

**President's Council of Advisors on Science and Technology (PCAST)
Public Meeting Transcript
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Welcome from PCAST Co-Chairs

>> JOHN HOLDREN: Well let us begin. Pleasure as always to welcome the members of PCAST, members of the Office of Science and Technology Policy Staff, and members of the wider Science and Technology Community who have joined us here in the room, as well as those who are joining us for the live stream on the web.

PCAST continues in this last part of the Obama Administration to be extremely active, just as the president has made plain that he intends to be going full speed right up to the end of this administration to get as much done in the interests of the American people as we possibly can get done in the time remaining, so PCAST is following that same model.

We have ongoing studies on health of the American drinking water system, the state of forensic science, biodefense. We are following up and tracking the implementations of recommendations of previous reports on affordable hearing healthcare, on electromagnetic spectrum, on energy technology innovation, climate change preparedness, combating antibiotic resistance, and others. We will be covering a number of those topics but not all of them given the limitations of time in today's public session.

Let me ask my co-chair Dr. Eric Lander if he has any welcoming comments and then following those we will turn to our agenda.

>> ERIC LANDER: Well just to underscore how much we appreciate how hard PCAST is working, there is no sign yet that the current administration is going to come to a close in January. It is going to come to a close in January, but you couldn't tell it by the work that is being done. There are multiple projects still going on, multiple reports still in flight, and I just want to express my tremendous admiration for the whole group for the energy that is behind the reports John's already referred to, some of which we're going to discuss in today's session, so thank you.

Forensics

>> JOHN HOLDREN: The first topic on our agenda is an update on the report on forensic science, a study that has been led by Eric Lander with participation by Bill Press, Susan Graham, Jim Gates, Michael McQuade, Dan Schrag, and of course all of the members of PCAST as in all of our reports are weighing in and participating in the development of this study. So I'm going to turn it over to Eric to lead a discussion of the state of progress on that report."

>> ERIC LANDER: Great! Let me give a brief update. We have given an update before and so let me update that update as to where we are right now. As folks will remember, science is a very valuable tool in many areas and law and justice is one of them. Forensic science is the application of scientific methods to be able to understand the evidence and make use of it in investigations and in

courts, and it's a very important topic. It's one that's received increasing attention in the scientific community. Most recently and notably, with the 2009 report of NRC that looked at the state of forensic science and identified gaps and needs. Concerns in particular about the scientific foundation and validity of some areas of forensic science.

So in response to that, the Obama Administration has already taken a number of steps, a notable one was the creation of a National Commission on Forensic Science. That's a group that reports to the Attorney General, and it has the involvement of NIST and it makes policy recommendations to the attorney general in a wide variety of areas, including certification and accreditation, and many other things; and I note that one the member of PCAST and a member of our working group, Jim Gates serves on that commission so he does double duty for the country, probably has triple, quadruple duties in other such things but I want to acknowledge Jim's service.

So in addition to the efforts that the administration has led with the creation of this national commission reporting to attorney general, there's also been scientific efforts by NIST and by NSF to begin to increase funding somewhat for forensic sciences. There's the creation of a center of excellence that NIST has. There have been more grants given by the National Science Foundation. So there are a variety of steps going on scientifically. There have also been, since 2009, a growing number of scientific studies addressing really fundamental validity questions. I think it's very encouraging to see that there's beginning to become some set of papers.

A notable paper I'll call attention to is work by the FBI published in the proceedings of the National Academy of Sciences on latent fingerprints. I think that's a great thing. It's fair to say that very little in forensic science has traditionally been published in journals outside forensic science.

In many scientific, this ones the most important and impactful papers, are published in general scientific journals. They rise to a certain standard, they appear in PNAS or in Nature and Science and I took it, and I think many of us took it as a very good sign to see that a paper on latent fingerprint analysis was appearing with a tremendous amount of detail and serious peer review in journals like PNAS. So it's all very good signs.

PCAST has tried in the study that we're doing at the moment to focus on this fundamental question of scientific validity. Is it the case that a scientific method, and particularly we focus on what we call 'pattern comparison methods,' that's a catchall phrase that includes several different disciplines in forensic science, and we just use the word "pattern comparison methods" to catch them all. But they largely have to do with finding features in a piece of evidence and comparing it to features in something that might have produced that piece of evidence. Latent fingerprint at the scene of the crime, perhaps, or elsewhere and the actual fingerprint of an individual, for example. It could be patterns on a bullet fired from a particular gun, attributing it to the gun. Obviously DNA falls into that category, impressions fall into that category.

So in regard to this broad area of pattern comparison methods, the question for PCAST has been from a point of view of science, 'what does it mean to be foundationally valid?' It's an area that is a subtopic of the field of metrology, the field of measurement and comparison. And so it's an area that's broadly understood in many different contexts. Make measurements and see if two things

resemble each other.

So what PCAST has tried to do and what we're continuing to work on is to try to just bring the kind of clarity that I think all scientific methods benefit from of what do you have to know. It turns out to be useful to distinguish between what might be called 'objective methods' and 'subjective methods.' The best kind of methods in all science are objective methods where any ten people who do something will get exactly the same answer or almost always get exactly the same answer barring a little slip up here and there because it's really well laid out. It's precisely defined 'what are the features your looking at?' DNA comparison from a single source is a good example of that. If you run DNA out or run it out on a sequencer, you have defined fragment links or sequences and any ten people look at it will get the same answer there. In fact, the machine gives you the answer, 'Yes, that's the size of the fragment.' And then you have pretty clear rules on how you compare two different samples. You take the list of fragments and you say "Are they the same?" If they're the same, that's a match. And if they don't, they're not.

But of course in many areas that are useful, there aren't yet methods that are objective. And so there is still room as there are in many parts of science for subjective methods. But subjective methods have to be tested also. And the way you test subjective methods we've come to understand, and I think broadly understood here, is you have to test them in practice to see how people do, how people are applying it. In the case of forensic examiners, and see when you give them a whole bunch of problems where they know the right answer and they don't know the right answer, how often do they get the right answer. You can compute a false-positive rate and a false-negative rate. It's very traditional that you do this in medicine as well, testing labs do that. These rates are never zero, it just doesn't happen in life that rates are never zero. And you need to know the rate in order to know how good your metrology tool is, how good is your method.

What's really important is to ask, and what we've been trying to do is read the literature together and understand for a variety of different forensics methods, how far has the field come in establishing whether the method is foundationally valid. So far we've taken a look at DNA analysis of what you might call simple problems. A sample from a single individual or mixture of two individuals as most commonly would be found in a rape kit. Particularly there when you can distinguish between the male and the female contribution by using different extraction methods. That sort of simple problem is a harder problem of a DNA sample from many different people that might involve an unknown number of contributors of unknown amounts, we'll call those complex mixtures. That's a distinct kind of problem.

There is a technology that people will refer to as 'bite mark analysis' and it's fair to say that there has been concern about bite mark analysis and so we've tried to read the literature closely on that and ask 'how well is it specified? How well do people do when you subject them to it?' I guess the words for subjective methods are black box testing were you just treat what's in the examiner's head as a black box. You don't try to exactly specify what features they're looking at and how they're comparing them but you look at how the black box preforms. There's bite mark's, there's latent fingerprints, there's firearms analysis, there's impression analysis such as you might have from a shoe or other footwear. Those are the areas where we have been trying to read the literature and understand and as I alluded to already, we're excited and impressed to see work by

the FBI on the latent fingerprints. What might be referred to as both black box and white box studies have come in the last six years or so after and in many respects in response to the 2009 NRC report.

These black box studies set up large tests where they gave large numbers of examiners large numbers of fingerprints and asked 'can you determine are these from the same source or a different source?' And actually measured error rates. And that was really impressive to see done. It would be great to have more such studies, but I think the FBI has given us a model for how to do that and that's very good.

White box studies are as interesting from a scientific point of view because there what they do is try to understand how do examiners actually think about this technology. And in a study that I think bears great reading, they looked at how examiners changed their opinions about the features in a fingerprint based on comparisons to a possible match. It's very interesting to see that back and forth. You might ask should there be a back and forth? Some have argued that no the future should all be specified in advance before you look at the possible match, because you might be influenced by it.

And I think the FBI in a remarkably thoughtful paper has noted that at least currently examiners do go back and forth to the match and revise their opinions and they note in the paper that could raise problems because you could tend to discard things that don't match because they don't match, and that could be a problem. On the other hand, empirically it is a practice that is used. So I think the idea of shining scientific light on each method to understand how people practice it, what is the accuracy level of it? It's really the fundamental thing that makes science strong and reliable, is that you know those things.

Now PCAST is still in the midst of reading the literature on all of this and reaching its judgments about what the state of foundational validity is, but we're very much aided by the fact that we made a public call for information. And from the forensic science community and the broader scientific community, we received a very large number of responses, 70-80 responses, maybe more by now. And we assembled a reading list of about. Diana will correct me, how many? That's what I thought. 2,200 papers that we have gone through to try to sort them into which ones are relevant for foundational validity. I think it's not clear that when we made the public call for information, we were expecting to get 2,200 references, but we're really grateful for it because i think it gives us a confidence. Particularly, many of them came up many times but it gives us a confidence that we really have a good handle on that literature right now. So I want to use this opportunity to express my gratitude to all the people in the field who have been writing to us with ideas and suggestions and things like that.

