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

>>JOHN HOLDREN: Welcome to the PCAST members, to the OSTP staff here, and the members of the wider science and technology and policy community who have joined us for this session and welcome to those watching the webcast. We have, as usual, a full schedule this morning, and in order to move smartly into it, I'm going to call on my Co-Chair, Dr. Eric Lander, to make a couple of opening remarks. Eric.

>>ERIC LANDER: Great. Let me add my welcome to John's, my thanks to everyone on the council working diligently on a large number of remaining projects. We're going to hear about one of them today for approval. We're going to hear a report about one that was recently publicly approved and has been made available. We'll have some other really important updates on aspects of nanotechnology and questions related to academic research. I wanted to particularly flag an activity that PCAST has begun. The PCAST has begun to explore how best to ensure the quality of forensic science based on reliable principals and methods in the criminal justice system. And PCAST is particularly interested in hearing from the broad community of experts and stakeholders in this area, and we have taken the step of posting six questions on our Website. And over the next 30 days we are inviting feedback from experts on these questions. Since we have a public meeting, I figured I would mention that to the many people watching on the web. You can find it on the White House.gov Website. The PCAST page, you can easily find by searching. The six questions there. And we thank people in advance for the input that you can provide. And with that, I think we'll dive right into our opening report. I'll toss it back to John.

Hearing and Technology: Public Airing of Report Findings and Recommendations; Context of Ongoing Project on Technologies to Help Aging Americans

>>JOHN HOLDREN: Good. So our first scheduled discussion is on hearing and technology. Public airing of the report findings and recommendations of an ongoing project on technologies to help aging Americans. And I'm going to call on Chris Cassel and Ed Penhoet to talk about that. And Chris, I think, will lead off. Chris.

>>CHRISTINE CASSEL: Thank you, John. First I just want to acknowledge that this is a report that PCAST has approved on an open telephone meeting. And so the report, as you mentioned, has been released and is available to the public and we have received a number of responses to it and made other presentations. This being the first in person PCAST meeting since that time, we wanted to present it more formally in this open public session for that purpose. So the first thing I want to point out is that

this report is the first of what will be a larger report on the topic more broadly of how technology can help people as they age to remain independent, remain productive, and improve their quality of life. There's a wide range of very available and promising new technologies that can help address a range of issues. And the issues that we're looking at in that report include social engagement, transportation, connectivity, mobility, cognitive impairment. And the ways in which various kinds of technologies can be helpful to sustaining quality of life. So stay tuned. You'll be hearing more from us on that. So I'm going to focus today's comments on our hearing report which as I said has been approved. And I mentioned it's part of this larger focus on aging and technology. One of the reasons we accelerated this focused report on hearing is that we recognize that it is a very focused issue where there are very specific kinds of technology issues. And we recognized a timely opportunity to comment and make recommendations about how changes in technology and federal policy could really accelerate improvement in both access and innovation in this area. We want to make very clear that we're looking at this very focused area. First of all, our remit is to look at that technology. We understand there is a broader hearing ecosystem and health system and that these are really important issues to address. We know that the Institute of Medicine is doing a larger report to address these issues. Our focus is the ways that technology can be enhanced and made more available. Secondly, we're looking, we're not looking at hearing problems for children, adults who have very severe hearing loss, and those with the kinds of red flag conditions that show underlying medical problems. So in this case we're looking at mild to moderate hearing loss, bilateral progressive related to aging. This is the working group, and I want to particularly acknowledge Ashley Predith, who is the Assistant Executive Director of PCAST who has really led the staff effort along with Diana Pankevich, and as always, Marjory Blumenthal. So this is the context. Hearing loss really is a major problem. A major public health and social problem for Americans. Roughly 30 million we think there's an underestimate of the number of people who have difficulty hearing. Because so few people who have hearing impairment actually seek help. Hearing loss is associated not only with inability to interact in social environments and with family members, but more broadly with social isolation, with depression, with inability to get around safely, falls, and even more recently studies have shown links with worsening dementia and other kinds of medical problems that just exacerbate the inability of older people to remain independent. And, of course, as our population lives longer, we're going to see more of this because much of it is related to aging. Something like half of the people over the age of 60 have hearing loss which really is an enormous number of people who could be helped if technology were more available as well as the broader range of services. And as we live longer this number will only increase. So in addition to the large numbers, this remarkable finding that only 15% to 30% of older adults with hearing loss use hearing aids. And so that's really the problem I want you to keep in mind and that we were focused on. So we asked ourselves, what are the barriers? Why do so few people seek help? The major barrier is far and away the major barrier, although not the only one, is cost. Hearing aids cost roughly, this is an average, so they're wide range, but roughly $2,400 per hearing aid. Most people, need one for each ear, so double that. And very few insurance companies cover this. Medicare does not cover this. Medicare does not cover it. So most people have to pay out of pocket. That is a major barrier. Unlike almost every other area of consumer electronics, innovation and progress in the field has not reduced

