of harm, 43 percent were medication errors that produced results such as delirium, significant hypoglycemia, and acute kidney injury. Patient care-related harms, which included pressure injuries, fluid disorders, and patient falls resulting in injury, accounted for 23 percent of the identified harms. Surgical harms, such as excessive bleeding, hypotension, and embolism, accounted for 22 percent of harms, and hospital-acquired infections accounted for 11 percent of the harms.

Dorrill added that adverse events in nursing homes—a top priority of HHS Inspector General Christi Grimm for the next five years—are also common. Furthermore, the harm rate in rehabilitation hospitals, according to a 2016 study, was 29 percent, while a 2018 study found a 46 percent harm rate in long-term care hospitals. Dorrill noted that the higher rate in long-term care hospitals may be due in part to the fact that the patients in these facilities are there for as long as 25 days.

OIG's recommendations to CMS, said Dorrill, included updating and broadening the list of events for payment incentives and detection to capture more types of harm; expanding the use of patient safety metrics for payment policies and service delivery; and developing interpretive guidance for hospital surveyors' assessment of compliance to track and monitor harm. She added that OIG believes it is important to conduct surveys of these organizations and that surveyors visit the facilities in person.

Dorrill said that OIG also made recommendations to AHRQ. They called on AHRQ to coordinate efforts to further develop HHS quality strategic plans; optimize the use of the event surveillance system, as the Affordable Care Act mandates, and automate data capture; develop effective models to disseminate national clinical practice guidelines; and develop new strategies to prevent common harm events.

The key takeaways, said Dorrill, are that high rates of patient harm persist and that the range of harm is much wider than what research, oversight, and tracking efforts capture. She noted that OIG plans to release an adverse events toolkit in December 2022 and a report to the CDC on nursing home event

reporting in March 2023. The next proposed avenue for investigation, she said, would focus on adverse events in Medicaid labor and delivery, an area of great need.

Christopher Hart, Hart Solutions, LLC

Christopher Hart discussed how successes in aviation safety can inform how to improve safety in health care. While aviation is vastly less complicated and less variable than health care, there are some structural similarities between these two fields. In particular, there are four transferable concepts:

1. Manage errors and threats that can lead to errors.
2. Apply human factors principles in the design of equipment and procedures.
3. Increase standardization where practical.
4. Learn from errors and near misses.

Hart said that the aviation industry began focusing on these four concepts at a time when it was struggling with a fatal accident rate that had been decreasing substantially for decades but had started to plateau in the 1990s. At the same time, the Federal Aviation Administration was projecting that the volume of flights would double over the next 15 to 20 years. So if the accident rate remained flat, there would be many more aviation accidents in the future. This realization drove the industry to act.

While Hart noted that there are other transferable concepts that come from the aviation industry, such as resource management and the use of checklists, the four he listed are more strategic in nature. He also commented that in his time serving on the Joint Commission, he has noticed that most efforts to improve safety address errors that occur within the facility walls but do not address the root cause threats that can lead to those errors. Hart said that not addressing those threats is akin to teaching people to drive better on icy roads without doing anything to remove the ice. This concept, he said, is called "threat and error management."

Hart said that studying human factors is important because medicine is a human endeavor, and disasters can result when humans are not comfortable with the equipment and processes they use. Despite this, human factors are often not taken into account during the design of equipment and procedures. Standardization is a big issue, and though it is often seen as something negative and not often found in health care, it can be helpful when done correctly. Indeed, standardization was a foundational principle for improving aviation safety. In terms of learning from errors and near misses, this is standard practice in the aviation industry, but information about errors and near misses is largely hidden in health care. However, every error or near miss in health care is an opportunity to learn about what is not working well in the system and how to make it better.

Health care has undertaken extensive improvement efforts since the 1999 Institute of Medicine report, *To Err is Human*, which was a wakeup call for health care. However, as the health care system becomes more complex and automated, the challenges to address medical errors are increasing. While there are many reports of progress in various areas, Hart is not sure that the needle is moving in the right direction overall. In fact, despite safety improvements in various areas and amazing advances in health care, the

number of undesirable outcomes in U.S. hospitals remains unacceptably high. Hart said this means that it is time to reconsider current efforts to improve safety and see if there are better approaches to implement.

Regarding threat and error management, Hart said that, while identifying and addressing errors is essential, "an ounce of prevention is worth a pound of cure." It is more effective to be proactive and identify upstream threats that can lead to errors. In aviation, some threats are so bad that the industry refers to them as "error traps," which means there is a high likelihood that someone will get caught in that error trap and take the wrong action. An example of an error trap is not knowing if a piece of equipment is in automation mode, so the threat is an inadequate or ambiguous display of the mode setting. This has led to many crashes in aviation.

Hart said that administering the wrong medicine is an example of an error from health care. In this case, the threat is confusing or misleading labels or containers that can cause someone to grab the wrong container. A recent example of this occurred in Nashville, TN where a nurse was ultimately convicted of criminally negligent homicide in the accidental death of a patient because the nurse inadvertently grabbed the wrong container. This is an illustration of how the system did not adequately accommodate the needs of the end users, resulting in a tragic outcome. Hart noted that most of the safety improvement efforts he has seen since joining the Joint Commission address errors, but he thinks health systems need to place more attention on the upstream threats that lead to those errors.