So clearly this is not work to be done just once by PCAST in a report. The business of continuing to look at the foundational validity of forensic technologies is an ongoing business and it's a scientific business because new technologies will continue to be invented. All of the technologies that are used today were somebody's brain child at some point, and a lot more ideas are coming along.

You hear things about hair analysis; "Why are we doing it by looking under a microscope as

opposed to doing a mass spec.? Why are we doing other things?" And then of course it's not just the classic CSI style physical evidence. Digital evidence. Is somebody defined by their web browser history? And if so, by how much of it? Those are again pattern matching and pattern comparison problems and our hope is to have thought through these things carefully enough that the same general paradigm will apply to either objective or subjective technology going forward. And of course it's going to be a question of who does that going forward, where is the right place. There have already been suggestions, publicly there's been suggestions from the national commission that NIST should perhaps play some role in the ongoing evaluation of those. I think it's certainly right that those questions need to be lodged someplace scientific with an ongoing mission, but we noted the suggestions that had been made by the commission. So we try to weigh all those various things.

So just to summarize, it is an incredibly important partnership between science and justice here. Everybody wants to get this right. Whether you're a defense attorney or a prosecutor. Certainly for judges, most importantly for the people themselves who are caught up in the criminal justice system. We all want to get the right answer. You want guilty people to be properly convicted of crimes, you want not to have innocent people wrongfully convicted for two reasons: one, it's an injustice to them, and two, it means the true perpetrators are still on the street, so where ever your concerns lie, in my mind both places there, we really have to get these answers right and it's not easy to get answers right all the time. Science can help but only help if we make the methods every bit as good as they can be and we insist on excellence.

I'll close by just noting that when DNA, now considered the gold standard, first came into use in the late 1980's and early 1990's, it wasn't really good. The evidence presented was actually pretty terrible. Many people got together. I was involved in those times, and I remember working closely with scientists at the FBI. It was folks at the FBI who were deeply worried this was a technology that was great in principle, but wasn't being practiced well in practice. They took a great lead together with many others, together with the academy to make sure it was practiced to a high standard. And because people stuck that high standard, we got gold the standard of DNA finger printing on simple methods today. And it's just an ongoing business in every decade that work continues to have to be done as new ideas come along.

So that's really where our focus has been. Not quite done yet. We, as I said, we didn't expect 2,200 papers to have to go through so it was a bit of work there. But I think we're pretty well done going through literature and sifting and have a pretty clear picture so I'm hoping we'll be able to converge on that. I want to give that as a public report of where we are. I want to show it open to PCAST for discussion. And I see a first flag is already up from Chris Cassel.

>> CHRISTINE CASSEL: Thanks, Eric. At the risk of adding 2,005 articles or more, I just want to ask you a question about the scope of this work because it does seem very important. And I just was thinking about this study when I read in this last Sunday's New York Times Magazine, the cover article about roadside drug tests. And the really remarkable lack of accuracy. And those tests that are used, I think that's actually what most of what you're looking at is evidence in the courtroom rather than evidence actually at the site of an arrest. But I wonder how you're considering the scope of this scientific question?

>> ERIC LANDER: It's a great question. I think many people saw this concerning article that appeared in the New York Times about roadside drug tests. The distinction isn't where it's being used in what we're doing here. It really has to do with is it a pattern comparison method. A chemical analysis method to ask is this chemical X not within our scope, because it's in the way we divided things, considered a different kind of forensic science method. It's a different kind of chemical, analytical detection method. We've really taken on those things where there are 7 billion people walking around with fingerprints, if you see one does it match somebody else or could it match another person? Same with DNA patterns. The question of is it a particular drug is really a chemical analysis question and we're just not doing it within this, although this article does raise that this is important.

Other things that people have raised to us are uses of science in the courtroom like Shaken Baby Syndrome. Where there's a great deal of concern about the science that underlies claims around Shaken Baby Syndrome. We're also not taking that on. I think what's fair to say is we've tried to bite off just a corner of the problem, and it's the corner about pattern comparison methods. We tried to bite it off and really work hard on it so we know the whole literature. I think there are so many different ways in which science is used in the courtroom, and they may require different approaches. So I suspect we could return to that or a future PCAST could return to that, or NIST could take those up. But just pleading that the 2,200 papers having to do with pattern comparison method, probably constitutes the right piece. We've also defined what we're not going to do, and we're really not going to go outside the bounds of those pattern comparisons in this report. But I think the conversation between the judiciary and the digital system and science is an important one at all levels and we've continued to see it get more and more sophisticated over time and I hope this will push others.

The academy itself has a long tradition of having issued these reports. There were two DNA reports, there was a report on compositional analysis of bullet lead that basically led to it stopped being used. Reports on polygraphs and lie detection, reports on the state of forensic science, on funding for forensic science at NIJ. So I suspect there will be an ongoing need for these things and I hope that in our wake the academy and others will step in.

I think Jim Gates' flag was up next.

>> JIM GATES: Thank you, Eric.

And thank you for the review on the process. And thank you also for the comments about my service on the National Commission for Forensic Science, which has been an educational experience to say the least. I think in general the public would benefit from understanding some things about why this is so critically important. And you mentioned the 2009 academy report of paths forward for forensic science. And one of the conclusions there is that some forensic science disciplines are supported by little rigorous systematic research to validate the basic premises and techniques. And that I think in the public mind very much a surprise. You mentioned the television show CSI, which has had an enormous impact on the how the public perceives the use of forensic science. So to find the reality is not that is one thing worth clarifying that this group is undertaking.

The other thing I would ask you to address is a slightly different question from the one that our

colleague Christine Cassel asked, because this is a segmented problem, as you're well aware. One part of it is getting the science right to do the experiments in the laboratory, but there is an entirely distinct part, which is how do you report in a scientifically defensible way the results from those tests in a courtroom situation. So this whole issue about how are we going to deal at all in our comments about how one should report on the science in the actual courtroom?

>> ERIC LANDER: Yeah, you raise two great points. I should say that this question of coming to understand the science is not perfect and not even as good as people might have thought. It's sobering and it's real. I think it's been a real shift in the recognition to be able to make an assertion that a technology is good, you actually have to measure it. That might seem obvious if you approach it as metrology. But I think it's fair to say that forensic science began much more from practitioners who were using things and said 'look, I'm pretty confident this match is that.' Then you come to realize that's a scientific claim and you need to test it. I have to give an enormous amount of credit to the Department of Justice for its recognitions for the need to revise thinking in light of scientific foundations.

Just a month and a half ago, there is a recognition where the DOJ talking about standards for the reporting of latent fingerprint analysis to their great credit cited a document from 1984 that the department had published then, which had this statement 'of all the methods for identification, fingerprinting alone has been proven to be both infallible and feasible.' And the DOJ cited it correctly as wrong. They said that's not correct. And I think the recognition that we come to understand that a lot of forensic science at the beginning came in because of the belief that these patterns could match things, and that increasingly as the DOJ has noted here, you actually have to put those beliefs to a test.

So then the question you raise is when you present evidence, whether its discussing it back in the course of an investigation, or in a courtroom, or wherever, how do you present evidence? It seems the only way you can do that is you have to have a statement of reliability. So I think a simple statement, hardly scientifically radical, is if you believe you have a method, you have to be able to state its reliability. If you think you have a ruler, you have to know does it measure things to within the inch. Or is something where the National Institute of Standards and Technology can measure things to a nanometer. It's very important to say if two people are the same height with a ruler only has demarcations to an inch or things down to a nanometer. You have to make some statement of accuracy, and I think that's a challenging thing for folks to say, because then you have to get the statement of accuracy roughly right.

So statements of accuracy like it's infallible, that's a statement of accuracy that's just wrong. No statement of accuracy, that's a problem too, because that's as bad as a statement of perfect accuracy. You have to grapple with what you know and that's why I think these black box studies that people have been doing more and more of is probably the best answer because it's an empirical measurement. Once you measure something, you have a desire to do better. And I think that black box measurement, just in scientific labs and medical labs, when you measure something, you find out 'oh my God, I actually make mistakes sometimes.' It makes you want to get better. So measurement is the key step in improvement.

So yeah, measurement has to be part of some reporting. Absolutely. And I think we're all trying to think through how best to do that.

I don't see any other flags. If not, we're going to be continuing on this. I want to particularly thank Diana Pankevich, because somebody had to organize 2,200 studies. And somebody had to get an awful lot of input and I just want to express our appreciation to you for all the work you've done to make sure that we're proceeding in a scientifically rigorous fashion. I want to thank the members of the working group who have been hard at work on this as we're trying to bring this to a close. I think we are just a little bit early and I will give those five minutes over to our next topic.

>> JOHN HOLDREN: Thank you, Eric, and all those who participated in the interaction.

Biodefense

>> JOHN HOLDREN: We now turn to an update on the biodefense study. That study is being co-chaired by Chris Chyba and Wanda Austin with participation in the working group by Eric Lander, Bill Press, Barbara Schaal, Ashley Predith is overseeing it from the staff side. And I don't know Chris or Wanda in some order. Chris?