the cost, if anything it's increased it. So that one of the market problems that we wanted to address. It's also very difficult for consumers to shop for best value. We heard this from a lot of people. The whole system as to how you get access into the hearing health system is obscure and not very user friendly. Consumers are used to shopping around, going online, and finding out what's available. With hearing, it's much less clear what your first step is, and the current processes that are largely how it's handled are bundled so that the hearing health professionals are tied into specific companies. So people don't have the ability to really shop around and find the best value and try out all of the different options that are available on the market. In addition to this, each state has different regulations about this. So it becomes much more complicated and leads to even greater limitations on distribution and restrictions for online access. So added to this, or perhaps made worse by it, is the social stigma of hearing loss. Unlike eyeglasses, which are kind of considered even fashionable these days, but certainly widely socially acceptable, many people are embarrassed to have hearing aids. So they put it off going to get help. And as you wait longer, it actually becomes harder to get back to normal hearing. And so that makes it even more important to kind of try to address the fact that this is half of the people as we get older in the population who are going to need this help in order to remain engaged. And then finally, in part I think because of the lack of insurance coverage, hearing is not considered as part of the normal medical evaluation when you go to the doctor for a checkup. Most physicians are not knowledgeable about it. And it's not considered a chronic illness by the CDC or a disability in the surveys that are done about disability. The whole mind set in our society about hearing impairment we think leads to a kind of lack of awareness and lack of emphasis. It needs to be changed. So our scope is to look at technology solutions for this major public health problem. Not every aspect of the problem, but where are the technology parts that could really help to address some of these issues. And specifically, since we are advisers to the President and to the Administration, what are the actions that could be taken administratively that could accelerate improvement in access, innovation and outcome. So specifically not looking for legislative solutions, but really looking for executive or government actions that could be taken. So our conclusion is that this is a problem that's ripe for change. This is something where we think a few key federal actions right now could actually give momentum to changes that are needed in the environment. It's a place where new technology is advancing rapidly. And I want to just remind everyone that our focus here is on this very specific, but large, population of people with mild to moderate age related bilateral hearing loss, and only in adults. We also concluded, as I said at the beginning, that if this problem goes untreated and unaddressed, that it really is a great risk to the well-being of a large number of older people in our society. And while there is a risk of medical conditions that are being, might be missed by allowing more consumer access, and we're going to say more about this. Most of those conditions are relatively rare and the much greater risk of this huge number of people not getting help for their hearing problems is a much greater risk. So FDA and other federal agencies and every public health official knows the principle of having to weigh the risks and benefits of different federal actions and regulatory approaches. And we concluded that the risk of keeping the system the way it currently is just too great. And we also think because of the innovation that is occurring in the technology space, that now really is a perfect opportunity to increase access to better and cheaper technology for mild to moderate hearing loss.