Human factors challenges, said Hart, increase when complexity and automation increase. The aviation industry addresses the human factors challenge in the original design of an aircraft, but it also goes beyond relying on human factors experts and puts pilots with a wide range of backgrounds and experiences in simulators to provide insights into real world use. Then, once a new aircraft enters service, there is further training of pilots and everyone else who touches the equipment, such as mechanics, to identify any idiosyncrasies. Last but not least, the industry uses operational error and near-miss feedback from pilots and mechanics to inform future design considerations and training procedures.

Hart said these are the steps that aviation has been good at historically, with an exception being the recent problems that arose with the 737 Max aircraft. That is an example where potential problems slipped through the cracks for many reasons, not the least of which was complacency. Hart explained that complacency set in as a result of the industry's good safety record over the previous 10 years during which airlines flew billions of passengers with only one passenger fatality.

Hart explained that when the industry started the process of applying collaborative action to address safety issues, many experts thought that it was not possible to improve the plateaued fatality rate. However, by applying these concepts, the industry further reduced fatalities by more than 80 percent in less than 10 years. That is the kind of sustainable and significant change that Hart is seeking for health care by digging beyond errors to identify threats and human factors issues.

Collaboration is important, said Hart, because anyone involved in the problem needs to be involved in developing a solution to that problem. If end users are not part of the design process, there is a good chance the end result will not be suitable for them. For example, it is likely that the reason health care employees do not wash their hands as often as they should is that the people who developed the checklists for handwashing did not include end users in the design process. Having a human factors expert

say that something ought to work is not sufficient. The exemplary aviation safety record, Hart noted, reflects a great deal of collaboration with end users in the aircraft design process, as well as throughout the life cycle of the equipment or process.

Standardization versus specialization is a significant issue in health care, said Hart. The aviation industry uses standardization for the most dangerous parts of a flight: the approach and landing of a plane. The United Nations body that oversees aviation—the International Civil Aviation Organization—sets the standards that allow a pilot to use the exact same processes when landing a plane anywhere in the world, and that ensure all airports around the world use the same numbers on the runway and markings on the taxiways. This standardization allows the pilot to focus on landing the plane safely.

On the one hand, said Hart, aviation uses specialization in that it licenses pilots to operate specific aircraft. For health care, the question is whether standardization or specialization is appropriate, and that depends on the context. For example, the same piece of equipment from different manufacturers should have knobs that all turn in one direction for 'on' and the other direction for 'off' to reduce equipment operations threats. Expecting staff to go seamlessly between equipment from different manufacturers without some standardization is a recipe for disaster.

Hart said that collaboratively standardizing equipment and processes usually creates better outcomes, which is why a group solving a problem often produces a better answer than an individual addressing a problem. While it is important to update standards as innovations occur, standardization can reduce errors significantly, especially for support staff. For example, nurses say that different physicians will want certain procedures in different ways, which can create errors when nurses are forced to remember which doctor does a procedure in a certain way. In short, said Hart, there is no blanket answer as to whether to standardize or specialize, and there are opportunities to do both to improve safety.

In terms of errors and near misses, Hart said the health care system is filled with passionate people who are trying to do the right thing, but the information they need to do the right thing is often hidden because of the stigma associated with errors and the fear of punishment and litigation. The litigation issue is going to be a hard one to solve, but he recommended no-fault compensation for health care injuries given that litigation is not a very effective or efficient way to compensate people for health care injuries. No-fault compensation would eliminate the fear of litigation and would likely lead to more people reporting errors.

In closing, Hart said that health care is much more complex and variable than aviation and that he did not mean to suggest that all of the improvements he discussed would work in health care because of important differences. A major difference, for example, is that the pilot—the first to arrive at the scene of a crash—has much more incentive to participate in near-miss reporting programs than a doctor who is not necessarily going to suffer injury because of a mistake. There was a time, though, when there was a stigma in aviation associated with a near miss, and pilots were reluctant to report them, which suggests that despite this difference, health care can learn from the aviation industry's experience in making significant and sustainable increases in safety.

Peter Pronovost, University Hospitals of Northeast Ohio and Case Western Reserve University

Peter Pronovost said harm has affected almost everyone, but harm to individuals is just the tip of the "harm iceberg." The harm to families is largely invisible but equally devastating, leading to divorce, trauma, people leaving jobs, mental illness, and bankruptcy. It is imperative, then, to look at the whole picture because health care harms happen too often, cost too much, and improve too slowly. Patients are suffering needlessly, as are the health systems and clinicians who make mistakes.

It is debatable as to whether health care has made progress over the past 20 years, said Pronovost, with some reports showing improvement and others showing little to none. There has been some progress in preventing hospital-acquired infections, but too little in other areas, with the COVID-19 pandemic revealing just how many gaps there are and how health systems might narrow them. While other industries faced unprecedented pressure from the pandemic, they did not buckle. Planes and trains did not crash, and the financial system carried on, but the stress of COVID-19 increased patient harms anywhere from 30 to 70 percent. The pandemic also revealed that much of health care is risky and relies on the heroism of clinicians rather than the design of safe systems. At the same time, the pandemic revealed bright spots for how the federal government might reduce burdens on clinicians and barriers to innovation, such as expanding home monitoring and telemedicine.