>> CHRISTOPHER CHYBA: Thank you, John. Thank you. So let me begin by reminding PCAST, as well as those listening today that throughout this administration PCAST has reported to the president on a series of important biological issues, those have included our 2010 report on reengineering the influenza vaccine enterprise to meet the challenges of pandemic influenza. Our 2012 report on propelling innovation in drug discovery, development and evaluation. And most recently our Herculean 2014 report on combating antibiotic resistance.

We've recognized throughout this process in our discussions that each of these areas, each of these studies has relevance directly or by analogy to also protecting the country against intentional biological attack. But we've never dwelled on those issues, although we've occasionally mentioned them in our reports.

Over the past year, though, PCAST has decided to address that issue directly. We have formed a working group working group of molecular biologists and biologists with the expertise among members of PCAST, and have held a series of intense meetings with government experts at both the working level and also much more senior levels.

We've been especially interested in the implications of the rapid pace of advances in biotechnology for both advances in biodefense, what we can do better, taking advantage of the tremendous growth and knowledge and capabilities that the biotechnology revolution represents. But also we've wanted to think about the implications for the misuse. The implications of the misuse of these, the potential misuse of these biotechnologies and growing knowledge about the human organism. Misuse either in state programs or by non-state actors.

We don't do this work in a vacuum. PCAST is well aware that there's been a great deal of previous work done both at the White House level and also in the agencies, in particular by the department of homeland security. Not just in this White House, but going back after 9/11 in the George W. Bush

administration and in fact by administrations prior to 2001. Since 2001, some of the key reports here that we're cognizant of, that we paid attention to in particular have included the 2004 Biodefense for the 21st century and the 2007 report on public health and medical preparedness. And also documents in this administration, the 2009 national strategy for countering biological threats, and in 2012, 2013 complementary documents on disease surveillance including the national strategy for biosurveillance.

So looking at that entire landscape and taking advantage of a whole series of conversations within the government as well as with outside experts, we have asked the question, the central question, which is whether the way the U.S. government has been thinking about these issues and the way it has configured itself, the programs it's put in place, whether we need to adjust or even rethink those approaches given the growth, the powerful growth in biotechnological capacities.

The changes we have to confront are both quantitative. For example, as has been well documented in the literature, the pace of gene synthesis, the pace of synthesis, excuse me, the pace of synthesis of DNA Oligonucleotides, comparatively short strands of DNA, has literally exponentially grown. We are exponentially more, we can exponentially do that more rapidly now than we could. Let me say this more coherently. We are familiar with the analogy in computing science, you're familiar in computer science with Moore's law, that every eighteen months the power of computers as measured by the number of transistors that can be put on a chip doubles. That has held true for decades. There is analogous exponential growth in biotechnology. For example the speed of which one can synthesis strands of DNA is exponentially decreasing, increasing that is. They are becoming more exponentially more capable. And the pace of that increase is as fast or faster than Moore's law in computing. So there are these quantitative changes in biotechnological capabilities, but there are also qualitative changes in the sense that there are both new fundamental discoveries about microorganisms, and about humans, but also there are new technologies appearing with increasing frequency.

So this area is fundamentally different from what we face with respect to other so-called Weapons of Mass Destruction. In particular, nuclear technology, the technology relevant to the production of nuclear technology. While it is evolving in ways that are disturbing, that evolution is a much slower evolution. A kind of evolution that one might expect in a comparative industrial era technology. We don't face the same kind of bottlenecks in the biotechnological realm as we do in the nuclear realm, where one either has to produce uranium or plutonium there a small number of well understood paths. And that disparity between what is happening in the biological realm and what happened in the nuclear realm grows year by year.

A better analogy in the biological realm that I already made is the analogy to computer science and the Moore's law growth of computational power. That is not only a statement about the increasing power available to groups that already have this knowledge, but the increasingly widespread availability of this knowledge to more and more actors around the world. And most of that is a very good thing. Across the board, that is almost uniformly a good thing in terms of ability, in terms of increasing capacity for public health, greater ability to conduct disease surveillance, advances in the economy. It's just that these advances bring with it a potential downside that could be taken advantage of by, let's hope a small number of bad actors, either in state programs or non-state, or

non-state actors.

Okay. With that context, and that understanding, we've looked at a number of key areas. We began by looking at leadership and coordination both at the White House and elsewhere. Is the government configured in the optimal way given the changing nature of these challenges. We need to look at threat awareness. The explosion of biotechnology makes it more important, not less, to understand the potential motives and intentions as well as the growth and capabilities of potential adversaries, state or non-state. We're looking at disease surveillance, both domestic and international. PCAST has previously addressed this context, this problem especially in the context of antibiotic resistance. We're building on our recommendations in that context to recognizing especially the international capabilities for the Department of Defense and the Center for Disease Control.

We want to look at medical countermeasures and in particular, a question we've been focused on is whether, is the extent to which we can decrease the time between the identification and sequencing a pathogen in an outbreak. Whether that's in a naturally occurring outbreak or whether, heaven forbid, it's an organism that's been genetically modified. Whether we can increase, decrease the time between recognition, identification of the organism and the time in which we can produce and distribute and effective countermeasure. Whether that's a vaccine or antiviral or something else. We're looking at that question both with respect to what can be done in an evolutionary sense in the medium term to try to beat that time scale down to be much shorter than it is, but also whether there are radical changes we might envision that could radically reduce that time scale to be much, much shorter than it is today.

We need to think ultimately, at least in this dramatically different way, because the capabilities we will be increasingly living with in the coming decades will also be dramatically powerful.

And finally, we want to recognize the important parallels, but without losing site of the important potential differences between intentional outbreaks, intentional attacks, and naturally occurring disease outbreaks. Diseases are emerging regularly, but in recent years it appears that annually there is an outbreak that is of sufficient concern that it requires a White House response. We want to understand what can be learned from the succession of experiences, both for addressing future of naturally occurring outbreaks, but also should we have to face an outbreak in the future involving an intentionally manipulated organism.

So part of this work necessarily requires classification, in particular were going to break out a separate document, a separate classified document on threat analysis. We're going to put out a report on threat awareness. So there will be two reports which will interweave and speak to each other. One of them will be, the much broader document will be an open document that will address the other areas of leadership, disease surveillance, medical countermeasures, and learning from infectious disease outbreaks, and then there will be this much more tightly focused classified document on threat awareness. Our hope is that PCAST can wrap up these studies in the coming months and give our advice to the president on these topics sooner rather than later. Thanks.

Let me ask my co-chair Wanda Austin what she would like to add to these remarks.

>> WANDA AUSTIN: Thanks, Chris. The only other point that I would share with PCAST to your excellent summary there, is that one of the other things that we're thinking about is how to support the science community, to support the government in working through these issues as Chris alluded to. It's an area where things are changing rapidly. So our current strategies are probably going to be unsatisfactory if you look at the longer time horizon. So what we need to be able to do is tap and leverage the scientific community to bring their expertise to bear on this issue, and support the government in whatever strategies they proceed going forward.

>> JOHN HOLDREN: So comments, questions for the biodefense group? Let me ask one. You've mentioned a number of times that one of the characteristics of this field is how rapidly things are changing, and the particular challenges that that poses. I wonder if you could elaborate on that a little bit and compare it more directly to other areas of threat that we have historically been concerned with? How fundamentally does this domain differ from some of the others?

>> CHRISTOPHER CHYBA: So let me elaborate a little bit on the nuclear analogy. As you know, there is a U.N. definition that goes back to 1947 of Weapons of Mass Destruction that lists nuclear weapons, chemical weapons, radiological weapons, and biological weapons. And it's natural when people think about this topic to think WMD, weapons of mass destruction and some sense their all similar to one another. But the pace of technological change in this area makes bio fundamentally different from those other areas, even the chemical area. The most profound difference is with the nuclear issue. It is possible in the nuclear realm despite challenges that we all understand, we read about in the newspapers every day, it is possible in the nuclear realm to have a largely credible monitoring and inspection regime that is enforced under the nuclear non-proliferation treaty by the IAEA, where the IAEA monitors about a thousand facilities globally. You can get your hands around the vast majority of the nuclear weapon threat in terms of the production of material, be it plutonium or highly enriched uranium, by keeping track of about a thousand facilities.

And then in addition, there is the question of covert facilities, which is always a challenge. But it has been the case historically that those facilities are large enough, that they have enough of a footprint that it's hard to hide them. That is slowly changing, especially with the development of the uranium centrifuge as the dominant technology for enriching uranium, it's getting slowly easier to hide those facilities but as we've seen, it's still hard to hide those facilities. And they still tend to get discovered.

It is not credible in the biological realm to envision a global regime of that kind of that kind of monitoring and inspection. There are hundreds of millions of computers hooked up to the internet. I'm sorry. Let me draw the analogy first of the cyber case. So look at the other end of the spectrum. This is not a WMD but it makes the point. If you were trying to address the potential threat of cyber weapons, you would not try to address it by constructing some kind of international monitoring and inspection regime. There are hundreds of millions of computers hooked up to the internet. An attack might come from any one of those sources. You have to think about that threat in a fundamentally different way.

Bio, if you think about this as a one-dimensional spectrum, just for this purpose, bio is closer to the cyber end of that spectrum than the nuclear realm. Because the results of the advances in

biotechnology, the result is that those technologies are increasingly available to small groups of technically competent people. And the facilities you need are much smaller than nuclear facilities. You don't need large quantities of materials, especially if you're thinking in terms of contagious agents.

So the kind of inspection and monitoring regime that we think about in the nuclear realm is just not very relevant. That doesn't mean there is not some potential role for a compliance component to the biological weapons convention. But as they stand, there is no analogous regime in place and it's unlikely to be extremely effective. So we have to think in a fundamentally different way. And that means that we have to think, we certainly have to understand motives and intentions and do a better job of that. Do as good a job of that as we can. But we also need to think in terms of disease surveillance so we have as much advanced warning as possible. And in addition, we have to think in terms of rapid response. And that's why there is this emphasis on reducing the timescale between detection of an organism and the production and distribution of an effective countermeasure.

>> JOHN HOLDEN: Michael McQuade.

>> MICHAEL McQUADE: Chris, I want to thank you very much for the leadership on what, I think as you say is a rapidly moving and really important technology area. We've been talking about it mainly in the context of an intentional bioterror. I wonder if you can spend a few minutes talking about what we learned, what the overlap is between how we look at this problem versus naturally occurring events, in particular as it relates to surveillance mediation, etc.

>> CHRISTOPHER CHYBA: So the good news, given, especially given what John has emphasized of the profound differences between bio and other types of weapons of mass destruction. Remember even in the chemical realm, chemistry is a technology that is evolving much more quickly than nuclear technology. But even there, there can be a chemical convention that tries to keep track of onward 6,000, I think, facilities globally. A bigger challenge, but it's at least not completely incredible. But I think what you're emphasizing points to the need to, without being naive, analogizing the intentional threat to public health issues and the important emphasis, and understanding the importance of disease surveillance so one detects an outbreak as early as possible. So some of the things that one wants to do are relevant to both a naturally occurring disease threat and also the threat of intentional use. One wants to have a disease surveillance system in place that allows you to detect and identify sequence, genetically sequence an organism as quickly as possible. One wants to be able to move out with medical counterparts rapidly. For a novel organism, or for an organism that isn't novel but for which you haven't previously developed medical counter measures and we seem to be seeing that a lot lately, that you can try to reduce the time scale between detection and response.

Having said all that, I think that analogy is important. And I think it was especially important back in the '90s and the early 2000s to break this misunderstanding, this misplaced analogy between bio and nuclear. But we need to go well beyond that analogy now. Because what could potentially happen in an intentional outbreak could look very different from what happens in a naturally occurring outbreak. That's both because a bad actor could choose, and there is a limit to what I

want to discuss in any open session. Obviously this is unclassified, but even there, there is a limit to what one wants to say in an open session. But a bad actor could clearly choose to attack multiple points simultaneously. A bad actor could manipulate an organism in a way or distribute it in a way so that the outbreak doesn't look very much at all like what a naturally occurring disease outbreak would look like. And one needs to be careful with that analogy to bear in mind that there is a potential for this being much more widespread, much more rapid, much worse in a variety of ways.

It's also the case, and I think this is overwhelmingly likely as we move down this road that the bad actor is going to screw up and not do a very good job at all. It would be good to detect those screw ups to get as much advanced warning as we can.

>> WANDA AUSTIN: I'll add a couple of comments there. Mike, to your question, one is that we see the natural outbreak as something that we know we have to live with. And an opportunity to really learn what are the opportunities for effective surveillance and response. And I think there is a lot that can be gained in focusing our efforts in working that side of the problem. The other thing is there is the accidental exposure, which is something that you hope doesn't happen, but nonetheless you have to plan for that occurrence. And again, the importance here I think is early detection. And in early detection, you have to have a recognition on the part of people working in these fields about the importance of self-disclosure and early identification.

The other thing I would share is that we also participate in some discussions with the U.K. Council on Science and Technology because there is a common concern here as we think about outbreaks that we have seen recently, they move across the globe very quickly. We need to think about how we partner with other countries to address these issues and these problems and make sure we have great communication to understand what we're seeing on the surveillance side of the picture. But I think there's an opportunity there for great partnership and participation on working some of the challenging problems.

>> JAMES GATES: Thank you, John. And thank you both Wanda and Chris for the great work. The comment you just made Wanda, you talked about partnerships across borders. But you know there's sort of an obvious partnership I would hope that either you and Chris could speak to the public health organizations in our country, because detection may come from some interaction in between public health and the government responsibilities. Can you say something, speak to that a little bit.

>> WANDA AUSTIN: I'm not sure I understood the point you were getting at there.

>> JAMES GATES: So if some biological agent is manifesting itself and breaking down our health the most likely people to first see that are public health officials, doctors, hospitals, what have you. One could imagine we should be thinking more robust plans for how to get that information across that barrier. And I just want to know have we been looking in that corner.

>> WANDA AUSTIN: So we've also been looking, again, this is somewhat in terms of thinking about the response. In order to respond, you actually have to have people that are looking to detect that this is more than an isolated case. And if you think it is more than an isolated case, what do you do.

So much of our public health is really localized. It's at the state level at best. One of the things that Chris alluded to the fact of thinking about how our government thinks about these issues, it's how do you do that communication that says I've got something in four states. Is there a connection? How do I make that connection? How do I pass that information back? And we certainly have had some experience with that.

The other concern that we've been discussing is how do you know what capabilities you have to even respond? When we had Ebola and we looked at what are the facilities and the training that is required so that you have the experts who know what to do and how to mitigate the risk of having this go even further. We found that there are fairly limited resources available to address this. So this is part of the discussion that I think that you're alluding to, which is it goes from being a public health, localized issue, to being a federal and potentially global issue. I would just point to Zika as another example where it started in South America. It's now in Puerto Rico. So you say 'Okay how do we prepare ourselves given the early indications and warnings that we've had?'

>> CHRIS CHYBA: I might just add to Wanda's fairly comprehensive comments that emphasize what she has already said, that public health surveillance in the United States begins as a local and state issue. That complicates things. But it's also in some respects a strength. The Centers for Disease Control attempts to support, given a very limited budget, local and state public health surveillance. In our antibiotic resistance report, you'll find a discussion of that in the context of trying to do surveillance for antibiotic resistance just to see where it's coming up. In that context, I think this analogy emphasizes the problem we face. In that context, we say in that report, we identified in that report, that there are states that do not have a single individual whose job is devoted to conducting surveillance for antibiotic resistance. So if one state has an outbreak of influenza say, that person gets pulled off because they have to deal with influenza and surveillance for antibiotic resistance just goes away for a while in that state.

The importance of strengthening just the fundamentals, that kind of fundamental infrastructure in terms of personnel and basic communication capacity at the local and state level I think needs to be emphasized.

Beyond that, and this is again an analogy to our antibiotic resistance report, beyond that you would like to help move at either a state, potentially for some hospitals a state level and also a regional level to much greater capacities for rapidly sequencing pathogens. In the antibiotic resistance report we talked about that with respect to antibiotic resistance. One needs to think about moving to that kind of greater capacity across the board, not just for antibiotic resistance, but for viruses as well as for bacteria. There is a great amount of work to be done there and there is always a budget challenge.

>> WANDA AUSTIN: One more thought is we've talked about the challenges with respect to biotechnologies, but there are opportunities, as well. In the sense that this new biotechnology can enable us to be much more effective in coming up with medical countermeasures on a much more responsive timeframe. I think we also need to make sure that we're looking at that side of the coin, if you will, that there are some advantages that can be achieved here. We had some great discussions with CDC and DOD also about how we protect our military as they go out, you know, to

points far and beyond and be prepared to be responsive to things that they may get exposed to and then develop countermeasures on a very quick timeline. So lots of opportunities here I think for improving public health, for leveraging the technology that is clearly available to us. And being smart about, you know, how these things might be used in unintended ways and be able to respond to that, as well.

>> JOHN HOLDREN: "I have one more question. And it may be that this is as much for Eric Lander as for the co-chairs, but it struck me when Chris, when you mentioned the possibility that people playing with these technologies for malicious purposes might screw up and be less effective in what they were trying to do than they intended.

But the other side of the screw up is the accident question. And if you think of all the sources from which dangerous bugs could emerge. You've got nations with VW programs. You've got potentially terrorists with malicious intent, fooling with bioweapons. You have legitimate and qualified researchers in academic institutions or research institutions who nonetheless might make a mistake which leads something to get out. And then you have what I would call 'amateur researchers' where you have some of these technologies are becoming so widespread that high school students are playing with them. What are the odds that somebody in the amateur researcher category without the level of oversight and control that accompanies major research institutions would end up doing something really dangerous? Is it easy or hard to do something really dangerous by mistake and let it out? And what role does that class of threat play in the overall constellation? And are there things we could do about it? Are there ways to think about the blundering amateur problem that would enable us to reduce it?

>> ERIC LANDER: It's always great when your co-chair springs on you.