Pronovost said that despite all of the data collected—HHS collects an estimated 2,400 measures—the system lacks timely, transparent, and valid data on how many people in the United States die or suffer harm from errors. This, he said, is unacceptable. Multiple federal agencies issue reports on safety, but they use different measures and methodologies to interpret the data. Often, the result is to focus on the most positive interpretations, and there is frequently insufficient transparency at the provider level.

While there are robust mechanisms for reporting some harms via the CDC, Pronovost said the nation lacks valid rates for common causes of harm. Much of the data collected is not reported at the facility level and thus lacks transparency. Claims data measures, he added, are stunningly old. For example, the most recent CMS Stars Rating data on hospital mortality goes back to 2017. In addition, many of the measures are burdensome and not viewed as important. For children, newborns, and mothers, the situation is worse, with little national data because these groups largely receive care through Medicaid, not Medicare. As a result, each state has its own database and quality metrics, with no data aggregation occurring at the federal level.

Moreover, said Pronovost, most of the measures focus on hospitals, yet most care is delivered in the ambulatory setting, which limits insights into the risks in that setting, as well as in home care. What is needed are simpler, more meaningful measures or frameworks for eliminating harms that focus on the real purpose of health care: to help people thrive; to prevent disease when possible, cure it when prevention is not possible, and to care when a cure is not possible; and to continuously improve the value that health care provides to people.

Pronovost explained that he got involved in patient safety after his father died at age 50 from a misdiagnosis and after a little girl who looked just like his daughter died in 2001 from an unrecognized infection and dehydration. At the time, infections killed more people than breast or prostate cancer, but clinicians largely accepted that as the norm and the cost of doing business. When he started working on this problem, HHS reported infections in five different ways, each producing various inferences. This

changed when AHRQ provided a grant to implement best practices, first in Michigan and then across the United States. HHS aligned around CDC's measures, and CMS aligned its payment with the CDC measures rather than to claims data. With collaboration involving many groups, including the Institute for Healthcare Improvement and the American Hospital Association, infections have been reduced by 80 percent nationwide.

In terms of what the nation can do to make care safe, Pronovost said a good starting point would be to replicate the learnings from the infection reduction effort. Toward that end, CDC should be charged with making rate-based measures for the top 10 causes of harm in each care setting according to race, ethnicity, primary language, and diseases that have two to three times the rate of complications when individuals with those conditions are hospitalized, such as Parkinson's disease, Alzheimer's disease, or severe mental illness. These measures should be electronic, easy to make, and available in real time or near real time. In addition, AHRQ should be charged with making toolkits for evidence-based practices to eliminate those harms, and CMS should be charged to align its rewards and penalties around eliminating those specific harms and revise its incentives to reward excellence toward zero errors as well as to punish those systems that do not make progress. State Medicaid data should be integrated to provide insights into maternal, neonatal, and child harms.

Pronovost said that a second step for making care safe would be to learn faster from less common causes of harms, risks, and threats. These learnings come largely from patient safety reporting systems and OIG audits, though sometimes the harms, risks, and threats are more difficult to measure. Nonetheless, these harms are real, and the opportunity to prevent them is large. Today, each well-intentioned health system tries to reduce these harms on its own, which is ineffective and inefficient. Health systems conduct superficial investigations because they lack the human factors engineers needed for such studies. With limited resources, the most common recommendation from an investigation is to re-educate staff. This, said Pronovost, will never work.

A better solution, said Pronovost, might be to supplement local efforts with sector-wide efforts similar to those in the aviation industry and other industries. In the aviation industry, for example, commercial aviation safety teams conduct sector-wide root-cause analyses into the factors that led to an error, which helps to design systems and technologies that can prevent errors from happening again. No clinician or health system alone is going to design the medication technologies that talk to each other, but together the health care industry could. No individual hospital is going to design alarms between an EHR and a ventilator, but together the health care industry could. Therefore, PCAST should recommend that AHRQ take on the charge to innovate and create the equivalent of a PCAST in health care and create sector-wide efforts to eliminate the leading cause of harms obtained from efforts such as the OIG report and AHRQ's patient safety reporting systems.

A third step, said Pronovost, would be to remove barriers to innovation and reduce the burdens on clinicians to improve safety and value. The COVID-19 pandemic showed how to do this. When COVID-19 struck, hospitals were short of personal protective equipment and available beds, and they were setting up military-style hospitals in tents. Yet most people have a home and a bed that could provide infinite capacity if the means exist to monitor them remotely. Toward that end, Pronovost called Joe Kiani (PCAST member), whose company is working on remote monitoring, and asked if the technology was ready. Kiani said he had submitted the required paperwork for a device to monitor opioid overdose, not COVID-19

patients, to the Food and Drug Administration (FDA) two years earlier. A call with the FDA resulted in an Emergency Use Authorization for the technology, and six days later, the technology was used to monitor its first patient. Thirty days later, the World Health Organization hosted a webinar on remote monitoring with 4,000 health systems in 70 countries participating. Today, health care systems are monitoring tens of thousands of patients at home.

Pronovost said that CMS was also helpful in reducing staff burdens during the pandemic by providing needed relief in terms of documentation, which consumes 30 to 40 percent of a clinician's time and adds little benefit. Because documentation distracts clinicians, it most likely increases, rather than decreases, the risk to patients and it leads to burnout. Still, nurses are the only professionals that have to document every interaction with a patient, and this needs to be revised. CMS also made welcome "micro policy changes" that allowed for the expanded use of telemedicine. This increased access to home care by not requiring patients to be homebound before they can receive home care, which avoids sending people to skilled nursing facilities.