(Laughter).

A question of vast scope! Unprepared. And asks for a probability estimate attached to the answer.

(Laughter).

So I'm going to respond with that as a disclaimer in advance. It's very hard to put probabilities on things and it's important to recognize that creating a good pathogen is hard. Nature puts a lot of work into creating great pathogens. They have to replicate, but not too fast. They have to spread. They can't, you know, harm the host too much. They've got to deal with the immune system. So, you know, the idea that a high school student will create the andromeda strain from scratch is pretty low, because scratch is usually not the place where you can solve all those problems. Could you take an actually dangerous agent and make it worse? Take something that solved most of the problems and make it worse? It's probably more likely to be the case.

You might not want to call that a blunder. There might need to be some intention in doing that. I got to say, I'm very much committed to our direction of taking this very seriously because bio is different. I think the chance that a high school student is going to do this in the next year or two or three is exceedingly low. I think what is most important about the study we're undertaking is that it's a rapidly moving problem, that the more we understand the more things could be undertaken. And for what it's worth, I think we need to practice a defense. And the best place to practice it

defense is on emerging infectious disease. So I would say if I were going to attach my, again I'm oversimplifying because it is a huge question you've asked, but if I were to ask what is the best long term solution to the biosecurity problem, it would be extraordinarily good to be able to defeat any naturally occurring infectious disease, because they tend to be incredibly clever. They've worked out all kinds of solutions. We take too long to do that today. So I think there's a great commonality of interest between the public health community and the biosecurity community around why for example do we still have fevers of unknown origin out there where it's very likely there is a virus or bacterial agent involved and haven't characterized it. We ought to know all of those and we ought to consider that aspect of public health to be a twofer together with biosecurity. We ought to be able to program solutions to a new virus rapidly, rather than two or three years to make a vaccine. Nobodies doing anything wrong today, that is what it takes to do such a thing but there is no reason it has to take that in the future. There are tools that could be more generic.

So I think the recognition from the work that Wanda and Chris have led here is a recognition that is going to say to us that security is security against natural and potentially malicious threats. And that the muscles that we have to exercise to get good at defending ourselves are largely the same muscles. So yes, I don't want to rule out the possibility that something could just go wrong and be disastrous, because it only takes one pandemic to ruin your whole decade and so such things happen. But if I'm trying to allocate probability it's much less to the kitchen experimenter and much more to really trying to understand how we can defend against all of those agents and get a general set of tools. So I don't know. That's all you get for asking such a big question.

>> JOHN HOLDREN: That's good. I think with that we will call this conversation to a close. We are scheduled to have a coffee break until 11 o'clock. So let us resume here in about 12 minutes.

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>> ERIC LANDER: All right! We are going to turn to a topic that is of great interest to PCAST: Hearing. And accessible and affordable hearing health. It's a topic where PCAST itself is focused on this as part of our larger topic on aging and technology, where in the course of a larger study we bit off a particular focus and produce add letter report on this. At the same time, the National Academies had a study going on, which was reported out since then. We are very eager to hear the results of that report. Spoiler alert, we have read it. But we're very eager to talk about the results of that report. And to chair this session, I'm going to turn to Chris Castle, who played a central role in leading PCAST's own hearing effort. And we'll have an opportunity for both sides to hear from each other. Chris?

>> CHRISTINE CASSEL: Thank you, Eric. And I think we are very excited to hear this report here in the National Academy building. And not only have we read your report, but I would say we have marked up the margins and we even have sort of a cheat sheet of side-by-side comparisons of the recommendations. So we've read it very carefully. And I want to congratulate the committee for the thoroughness of the work that you did and also thank you for the interactions that we had over the course of that time.

As you know, the PCAST report released last fall was very focused on this issue of technology solutions and the issue of mild to moderate hearing loss, age-associated hearing loss, rather than other kinds of pathologies. So we had a much narrower scope than what you did. And so I think your report will really set in motion lots of needed changes on a much broader front. So congratulations for that.

So I'm just going to turn this over to the panel and ask each of them to give their piece of this report and then open it up for comments from PCAST. We're very lucky today to have the three people who are presenting here. Dan Blazer is a Professor Emeritus of Psychiatry at Duke University and has been a leader in the field of gerontology and gerontological sciences, and who I've known and admired throughout my career. And who is also a very skilled and experienced Chair for National Academy reports. He chaired this report, as well.

He is joined by Frank Lin, who is an associate professor of otolaryngology and geriatric medicine, and mental health and epidemiology at Johns Hopkins University. And I think you'll hear from Dr. Lin's presentation and how he weaves all those different and complex sciences together.

And Brenda Battat, who is currently an independent consultant, but formerly Executive Director of the Hearing Loss Association of America, who is the major consumer organization of people and families concerned about hearing loss. So with that, Dan, I'll turn it over to you to get it started.

>> DAN BLAZER: Thank you, Chris, for your introduction. And thank you for inviting us here. I think it's very important for us to communicate with one another.

I just want to note that I will give the main presentation in terms of just what's in the report. But I have a kind of unique position on this report. I'm totally ignorant of the topic. And so that's why I was chosen to be the chair, because I'm unbiased. And therefore I will begin to turn things over to Frank and Brenda very quickly after I finish my part of the report.

These are the members of the committee. I'm not going to read these names obviously. All of them are experts except me. And we covered the range of individuals that I think such a report requires.

These are the sponsors of the report and we always are very fortunate with the National Academy to have when we have, when we are able to have a wide variety of sponsors including advocacy groups, National Institutes of Health, and other groups, the FDA et cetera. This was extremely important and they all contributed to making this report possible.

This is our abbreviated statement of tasks. I'm not going to read through this in detail, except to make the clear point, and Chris has already made this, and I don't want to emphasize it again, that our task was much broader than simply looking at the technologies.

And technologies are central to hearing healthcare obviously and deserve great attention. But it's not the only factors that are related in this area. So we want to be sure that you note that our recommendations and the focus of our report cover a much broader range by definition in terms of the task that it was set out to do.

Overview of hearing loss. I don't need to go over this. You have heard this before, and you've been talking about this. One thing I want to focus on, though, is the second bullet here. And that is an area we don't know much about, is the health consequence after hearing health loss over time especially in older persons. So we wonder is hearing loss is just something that happens to you with aging or is it something that in fact can lead to significant medical outcomes that we need to be paying attention to? Is it a significant risk factor in other words, and Frank is someone who has done considerable work in that area. I want to emphasize that area of our overview. You don't need to see these slides that the increased frequency of hearing loss. Why focus on it now? The changing demographics. Hearing loss is more frequent in older persons, and we have the aging tsunami upon us. It's almost becoming a trite term, recognizing that hearing loss as a public health priority and social responsibility. This is not something that individuals need to deal with on their own. We see this as a societal responsibility that we all need to be involved in, whether we hear well or we don't, we need to be involved in this. Rapidly-changing technologies. A term that was used

over and over in our committees was disruptive technologies. And the fact that we have significant changes occurring even as we speak in terms of hearing paradigms.

We use a socio-ecological model. I am not going to go into these models in any depth. Each of these areas, individual and personal, organizational community and public policy, we had something to say to every one of these.

Now some guidelines. Again, I'm not going to emphasize these in detail. But I do want to emphasize the fact that we really wanted to empower individuals who had hearing loss. We're not talking about the deaf from birth. We focused more on those who lose their hearing primarily during the adult years, but that's not exclusively the case. I have already mentioned the public health concerns. A very central focus of our report was on equity and transparency. We recognize that hearing loss can have a range of solutions. The number of things that can be done is not just technological, but they involve many other areas. We want to improve outcomes with hearing quality and safety. And working for an integrative approach that provides options. This focuses back on the individual being able to have a choice.

Definitions, I'm not going to read through these in depth. I think these slides will be available if people want them and certainly parts will be available. But what I do want to emphasize here is when we talk about hearing healthcare professionals, we are talking about in our report otolaryngologists, audiologists, and hearing instrument specialists, all three. We did not try to make the distinction. These individuals often may be in some conflict, but they are working in the same area. So our recommendations in general apply to all of them. Keep that in mind.

Our findings, this is not going to be surprising to you given your PCAST report, but hearing can be vital to communication. I'll come back to that a little bit later, but also health function. It involves a wide range of services and technologies and is a public health concern. So this idea of a societal problem permeates our report.

Now this is an overview of the recommendations. I'm not going to go through this because I'm going to spend time on the recommendations themselves. This is recommendation one. We have a goal and then a recommendation. As you know, National Academy recommendations must have an actor and must have an action. The actors are long and I'm not going to read them out. You I think have a copy of those available to you. I'm going to read the actions and I'm just going to make a comment or two about each one of these actions. We have 12 recommendations, so I'm not going to overburden you with these.

So the first action, the goal is to improve population-based information. And the action is to strengthen efforts to collect, analyze, and disseminate perspective population-based data on hearing loss in adults and effects of hearing loss and its treatment on patient outcomes.

I'm an epidemiologist and I was surprised at the paucity of data that was available for a problem that is so widespread as hearing loss in the United States.

Goal number two, develop and promote measures to assess and improve quality of service healthcare of hearing health services and develop and align best practices and core competencies across the continuum of healthcare and to implement mechanisms to ensure widespread adherence. This is a fragmented area where practices range not only in type, but in quality dramatically. We feel there needs to be focus placed on bringing practices up to standards and having core competence be central to what is done.

Second bullet. Research, develop and implement a set of quality metrics and measures to evaluate hearing healthcare services with the end goal of improving hearing and communications at patient outcomes.

The point I would make here is when you talk about hearing loss, one individual may be talking about one thing and another may be talking about another. And I'm not just talking about consumers. I'm not talking about providers. Because the way they measure it is different. Levels at which they consider hearing loss to be important may differ. Terms mild, moderate, and severe are used, and yet there are no clear demarcations across those different areas. So there needs to be more standardization.

Recommendation three, and this goes specifically to the FDA. Remove the regulation that an adult seeking hearing aids first be required to have a medical evaluation or sign a waiver of that evaluation and to ensure that consumers receive information about the medical conditions that cause hearing loss and through continued inclusion of that information in hearing user instruction brochures.

Right now if you go to COSTCO or if you go to an audiologist to have your hearing tested, you have to sign a waiver stating that you realize that you should have quote gone to a physician first, but you are signing this waiver saying that you have not. You are in turn informed about red flag conditions that could interfere with hearing that would require attention of a physician. It turns out the majority of individuals, it's hard to pin down the exact percentage. But the vast majority of individuals it could be, do not go seek medical care first when they have hearing loss. They may go to an audiologist or hearing instrument specialist first, and they sign the waiver. We felt that that waiver was redundant.

Goal four, empower consumers and patients in use of hearing healthcare. Ensure that patients are aware of and understand how to exercise their access to information about themselves under HIPAA, including their audiograms and their hearing and programming history. Right now, they do not get the information in many cases. And then if their provider leaves the area and they go to a new provider, they have to start the program all over again. We feel that this is information that should be available and could be taken by the individual from one provider to another.

Goal five, improve access to hearing healthcare for underserved and vulnerable populations. Collaborate and partner with hearing healthcare providers to ensure hearing healthcare accessibility throughout rural and underserved areas using mechanisms such as telehealth and outreach centers, including federally qualified community health centers, and community health workers. Support and promote programs including incentives such as tuition assistance, to increase diversity in all sectors of the hearing healthcare workforce, and promote training of cultural competency in the hearing healthcare workforce and incentivize practices in underserved communities. Okay, the facts are the following. There are not that many hearing healthcare providers. They're located in urban areas almost predominantly. And they're almost all white. And so in an area where you need to be able to communicate adequately, we need to improve dramatically in this area in terms of both geographic diversity and racial/ethnic diversity, etc. We saw this as a big need.

Goal six. Promote hearing healthcare visits, as well as medical visits. As you know, under the Affordable Care Act, there is a Medicare annual wellness visit. Right now the requirements for that visit do not include any check of hearing healthcare. It doesn't take much to ask a simple question, how is your hearing? Do you have trouble hearing in restaurants or noisy places? If you go to your place of worship, do they have accommodations for you if you are having difficulty hearing? That takes about 30 seconds to ask that question. And an answer can come in an equal period of time.

A physician's office at the present time is probably the absolute worst place to check hearing because it's quiet. It's communication between two people. And people who have hearing loss can read lips. And so you put all that together. And physicians just miss hearing health hearing loss. We feel like, even though this is not a requirement, we feel that this is something that needs to be brought up, if given more attention. (Phone ringing) I heard that.

(Laughter).

Implement a new PDA device category for over the counter wearable hearing devices. This is the recommendation that coordinates most clearly with PCAST's recommendation for over-the-counter devices. Ours is a little different. My expert Frank can explain that a bit more. We wanted to establish a new category of over the counter wearable hearing devices. This would be separate from hearing aids. Over the counter wearable hearing devices would be defined as wearable OTC devices that could assist adults with mild to moderate hearing loss. Now we want to keep the FDA involved for one simple reason. That is we want to ensure that these instruments are used are safe. We would like to build in some safety. But we do not want the regulation to be such that they jack up the cost and the accessibility of these devices to where we see hearing aids at the present time. So we very much are in concert regarding the need for over the counter devices.

Goal eight. Improve the compatibility ask interoperability of hearing technologies with the communications systems, and the transparency of hearing aid programming. Develop standards to ensure that hearing aids and over-the-counter wearable hearing devices are compatible and inter-operative with other technologies and communications systems.

Increase public awareness and consumer friendly information on the availability, connectivity and use of hearing aids and hearing assistance technologies and develop and implement standards for open platform approach that allow any hearing health professional or as evolving technology allows, allow device owner to program the device settings and prior point of service information about the programming features and programming portability of hearing aids in order to enable more informed purchasing decisions.

This is an example. I expect two-thirds of you around this table have similar examples. You have an older relative. That relative has a hearing aid. That relative is on a fixed income and does not have a lot of money to spend. The provider of that hearing aid leaves the area. A new provider moves in, working for a different company.

And the provider working for the new company says I can't do anything about your hearing aid, it comes from another company. That is a problem.

And what it means is that the only option you have is to get your hearing aid up to the standard where it is usable again, is to buy a new one, and those expenses are very great.

This is just expanding the types of hearing-related technologies and interoperability between communication systems. This includes medical devices, consumer electronics, not intended for hearing, such PSAPs, and hearing assistive products and technologies, and communication technologies such as captioning, which we're using today. Interoperability technologies and emergency information technologies.

We are making progress in this area, but we're still far beyond and Brenda can certainly speak to that.

Goal nine, improve affordability of hearing healthcare professionals should improve transparency in their fee structure. Talking about unbundling here. The prices of technologies and related professional services to enable consumers to make more informed decisions. CMS should evaluate options, including possible

statutory or regulatory changes to provide coverage so the treatment of hearing loss is affordable for Medicare beneficiaries. And more specifically, and we know this is a reach, CMS should examine pathways for enhancing access for and pathways and assessments for delivery of auditory rehabilitation services for Medicare beneficiaries, including reimbursements of audiologists for these services. Right now audiologists are only reimbursed for doing an assessment. Services that would enable an individual to hear better and communicate better are not reimbursed even if referred by a physician. We feel that needs to change.

Goal nine, improved affordability. Appearing healthcare continued. Evaluate options for providing coverage and treating hearing loss into adulthood for children who are now currently covered. The point here is that individuals in many states age 18, it may be age 21, who have been covered by Medicaid, whether there are hearing assistive devices, such as a hearing aid, all of a sudden that coverage is cut off.

And they're not at a position at that point where they can independently support that. And therefore they're in danger of not being able to use their hearing aids into the future. Voc rehab agencies should raise awareness about their services that would enable adults to participate in the workforce. In other words, that is a resource that we is available that we feel to be definitely underused. Hearing healthcare professionals and professional associations should increase their awareness and understanding of vocational rehabilitation programs where they feel it is appropriate. Again, making the connection. We have a disintegrated system now and that needs to be more integrated. Employers, private health insurance plans, and Medicare advantage plans should evaluate options for providing their beneficiaries affordable hearing healthcare insurance coverage. We know this one is a reach. Medicare has many demands upon their resources and those resources are finite. But we feel that it needs to be looked at because we are just learning some of the significant adverse consequences that can occur from hearing loss in adults.

Goal ten, evaluate and implement innovative models of hearing healthcare to improve access, quality, and affordability. We want to prioritize and fund demonstration projects and studies including randomized control trials to improve the evidence base for current and innovative payment delivery methods for treating healthcare. Just like we have a posit of data in the area of hearing healthcare over time and its consequences and antecedents, we have a significant posse of information of how to fund these programs and what would work best in terms of funding. The absence of that is significant.

Goal 11. Improve publicly-available information on hearing healthcare, improve public information on hearing health and hearing related technologies and services and promote public awareness and improve information about hearing healthcare. So my example here is I don't know how your newspapers are. When I open up my paper, there will be on average 2-3 full-page ads regarding some potential hearing instrument product. Now compare that with how many stories there are in the newspaper regarding hearing loss and hearing healthcare. It is really hard to find one.

PCAST coming in this year and our report coming in, we have probably half the publicity on hearing healthcare that has come out recently. (Laughing) That's the issue here.

Goal 12. Promote individual employer, private sector and community-based actions to support and manage hearing health, and effective communication. The bottom line here, and I'm not going to read through this, is basically again emphasize the fact that this is a public health problem. We're not just talking about public health in the sense of what public health agencies deal with. Families, communities, organizations of various types all need to be involved and recognize that this is a societal-wide issue and it needs to be addressed.

We thank you for your attention. I'm going to turn it over to Frank and Brenda for any comments. And then we'll take questions. This is where you can get the report. You already have the report. You earmarked it. I'm wondering what you did at night.

>>CHRISTINE CASSEL: Well this is a public session, Dan, so it's good for people to know that they can get this report.