Pronovost said PCAST should recommend that the Secretary of HHS coordinate a research and innovation group that links all HHS agencies so they can learn and bring their diverse disciplines together. The FDA, he added, needs the authority and charge to revise its regulatory framework for improving health delivery innovations that can evolve over time. CMS should be charged with reviewing the regulatory requirements for providers, and it should eliminate those where the burdens exceed the benefits and where there is a barrier to improving value. CMS should also review its measures and incentives system, and eliminate those with little value or that are not important, and it should include measures that reflect population health, total cost of care, and the inequities that are morally unacceptable in this country.

Pronovost said that CMS should use rewards instead of penalties, which have not moved the needle on harms, and should continue being as flexible regarding telehealth as it was during the pandemic. CMS also needs to ensure that ONC identifies and tracks digital readiness as a distinct social determinant of health and ensure that digital equity is on ONC's radar. In some zip codes, as many as 50 percent of people lack access to broadband or smartphones. Unless this disparity is addressed, the great promise of digital health technologies may worsen, rather than reduce, inequities.

The nation needs to reimagine how it designs safety into the health system, said Pronovost. For example, a typical American ICU has 40 pieces of equipment, none of which talk to each other. There are evidence-based practices, but determining whether a physician follows the most common evidence-based practices requires hundreds of computer clicks by the clinician. It is doubtful, too, that any of the available ER systems would pass a rigorous usability test. Each device, he noted, produces a unique alarm that competes with one another in the ER. This produces what he called an alarms race, where the least important alarm gets the most attention from the clinician, and nurses are answering alarms every 49 seconds. This lack of data sharing would be the equivalent of an aviation company that makes landing gear saying to Boeing that their landing gear will not send information to the cockpit as to whether the landing gear is up or down. It is imperative, he added, to break down these data silos.

Pronovost said that clinicians are forced to work with clunky and clumsy technology that has poor usability and often produces meaningless alerts, the solution for which is more robust systems engineering. In fact, he said, health care is the only industry that spends heavily on information technology but has little

to show for it. Safety has barely budged, and the only things that look to have increased are billing and burnout.

This is not just a problem for hospitals, said Pronovost. Patients are trying to manage their chronic diseases through clinic visits and are largely left to navigate their care themselves, with many falling through the cracks. Instead of having a care system that is proactive and relational, the United States has one that is reactive and transactional.

Pronovost pointed out that health care is the only high-risk industry that has not embraced systems engineering. The United States, he said, has the opportunity to be the world leader in health care systems engineering, and there is an economic opportunity because nations around the world will buy these systems, but seizing that opportunity requires imagination and the drive to achieve this goal. This will require investments in innovation, people, process, and technology. Toward that end, AHRQ has been funding some systems engineering projects, but that level of funding is about 10 times less than what is needed. The Department of Defense (DoD) and the Veterans Health Administration, said Pronovost, have brilliant systems engineering capabilities that could serve as role models from which health care could learn.

Finally, said Pronovost, these efforts will need to be coordinated. Today, a different agency is handling each piece of this problem, but together they can have a much bigger impact. This will not be easy, and it will take creative, courageous, and collaborative leadership across the health care sector. No one group or action alone will lead to these significant improvements, but if the health care enterprise chooses to learn and improve together, the future could be brighter for American patients.

Julie Morath, Morath Consulting

Nurses, said Julie Morath, are practical, innovative, and have a real bias for action. Nurses are everywhere and could be doing more for patient safety if it weren't for barriers that affect how they can work to the full scope of their preparation and license. These barriers are tied to the privileging and credentialing policies of state boards and individual hospitals. She noted that the ability for advanced practice nurses to work to their full capacity has tremendous implications for access, surveillance, and reaching patients in underserved and remote areas.

Morath said that nursing is an endangered profession with high turnover after difficult years during the COVID-19 pandemic. Nurses stepped up to take care of patients and families during the pandemic, and now the nation needs to step up for them. Nurses need safe places to heal and optimize wellbeing, and discussions about patient safety need to include workforce safety. Safe providers and safe spaces for people to practice in contribute directly to safe practices for patients. In addition, diversity, equity, and inclusion—both for patients and the workforce—need to be considered in every discussion, though it is often not included.

Nurses, said Morath, fill gaps between technology and the patient, and they are on a continuous journey with the patient. This is particularly important with care migrating from hospitals into the community and the home. The COVID-19 pandemic emphasized these gaps and made these gaps into chasms.

Morath stated that nurses need to be part of health system leadership as opposed to having their duties determined by others. They need to be on boards and in the C-suite, and they need to be full partners on care teams. Nurses are also process experts who can lead improvement cycles versus a massive rollout of change. This would allow for improvement and learning cycles that can reduce the need to rework programs.

Even at their best, the available technology, particularly devices and the EHR, is woefully inadequate for the jobs that nurses are expected to perform. Patient safety needs real-time data, greater knowhow and discipline, and rigorous after-action reviews when there is harm. Morath suggested creating a national patient safety board that would provide timely, actionable, and shareable information when things go wrong. Instead, cycle times are protracted, and often the issues have changed by the time information gets to the end users.

Morath said that nurses working in parishes, home care, urgent care, shelters, and street services can all help with surveillance and correcting issues before hospitalization is needed. She specifically emphasized the role that school nurses can play, though a school nurse does not exist in most school districts because of funding. In the past, school nurses provided surveillance and issue spotting, empowered healthy choices, reduced reckless teen behavior, and helped produce healthy adults. The importance of the school nurse needs to be revisited.

Transparency and focused measurement are important, said Morath, and require aligning processes to move the measures. This means connecting best practices to the measures and applying them consistently. While scientific research is seen as the gold standard for all inquiry, health care should use action research, such as qualitative processes and structural measures, and patient and family experience to help improve patient safety.

Morath said that 30 to 40 percent of a nurse's time is spent documenting care, which is disproportionate to the time nurses need to spend on care, improvement, and collaboration. This is where the EHR and other technologies need to better support nurses and not take away time from their primary responsibility to patients.

Morath credited OIG with including nurses and other disciplines in its work of selecting and designing measures. It is important to have a diversity of perspectives because a lack of perspectives at the table often produces an outcome based on an impoverished understanding of the problem. She also called for stepping back from the fascination with stoplights and rates that just scratch the surface of understanding. Toward that end, she called for health care to capitalize on learnings from engineering and other high-consequence industries.

Morath said that nurses in all areas of health care need to practice in a climate of psychological safety and in a just culture. Nurses are often the last person to touch a device, inject a medication, hang an intravenous bag, or program an infusion pump. Therefore, the nurse is often the individual blamed when a patient suffers harm resulting from a chain of multiple system breakdowns that occurred because of a lack of safeguards and engineering designed to detect, warn, and prevent errors from happening. The recent conviction of a nurse in Tennessee on the charge of criminally negligent homicide and abuse of an impaired adult after a medication error contributed to their death is a vivid example of the "blame the nurse" phenomenon. What is needed, she said, are operations, engineering, intelligence systems and

technology, rigorous usability testing, and investigation within a just culture that has accountability without blame.

Morath offered several recommendations for PCAST to consider. The first was to have the U.S. President declare that patient safety is an urgent priority, that current performance is not acceptable, and that health care needs to change its attitude from one of grit—that health care will get through this situation—to one of hope for a climate of psychological safety for patients and workforce collaboration. An action following such a recommendation could be to appoint a commission or national patient safety board to oversee and help integrate all the important but disparate activities that are taking place in this area.

Other recommendations that Morath made included:

- Simplify and reduce improvement measures to a more parsimonious set of five or six measures that are defined, meaningful, impactful, and reported in real time. The process for developing this smaller set of measures should involve diverse perspectives arriving at consensus.
- Federal agencies should align their data and reporting requirements to increase transparency. Such a move would be helpful for end users who are trying to improve care.
- Establish hospital-specific performance transparency, perhaps via a digital transparency dashboard, with a process to advance best practice implementation and begin focusing on two areas that are most problematic: maternal mortality and sepsis.
- Re-engineer the EHR so that it can fulfill its intended purpose.
- Develop triggers, populate quality metrics, require EHR interoperability, and create an artificial intelligence architecture for decision support alerts, prediction, and monitoring.
- Provide access to a reliable communication reconciliation program that would provide a process in the event of harm to support patients and families, and, over time, create an environment for physicians, caregivers, and families to restore trust and understanding with engagement and responsible transparency. Such a program should be based on known principles and frameworks.
- Tackle medical errors, a leading cause of harm, by commissioning a work group to design the safe medication system of the future. The work group should comprise nurses, pharmacists, human factors experts, scientists, information technology engineers, device manufacturers, and pharmaceutical companies. Such a medication system would:
    - always use a drug's generic name rather than the current mix of brand name and generic name,
    - use five-alpha entries for matching dispensing technologies,
    - have guardrails for alarms and addresses alarm fatigue,
    - eliminate lethal drugs from dispensing units,
    - require pharmaceutical manufacturers to apply human factors science to drug packaging, and

  - require device manufacturers to use human factors science for engineering and conducting usability tests for drug dispensing and delivery systems, most of which were designed originally for financial tracking and drug use studies, not for safety.

- Have CDC shift from data for publication to data for action, and include skilled nursing facilities and long-term care facilities in the National Healthcare Safety Network tracking system.

- Unite public health resources across agencies to be more proactive and become improvers and inventors versus defenders of the status quo.

COLLINS MODERATED THE Q&A AND DISCUSSION BETWEEN PCAST MEMBERS AND SHERIDAN, DORRILL, HART, PRONOVOST, AND MORATH.

ADVANCING THE U.S. INNOVATION ECOSYSTEM

Secretary Gina Raimondo, Department of Commerce

Secretary Gina Raimondo began her comments by stating that if the United States is going to continue to lead on the global stage, it is vitally important that the nation lead in research, development, and innovation. Thanks to President Biden's leadership, Congress passed the CHIPS and Science Act, which makes a $50 billion investment to incentivize domestic semiconductor production. Secretary Raimondo noted that the most exciting part of the investment is the $11 billion that will go toward transformational research and development capability and infrastructure, with a portion of that funding going to the Commerce Department's National Institute of Standards and Technology (NIST). NIST has deep technical expertise and is going to establish a National Semiconductor Technology Center, an Advanced Packaging Center, and probably one or two new Manufacturing USA Institutes. She added that NIST has an incredibly dedicated team that includes some of the world's experts in chip research and development leading this effort.