>>FRANK LIN: I would like to comment again and thank everyone at PCAST for approaching this issue. I think for the last 40 years, there's been very little movement, if any at all on this issue. And I think clearly there has been a tremendous grassroots effort that has not led to any changes, and there's fundamental regulatory forces in place here that are subject to inertia. But with PCAST and the National Academies now, just literally within the last year, I think Brenda would agree, we've seen more movement on this issue than essentially in the last 50 years of U.S. history. It's mainly a thank you to all of you who have been involved and actively engaged in this issue.

Mainly because there's a lot of low-hanging fruit here to make a tremendous difference for many people's lives, quite simply, at the benefit of public health.

>>BRENDA BATTAT: I second that. I spent most of my career trying to implement many of the things that you and the Institute of Medicine report are talking about. Hearing loss, for years, it's underappreciated. It's not valued. It's not seen as a real problem. Actually even by the individuals themselves often don't see it as a real problem. And we still have, you know, the stigma to deal with, and that's going to be an underlying theme when we try to implement a lot of these things that we want.

But I have to say this. The organization that I was with for 25 years would not have existed if the system was working well. We wouldn't have needed it. But people came to our organization because they weren't getting the help they needed professionally. They were not being told of the basic things that would help them. They didn't have access to the devices that they needed. The number one inquiry that we got to our office was "I've just been told I have a hearing loss, but I can't afford a hearing aid, so what should I do?" So it's extremely frustrating to us. We were not able to get any movement on this issue. So I'm so delighted that you saw hearing as part of your technology for independence as being a key issue and we are all together hopefully able to move this forward. So thank you, also.

>>CHRISTINE CASSEL: All right. Well I would just encourage members of PCAST who have questions, as you can see this is our practice. Just like yours, I think. You put your name tag on the end. So Ed, you got the first one.

>>EDWARD PENHOET: Well, first of all thank you for the exhaustive work that you've done on this subject. I think it's a landmark in the entire field of hearing. So thank you to you and the rest of the committee.

Frank, you're recognized as an authority on the link between cognition and hearing. Would you take a few minutes to describe your work and the state of that field for us and where you see it going? Where you see the needs are for the research in that area?

>> FRANK LIN: Thanks, Ed. I think the big picture here is that hearing loss, as Dan showed before, is very much for almost all of us a natural, usual process of aging. Two-thirds of people over 70 have a meaningful hearing impairment. For decades people thought it was natural hence it is a natural part of aging and hence it must be inconsequential. When we began studies five or so years ago, it was just based on an inference, it was not based on evidence. We started bread and butter epidemiology just like we link smoking to lung

cancer. The bread and butter epidemiological methods we use to look at associations and whether they're meaningful or not. And increasingly over the last 5-10 years now, we've been studying this, we've seen some incredibly strong links between hearing and cognitive decline and dementia. The reason we're seeing this is likely through some type of common cause, namely is it aging, or cardiovascular disease, likely through some direct mechanistic paths, it makes hearing loss so interesting. When we have hearing loss, it basically means, and we see some functioning imaging, basically means the brain literally has to expend quote and quote more resources and more energy to dealing with that hearing loss, to expend more energy to dealing with that auditory sound. And that likely comes at a consequence of high order cognitive and memory systems.

At the same time in other studies, we are also seeing that hearing mainly from auditory deprivation, reduced stimulation of cortical areas of the brain and interesting rates of brain atrophy with people with hearing loss, even mild to moderate hearing loss and much faster rates of atrophy. And likewise we're also seeing that hearing loss for a subset of people can lead to a loss of social engagement. You may not go out as much as you used to and if you do, you're less likely to be engaged. All of those pathways, cognitive load, changes in terms of the brain, and social engagement problems have all been directly linked with more serious downstream consequences, mainly things like cognitive decline and dementia.

The reason why those mechanisms are interesting is as we think about our current therapeutics for hearing loss, getting well fit for hearing aids, and communicating properly, there is every reason to think that those existing interventions where there is essentially no risk, could only possibly have a benefit. We don't know how much of a benefit yet. We're awaiting a clinical trial right now which is being reviewed by the NIH, to see whether or not if we treat hearing loss can we delay the onset of dementia? There's every reason to think that there would be a benefit. I say that not only from a scientific perspective, but also from my perspective as a clinician. When I see my patients and my own family members who have had their hearing loss addressed, it's very dramatic sometimes, the trajectory that they appear to be on from that point on.

Cognitive decline and dementia is one of the biggest concerns one of concern in the United States right now. But beyond that, we're seeing strong links between hearing loss and the issues of falls, even hospitalization rates. It comes down to issues of cognitive load, and the ability to communicate effectively. But again, the reason why we think this is very critical from a locale standpoint is because hearing loss is so common and the therapeutics that we have right now which are existing that are no risk and that are underutilized can only exert a positive benefit.

>> BRENDA BATTAT: To follow up on that point. And that is that there is another aspect to this. And that is that many people in nursing homes who actually have a hearing loss but are thought to have dementia because of untreated hearing loss. And so they will often not have hearing aids and nobody will recognize the problem and they're being treated as if they had dementia, whereas if they would actually take a look at their hearing and treat it, they suddenly become more engaged and be able to participate in the everyday life of the nursing home. So that's another side of it that I think is important to recognize.

>>CHRISTINE CASSEL: Good, thank you. Bill Press?

>>WILLIAM PRESS: Thanks. So let me add my thanks to you and the rest of your panel for a really wonderful report. When I read it, I was struck by the quality of the argumentation and the scholarly treatment that was brought to bear on it, and I wished PCAST had done the report and you could go on and do the second scholarly report on that.

I want to ask a question, which may be a deep dive, maybe a medium dive into the question of PSAPs, personal sound amplification devices. I thought it was striking that PCAST and the Institute of Medicine were virtually and completely aligned on the question of OTC hearing aids, but when we went to this other category of devices, I had a hard time figuring out if we were aligned or not. I wanted to ask about that.

Just to review, I think we and you agreed that the current situation, the 2013 FDA draft guidance is not a reasonable stopping point. Something needs to be changed in that. PCAST suggested simply going back to the existing, technically still enforced 2009 guidelines. You suggested either doing that or changing the 2013 guidelines. But I was a little unclear about what changes you were going to ask for. And then maybe illuminating that.

PCAST thought that PSAPs should be quite broadly defined as devices not just for amplifications, but devices that could augment, improve, or extend a sense of hearing in individuals, not excluding individuals who have mild to moderate hearing loss in the way that certainly the 2013 FDA guidance would strive to do.

Now it's a hard needle to thread. I think you and we are agreed that PSAPs should not be marketed for mild to moderate hearing loss. The question is just to what extent you or we would like the FDA to allow PSAPs manufacturers to simply give objective statements on what their devices do without recommending them for any specific medical condition.

Can you help me understand where there is light between us on that?

>>FRANK LIN: Bill that is a great question. It is one we have discussed at length as you can imagine. I think we are in full agreement that among, for current PSAPs right now, the issue, why it's sort of a wild, wild west, is because the way the FDA regulates its devices is it doesn't matter what the device does but it says it's purely how you label it. With the development of an over the counter classification, it could be called a hearing device, or an over the counter hearing aid. It would allow for over the counter marketplace that could be created for devices that are specifically designed to address hearing impairment. With regard to PSAPs, basically devices that are not explicitly used to treat hearing loss, we agree that the 2009 and the revised 2013 design should be applicable. Mainly that they should be able to say these devices could be used for music purposes or could amplify sounds, but specifically should not be said that they could treat hearing loss. I think the big difference is that the language there would specifically say it's not specific for treating hearing loss. And I think there are some nuances there in terms of which terms and phrases you can use, which is what the 2013 document was getting at. Which is why we would not endorse that. There needs to be either further revision, or the adoption of the 2013 guidelines, which are more loosely worded allowing for more leeway.

>> CHRISTINE CASSEL: Maxine.

>>MAXINE SAVITZ: I want to thank you for your panel for your very good study and complimentary. I noticed you had a broad group of sponsors, which is useful on a study like this. I wonder what has been the reaction as you out briefed them of the report, and also some who weren't sponsors who were mentioned to do action, and Brenda's comment about implementation. The academy often will do a very good job of briefing the report when it's done. What happens on the follow-up six months from now or a year from now to see what has happened? Are there any plans to have an ongoing implementation track?

>> DAN BLAZER: I'm going to answer that in two phases. Number one, I think the academies overall are very much interested in taking a step beyond what we've done in the past, which is basically write a report and then go do something else. There really is a sense that dissemination is very important. We have a number of dissemination products. Kathy over here and Sarah, they were the study directors for this

project. They've been working diligently since this report came out in providing and trying to get individuals together to do things. So this is an academy-wide approach, which was actually just discussed just fairly extensively at the council meeting this past Monday. I was there as a head of the one the boards.

But I think in this particular case there are two things. We've got organizations that to some extent have been at odds with one another over many, many years as best I can tell. I was very pleased I think on balance we got positive feedback from certainly major segments of every one of the organizations, which said that our report, which was not just a vanilla report. We had some very specific recommendations. There certainly are concerns expressed by some individuals. And maybe if they read the report more in depth, there will be more concerns, about where this takes us. But at the present time, I think what we're seeing are two things. Number one, we're seeing that this report has legs. It's moving. There's action that's being taken place. There are discussions that are ongoing. And so that's number one. I think number two is that, and I think Frank alluded to this very importantly. This is sort of like the first big boost that hearing healthcare has received in a very long period of time. So I think each of the groups that supported this report recognize that and recognize that now is the time to strike. If we wait a year or two or three years, we kind of lose the momentum that we have.