Secretary Raimondo also noted that the CHIPS and Science Act creates an opportunity for the nation to augment the $11 billion with private-sector and university funds. The federal government, working in partnership with academia and industry, has an opportunity to supercharge the semiconductor chip ecosystem, including research and development activities.

The CHIPS and Science Act, explained Secretary Raimondo, authorizes new programs that will build capacity to deploy next-generation technologies and establish new technology hubs. As this work progresses, it will be important to attend to equity and diversity, which means including women, people color, and diverse locations in this effort. Toward the latter, the nation will have the opportunity to make technology hub investments outside of the traditional technology hubs of Boston, Silicon Valley, Austin, and others. This presents a truly historic opportunity to bring capital and resources to U.S. researchers and entrepreneurs that have the best ideas, regardless of where they live, their gender, or the color of their skin.

In closing, Secretary Raimondo said that the Department of Commerce cannot do this work alone. When it comes to research, development, and innovation, collaboration is the key. Government at every level,

the private sector, public and private research universities, and all educational institutions will have to collaborate if the nation is going to stimulate research and development activities, and more importantly, translate that research and development into the next wave of innovation and technologies to solve problems.

ARNOLD MODERATED THE Q&A AND DISCUSSION BETWEEN PCAST MEMBERS AND SECRETARY RAIMONDO.

INNOVATION HUBS: IMPLEMENTATION OF THE CHIPS AND SCIENCE ACT

To introduce this session, Zuber noted that technology hubs have become a sought-after mechanism to ensure that Americans nationwide have the opportunity to contribute to and benefit from science and technology. Both the American Rescue Plan and the CHIPS and Science Act, as well as other legislation, have called on various agencies to create these hubs.

Erwin Gianchandani, National Science Foundation

Erwin Gianchandani began his remarks with some history to provide a framing for the Regional Innovation Engines Program at the National Science Foundation (NSF). Seventy-five years ago, at the request of then-President Roosevelt, Vannevar Bush wrote *Science the Endless Frontier* to make the case for federal investment in basic research to secure the nation's longer-term competitiveness and the health of the economy. For the better part of 75 years, that mindset has served the nation well, fueling many generations of discoveries and advances that have benefited the quality of life in the United States.

Today, said Gianchandani, the nation is facing another defining moment, much as it did 75 years ago. As the National Science Board wrote in its *Vision 2030* report, the United States faces key challenges in global competition with respect to technology, such as artificial intelligence, advanced manufacturing, advanced wireless, and the bioeconomy. He said the nation needs to do a better job of harnessing a unique national asset: the diversity of talent that exists in all corners of the country. The challenge here is to engage and inspire the "missing millions" of Americans in science, technology, engineering, and mathematics (STEM).

Another aspect of today's defining moment, said Gianchandani, is that the nation is facing a suite of socioeconomic challenges, including climate change, clean energy, equity, equitable access to health care, education, broadband connectivity, and the currency of information. At the same time, the research and innovation ecosystem is evolving, with the pace of discovery in nearly every field of science, engineering, humanities, and medicine accelerating as a result of access to unprecedented amounts of data and emerging technologies, such as machine learning and artificial intelligence, that allow researchers to extract meaningful insights from these data on the fly.

Gianchandani said that many of today's early career researchers are going into STEM because they want to put their work to use for the benefit of society. They have seen what vaccines have been able to accomplish during the COVID-19 pandemic, for instance, and they want to emulate that success in other ways going forward. Today, STEM talent is no longer going solely to U.S. institutions of higher education and industry, but it is also going to civil society; state, local, and tribal governments; and nonprofit organizations. This trend allows the nation to create blended and diverse teams that bring diverse

perspectives capable of driving forward the U.S. innovation ecosystem and addressing today's pressing challenges.

Gianchandani said the nation is at the precipice of a paradigm shift in the research and development ecosystem. For the last several decades, NSF has largely funded investigator-driven science, primarily done by academic research teams. This approach has fueled a steady stream of discoveries that have improved Americans' overall quality of life, and NSF does not intend to forgo that approach as the basic science agency within the federal government. However, NSF is also cognizant of the fact that the nation needs to engage users, beneficiaries, and consumers in shaping and conducting research. The nation also needs multisector teams that can drive research to address some of the societal, economic, and technological challenges facing society today. As investigator-driven research and the stream of discoveries push advances to the market, the expanded list of participants and societal challenges will create the market pull for innovation and practical use in the near term.

Gianchandani said that the book *Jump-Starting America: How Breakthrough Science Can Revive Economic Growth and the American Dream* speaks to the challenges, opportunities, and talent that exists across the country. It also talks about how the United States has the chance to harness this talent through the types of investments the nation makes in different corners of the country. The book served as a small part of the inspiration that led to the CHIPS and Science Act and the authorization, along with $20 billion, to establish the new NSF Directorate for Technology, Innovation, and Partnership (TIP) and the Regional Innovation Engines Program.

Gianchandani said this new directorate will intentionally work closely with all of the existing directorates, other agencies, industry, and beyond to strengthen and enhance use-inspired and translational research that already occurs to varying degrees within NSF. This effort could be scaled further in the future. Over the past nine months, TIP has announced partnerships with Intel, DoD, and the government of the United Kingdom to advance key technology areas such as semiconductors, wireless communications, security, and privacy. TIP has also introduced new pathways to enable open-source ecosystems and new translations pathways, and it has launched the Regional Innovation Engines Program.

Gianchandani explained that the Regional Innovation Engines Program is meant to cultivate innovation ecosystems across the country, particularly those in regions that have not benefited from the technological and innovation booms of the last several decades. One of the program's goals is to understand the major scientific and technological challenges while also considering societal and economic challenges. For example, there is a bidirectional connection between climate, equity, critical infrastructure, and other pivotal societal and economic challenges and key technology areas such as advanced manufacturing, advanced wireless communications, and artificial intelligence. As an example, he pointed out how addressing climate change serves to inspire new approaches in sensing, wireless, and artificial intelligence techniques, as well as in the circular bioeconomy and other areas. At the same time, innovations in those technology areas provide new lenses into climate change, equity issues, and critical infrastructure challenges.

Gianchandani added that the challenges the nation faces are not uniform across the country, so balancing technological innovation and geographic innovation is another key piece of the Regional Innovation Engines Program. Toward that end, the program is trying to stitch together a loosely connected set of constituents into a more tightly coupled coalition of regional partners who work together and serve as

the nucleus for the engine. Over time, these coalitions will work together on a shared topic of relevance to their particular region, as well as to the nation and society at large, and grow into an innovation ecosystem that will become self-sustaining over time. One goal is for these regional innovation ecosystems to feed into the proposed Regional Technology Hubs that are called for in the CHIPS and Science Act.

The regional innovation engines, said Gianchandani, differ from any previous efforts at this scale. The level of investment for a regional engine is an order of magnitude greater than some of the largest investments NSF has made to date. They will be led by chief executive officers and include partners from industry, institutions of higher education, government, and nonprofit and community organizations. They will engage in iterative co-design and co-creation through intentional engagement of broad and diverse stakeholders. NSF expects these engines to share knowledge and best practices, and form cohorts that go through the experience of building innovation ecosystems together and learning from one another.

Gianchandani said that NSF will apply metrics of success and milestones to ensure that the engines are satisfying those metrics to receive continued funding. Judging the success of the engines, however, will be different than for typical NSF programs. These efforts start with research, so defining success will include traditional measures such as publications and conference proceedings, in addition to new technological outputs, new workforce options, and talent development to boost participation at all levels. One thing that is most important to NSF is that evaluation occurs in a way that enables course correction and learning that can be applied to future engines and innovation ecosystems.

NSF's hypothesis, said Gianchandani, is that a significant infusion of funding, together with the regional engine framework, can serve as a magnet that attracts co-investment and co-creation, and builds innovation ecosystems that are unique. No two regional innovation engines will be identical, and that will enable the program to harness the geography of innovation that exists across the nation.

NSF launched the program in May 2022 with an intense set of regional road shows and webinars, said Gianchandani, with an end-of-June deadline for interested teams to submit concept outlines. Nearly 700 concept outlines were submitted, with at least one from every state and from many U.S. territories. Full proposals, due in January, will be for two-year planning and development projects for $1 million, with teams progressing to projects that the program will fund for $160 million and that are expected to run for up to 10 years.

Gianchandani said that NSF sees the role of the regional engines as a spectrum, ranging from fundamental research to economic growth. Traditionally, the Economic Development Administration (EDA, an agency under the Department of Commerce) has focused on the economic growth side of the spectrum, which the Regional Technology Hubs emphasize, while NSF has focused on the fundamental research side of the spectrum, where the regional innovation engines start. There are other actors in this space, such as Manufacturing USA, a number of the Department of Energy laboratories, and other NIST activities that occur at different points in this spectrum with very specific foci. The point is that the engines will feed into the hubs, with other participants contributing along the way.

Gianchandani said there will be healthy and robust overlap between NSF and EDA, particularly if coordination between the two agencies continues. The Regional Innovation Hubs will start with fundamental research and add innovation and translation ecosystems to broaden participation through

the intentional engagement of populations underrepresented in STEM. The Regional Technology Hubs will build on a region's current and future economic drivers, and their work on later-stage technology development will scale capacity to deploy breakthrough technologies. These programs overlap will generate place-based efforts requiring long-term investments to produce economic growth with a technology focus. Together, the two programs will serve as the connective tissue for an innovation ecosystem built on public-private partnerships.

Alejandra Castillo, Department of Commerce

Alejandra Castillo said the Department of Commerce is working closely with NSF, collaborating not just on ideas but also thinking ahead in terms of how to implement these programs. EDA is the only federal agency focused exclusively on economic development. While EDA does not invest directly in businesses, it does work closely with local economic development officials to support competitive, bottom-up, regionally owned development strategies focused on stimulating private investment and creating new jobs. EDA's investment policy is designed to establish a foundation for sustainable job growth and build durable regional economies throughout the United States.

This foundation, said Castillo, builds on two key economic drivers: innovation and regional collaboration. Innovation, she said, is key to global competitiveness, new and better jobs, a resilient economy, and attaining national economic goals. Regional collaboration is essential for economic recovery because regions are the centers of competition in the global economy, and those that work together to leverage resources and use their strength to overcome weaknesses will fare better than those that do not. EDA encourages its partners around the country to develop initiatives that advance new ideas and creative approaches to address rapidly evolving economic conditions.