So getting this out to the public is extremely important. And so I think we're specifically related to this report, I think we've done a lot in terms of implementation already. And I think we have plans to do more in the future. Kathy sent me an e-mail this morning, can you come to this meeting, can you come to that meeting. So there are things that are happening.

But overall I think that the academies recognize that we've got to become more of an advocacy organization for the empirical findings that we have. We cannot just sit and expect these reports to have a life of their own if we don't do something to promote them.

>> CHRISTINE CASSEL: We look forward to watching that unfold. And Craig, I see your flag up.

>> CRAIG MUNDIE: To varying degrees, both your report and the PCAST reports focused on technological change. In your summary, you didn't comment that much about it. You know, my view is that -- and I think we found doing the PCAST work, there are many organizations, businesses that aren't classically in the business of hearing aids who have access to a lot of technology that comes out of other, you know, applications today. That appears directly applicable. If you think of this less as trying to compensate in classical terms for the loss of hearing, and try to produce and improve functional ability to hear. And you can think of those as quite different. And it doesn't seem that there is enough combination I'll say of research and market access to really draw these people in to providing disruptive technologies. And the incumbent, you know, manufacturers don't seem all that inclined, or maybe don't even have access to some of these technologies. Very low-power radios. You know, everybody is comparing a computer around in their pocket that is very powerful, equipped with microphones and other things.

What do you see? And what do you think should be done to encourage the emergence of totally different approaches to this problem based on off-the-shelf available technologies.

>> DAN BLAZER: I'll make a brief comment and then turn it over to Frank. We discussed at some length the role of disruptive technologies and a fair amount of that is in the report. The problem with disruptive technologies is we don't know where they're going to go right now. We can't predict. So our ability to say we feel like the field will be here in five years was greatly limited. We do feel, and I hope we reflected that in the report, that this is going to be a very different environment from a technological perspective five years from now. So that we very much put emphasis on.

>>FRANK LIN: I think that's a key question. And something as Dan mentioned we discussed at length. I think the whole issue of disruptive technology here, one of the big things that we felt as the committee was holding things up, essentially was the current regulations. Mainly on two different fronts. One is the with the current regulation at the state level where any type of device that is quote unquote marketed for hearing loss can only be sold through an audiologist or hearing dispenser. It essentially limits the marketplace for the big six right now when they design devices. The devices perversely are not designed for the end user, but are designed for the customer who is the audiologist. It perverts how these devices are designed from the get go. On top of that, the current ambiguity with the regulations as to how PSAPs can be marketed, designed, labeled, as well as the state-level requirements for where things can be sold related to hearing loss, I think it adds enough ambiguity to the marketplace that you essentially don't have the larger consumer electronic companies willing to invest in it, because essentially you have to battle it state by state whether or not you can put it on the shelf and which words can be used. And I think if you have that ambiguity, and at the same time, there is a consumer demand, yet they don't even know what these devices are called. It hinders the development of the marketplace for this.

So we were, there is no question that our recommendation seven, asking for the FDA to be regulated is very much along with PCAST. We see this as a major impetus. If you clarify the regulations, it essentially allows for the natural pace of technology to take place. There is no doubt now with the whole idea of augmented reality with Google glass, and now the issue of hearable devices. There are many, many talks about the potential for hearable devices to allow us to be able to communicate more effectively and to communicate in a theater regardless of whether you have hearing loss or not. Clearly, one of the main things hindering that is the current regulatory structure, which provides enough ambiguity that people don't want to move into the marketplace.

>>CRAIG MUNDIE: And do you think we should collectively do something more, not just hope that regulation relaxation should improve this? But should we point in some ways to different research programs that talk about the use of these technologies and show in clinical terms that there is more than one way to skin the cat or improving your ability to function in these environments?

>> FRANK LIN: I think that's a great question. From the research public health scientific standpoint now, these studies aren't done. And the reason for that is because the people who would be typically interested in hearing loss are people like audiologists or otologists, like me for example. When we do research, or a lot of my colleagues do research, is part of the same old/same old, that they are not bridging to the next gap or to the next frontier, and I think that could be addressed essentially through funding programs and the NIH to encourage those type of programs. But there's been a gap in the literature. If there's a dearth expertise, people could bridge those areas. Thanks.

>>CHRISTINE CASSEL: I know we have a public comment period. But can I ask one more question of Brenda before we wrap up? Oh Ok, thank you.

Okay, thank you. I'm glad Craig you asked that question. Because I think that idea of innovation was a big one, and I was interest that most academy reports start by saying we need more research to improve this. And the research that you're calling for is the epidemiology research and to understand the effects of the condition, and kind of this sense that the marketplace itself, once it's opened up, will take the place of innovation. And you know, that's a reasonable hypothesis, but there may be another need.

I want to shift gears, though, Brenda, and ask you this question. Our report and your report and every, you know, discussion of this topic always talks about the stigma. And we heard yesterday from V.A. Now V.A.

pays for all the services associated with hearing loss, and yet they don't believe that every veteran with hearing loss comes for help. We heard you heard in your open sessions from people from European countries that cover these services completely and they don't have 100% uptake, and particularly early on when if you listen to Frank talk, that it would be really important early on with mild hearing loss to get help so that you don't have these declines that happen.

So I'm just curious about the stigma part of it. And what you think can and should be done about that.

>> DAN BLAZER: I'll comment briefly, but I'll turn it over to Brenda who is much more of an expert. I think from my perspective you cannot uncouple the issue of stigma from the need for public education. That was a very strong and central part of our report. In a couple of areas. Number one, just for the public at large to have a better understanding of hearing loss and the problem that it is. And we were in geriatrics. There was no Alzheimer's disease as we know it before about 1977. That was a relatively long time. But there was an example where what was considered to be a normal part of aging became a disease and then everybody became aware of it. But nothing in terms of the actual disease itself has actually changed that dramatically over that period of time.

So I think hearing loss may be at that kind of early stage in terms of where it is in terms of being recognized for what it is and what perhaps can be done. Not everyone suffers from hearing loss, and so therefore we have to consider that.

There's another area that I think relates to stigma. And it's not the stigma of hearing loss itself, but it's the stigma of the hearing aid, all of the horror stories that people tell about the difficulties they have in using hearing aids, et cetera, that I think probably contributes to the stigma, as well.

I became -- and I think all of us to some extent may be kind of guilty of that. I tell a brief story, and I'll tell it to you briefly, too. I have a very close friend at another university, and I was at a meeting with him. And I noticed he was wearing a hearing aid. I jumped. I was shocked the fact that he had the hearing aid on. And I was right in the middle of this report. I said why did I jump? Why did that shock me? And I think we've got to recognize that there is a stigma around the devices themselves. Now I think we're overcoming that to some extent because people are wearing all sorts of things in their ears now. It's not just earrings. I'll turn it over to Brenda to make some comments, also.

>> BRENDA BATTAT: Yeah, this is a really important question. As Dan said, stigma is really coming out of the closet. But it's still there particularly in the workplace, particularly for teenagers in school and college. You know who wants to say that they have to wear a hearing aid or they have a hearing loss? And I think the reason for it is that you can bluff. You can get by if your hearing loss is not that bad. You can bluff. So people don't really recognize. And they often will think that it's some other reason. That you're rather standoffish, or you're not with it or you're losing your marbles, and don't always necessarily think that it's something simple like something wrong with your ears, like hearing loss. I think education is important. I think we are seeing some changes. I mean I have people in my peer group now who half the time they're talking about hearing loss at cocktail parties. That never happened before. And they are also talking about how much they love their hearing aids. That never happened before.

I think it's also important to note that when you're in that early stage, you can get by. And sometimes you don't realize what you're missing. But when you get so you have very low uptake with somebody with mild to moderate hearing loss, but when you get into people with more severe hearing loss, you have 70% of people using hearing aids. There is nothing else you can do. You just have to do something. It's in those early stages where you really can kind of pretend. And the reason you want to pretend is because the fact

that it's a communication problem. And it's not just something that you do that will solve it. You are asking other people to do things to solve the problem. You have to ask them to speak more clearly, to face you, to turn the music down, to move to a quieter environment. Just because you have a hearing aid doesn't fix the problem, particularly in noise. So it's not like you have a solution and that's it. You have to ask other people to help you and that's what people find so difficult.

>>CHRISTINE CASSEL: I'm not seeing any other questions, John. I think I'll thank our panel and turn this over to you. So thanks to you. And on behalf of that amazing group of people who did this report, we really appreciate this and look forward to all of the impact that is likely to flow from it. Thank you.

[Applause]

>> JOHN HOLDREN: Well since we have no public comments on the agenda today, that brings our session to a close. As usual, I thank our panelists, the PCAST members, the supporting staff at OSTP, and all the members of the wider science and technology community who joined us for this meeting either in person or on the web. We look forward to seeing folks again at our next meeting, which will be in September. So again, thanks to all. We are adjourned.