Castillo noted that through EDA's priority to invest in technology-based economic development, it supports planning or implementation projects that foster regional knowledge ecosystems. Those ecosystems then support entrepreneurs, startup companies, and commercialization of new technologies that create technology-driven businesses and the high-skilled, well-paying jobs of the future. EDA's top investment priority is equity. This speaks to EDA's continued commitment to work closely with the nation's underrepresented populations and communities, which has been its mission since its creation in 1965 as part of the Public Works and Economic Development Act.

The CHIPS and Science Act, Castillo explained, created two new programs at EDA, though Congress has not yet appropriated funds to implement either program. The Technology Hubs Program authorized EDA to design 20 geographically distributed Regional Technology Hubs that will focus on technology development, job creation, and expanding U.S. innovation capacity. The RECOMPETE Pilot Program authorizes EDA to make concentrated economic development investments in communities with large prime-age employment gaps, covering ages 24 to 54. EDA has no role in the semiconductor piece of the CHIPS and Science Act.

Castillo said that a team in EDA's headquarters is working on preliminary plans in the event that Congress appropriates funds for either of the two programs. EDA's history of running numerous successful technology-based funding competitions is helping to guide this endeavor. She strongly believes that for federal investments to benefit a diverse range of local economies, there needs to be place-based

programming such as those delivered through EDA's $3 billion allocation from the American Rescue Plan. EDA's American Rescue Plan Build Back Better Regional Challenge was designed to let communities define their own economic priorities and compete for the resources to deliver on them. On September 2, 2022, President Biden and Commerce Secretary Raimondo announced 21 coalition winners from around the country that will receive these once-in-a-generation investments.

Castillo explained that the selected coalition—comprising universities, nonprofit businesses, community organizations, and state and local governments—developed bold and ambitious visions for economic transformation that will accelerate the growth of globally competitive industries in communities that might otherwise be left behind. Their success will not only create new, good quality jobs but will also help the United States address critical national challenges. The challenges that awardees will address include securing a domestic supply of essential medicines in Southeast Virginia, improving the productivity of hundreds of family-owned farms in California's Central Valley that will produce better jobs and more resilient food systems, and upgrading the capacity of legacy manufacturers in El Paso, Texas to bring critical aerospace and defense supply chain back to the United States.

Regarding workforce development, Castillo said that EDA's American Rescue Plan Good Job Challenge offered a new model for public investment that is flexible, encourages a comprehensive approach to skill development, and puts employers at the center of the equation. The goal of the challenge is to support the unique workforce needs of communities and options outside of traditional 4-year college. This grant program supported both employers and working Americans. EDA is excited about this model, which integrates industry into every step of the process while also supporting the holistic needs of job seekers and workers.

Castillo noted the nation cannot assume that broad national funding will naturally expand the economic competitiveness of all geographic regions equally. Rather, the nation needs programs such as the Build Back Better Regional Challenge and the Good Job Challenge that provide flexible federal dollars to support locally-created strategies and prepare regions to take full advantage of national investments.

Castillo said that the EDA's Office of Innovation and Entrepreneurship (OIE) is committed to furthering technology-based economic development initiatives that accelerate high-quality job creation, create more economic opportunity, and support the next generation of industry-led companies. These include programs such as the OIE's Build to Scale program that supports regional economic growth through two separate competitions: The Venture Challenge which supports entrepreneurship and accelerates company growth in communities, regions, or a combination of regions; and the Capital Challenge which helps to increase access to capital in communities where risk capital is in short supply.

OIE also administers the STEM Talent Challenge, said Castillo. This program provides funding to organizations creating and implementing STEM talent development strategies that complement their region's innovation economy. EDA hopes to announce the next funding opportunities for this program in the near future.

Castillo briefly discussed EDA's National Advisory Council on Innovation and Entrepreneurship (NACIE). NACIE is charged with advising the Secretary of Commerce on policies and programs that will accelerate the pace at which new technologies will come to market and foster innovation. This includes generating innovative ideas and aiding in the deployment and adoption of innovative technologies. NACIE's 33

members include agency heads, entrepreneurs and investors, and academic and research institution leaders. These individuals provide recommendations on how the Department of Commerce, other agencies, and non-federal organizations can design policies and programs to enable entrepreneurs to bring impactful technologies to market.

On a final note, Castillo said that EDA collaborates with sibling agencies that also pursue economic development, including NSF, to design and implement complementary programs that support regional clusters. These clusters build capacity to generate innovation through research and development and to benefit from that innovation through demonstration and deployment. EDA is excited to continue strengthening regional innovation ecosystems and is proud to build on the accomplishments of the American Rescue Plan and the Build to Scale programs. EDA is committed to ensuring that no one is left behind as the economy transitions by growing the economy from the middle out, ensuring that everyone who wants a job can get a job, and helping people make a good living in the places where they want to live.

ZUBER MODERATED THE Q&A AND DISCUSSION BETWEEN PCAST MEMBERS AND GIANCHANDANI AND CASTILLO.

PUBLIC COMMENT

Karen Wolk Feinstein, Jewish Healthcare Foundation, provided two minutes of public comments.

CLOSING COMMENTS

Collins noted that the recording of this public meeting would be made available on the PCAST website (WhiteHouse.gov/PCAST). He thanked everyone from the public who tuned in to the webcast, as well as the speakers and PCAST members who made the day's discussions interesting.

MEETING ADJOURNED: 4:40 PM 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

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