And we used an analogy with reading glasses. And I'll say more about that, as a way of bringing more people into the hearing health system. Regulatory changes that were made about 20 years ago and how ophthalmologists and opticians do prescriptions for glasses, how people can get over the counter reading glasses, really inspired us to think about how this can apply this to hearing aids. I want to emphasize, particularly because of the some of the input we have gotten, that we do understand that it's not the same. And that hearing the technology that addresses hearing loss is not identical with the kind of refractive prescription that you get for glasses, or even the simple magnification that reading glasses allow. But we do think there are meaningful parallels. And so we believe that hearing technology could be made available in some of the same ways. Our goals for the recommendations are to reduce cost to consumers, increase the number of people who use this technology, and to stimulate innovation and technology development. We had four major recommendations. And these are small print, apologies for this. But I wanted to display the actual language of the recommendation and, of course, the reports are available. So you can go to the full report and read the background. The first recommendation is that the FDA should designate as a distinct category basic hearing aids; non-surgical air conduction hearing aids intended to address the kind of bilateral and gradual onset of mild to moderate age related hearing loss, and should adopt distinct rules for such devices. That these basic hearing aids should be available for over the counter sale without a requirement for consultation with a credentialed dispenser. FDA would still regulate these as they do as with any over the counter products and we believe should require a list of red flag conditions be listed there. And as you know, many retail dispensers now actually provide basic clinical services from a pharmacist or a nurse or nurse practitioner. And that those kinds of making this over the counter would not eliminate actually the opportunity for those kinds of basic medical evaluations to occur. We also recommended that FDA should exempt this class of hearing aids from the current quality systems regulation that they do for other over the counter products which are not electronic and are very different in the way they are manufactured. So this recommendation is that FDA should look not at eliminating oversight for the manufacturing of electronic devices, but should work with the electronics industry to come up with regulations that are appropriate for the kind of manufacturing processes that electronic devices involve. Recommendation number two is that the FDA should withdraw the draft guidance of November 7th, 2013, which addresses personal sound amplification products, PSAPs. PSAPs are currently regulated only as consumer electronics. They are amplification and sometimes even more sophisticated forms of hearing assistance that are available online and through other venues. There is a great deal of innovation going on in the PSAP area, but PSAPs are not allowed to call themselves hearing aids or be marketed or labeled as helpful for people who have hearing impairment. This particular guidance in 2013, which still remains a draft guidance and has not been formally approved by FDA, goes even farther though. And says that PSAP should not say that they can be helpful to people with normal hearing in difficult environments such as noisy restaurants, or a large lecture hall and places like that. We feel that that's actually very confusing for consumers. Because in fact these PSAPs can be very helpful in those kinds of settings, so that if FDA were simply to withdraw this guidance, it would allow the producers of PSAPs to make accurate claims about what their products could do. Recommendation number three, and this gets to the parallel that we felt was relevant with the

eyeglass rule. The Federal Trade Commission should require audiologists and hearing aid dispensers who perform standard diagnostic hearing tests and hearing aid fittings to provide the customer with a copy of their audiogram and the programmable audio profile for hearing aids at no extra cost, and a form that could be used by other dispensers and hearing aid vendors. Now, we do understand that the way the current prescriptions, if you want to think about it that way, are configured, actually doesn't allow this kind of interoperability between kind of manufacturers, and we think that would be a very important part of solving this problem. So that consumers truly were empowered to shop around, find the best value, and particularly if they move from one place to another, from one state to another, to be able to take that prescription, or profile, to a new vendor or a new audiologist. We also remarked, and this is variable in the United States, but there still are places where the availability of hearing tests and fittings are conditioned on a basic, if not a legal agreement, sort of understanding that the person has to purchase from that hearing aid professional. And that often dramatically limits their choices to devices from only one or two companies. Recommendation four is similar to the Federal Trade Commission contact lens rule which defines the process by which patients can authorize vendors either in state or out of state to obtain a copy of their hearing test results. So they don't have to carry it in their own hand or electronic form. But they can authorize another professional to get that information from the initial person. So we want to acknowledge that we do understand that FTC has the legal authority to be able to initiate new rules like this. But we also understand that it is usually the case that FTC acts in response to congressional requests. So here's a place where we would encourage Congress and constituent who agree with this to add that message to the FTC to move these ideas forward. So in summary, as I said, untreated hearing loss is a major health and social problem. Consumers have lots of difficulty accessing hearing technologies because of costs and because of the complexity of the system. And we actually find that unlike many problems, this is an area where just a very few federal actions could actually make great progress, open up the market, and allow for more innovation and lower the cost. So, John, let me stop there and see if Ed has any comments.

>>JOHN HOLDREN: All right. Let us open it up for questions and comments from the PCAST members following our usual procedure of raising your flag if you'd like to comment. And I see Bill Press as number one.

>>WILLIAM PRESS: Thanks, John. Chris, as you mentioned, we have had a lot of interesting responses from various organizations to this report. It's been out for a few weeks now. And I've noticed reading them that maybe predictably many of them align with the financial and professional interests of the groups that are responding. And it would, so, of course, much more interesting if there are responses that don't have that potential conflict that could be seen as more unbiased responses. And I wonder what your assessment is on whether we've received comments of that type.

>>CHRISTINE CASSEL: We have received lots of different responses. And I would, I think it's fair to say, most of them quite positive. And many of them who with constructive suggestions that I think are very useful. At first I have to say that I think, you know, it's normal human behavior to come from the perspective that you're in any multi-stake holder environment. And so I don't think it's necessarily a

bad thing that people have a perspective that is consistent with their own economic self-interest. But I do think that's the reason why we need transparency. And that's why it's so important when people evaluate these responses that they keep those issues in mind. So from my perspective, I think the most important voice that we keep hearing over and over again is the consumer, and the patient. And we've heard from AARP, we've heard from the Hearing Loss Association of America and others who are very knowledgeable about this issue. It isn't that they are naive about the complexities, but who have been very, very positive about these recommendations. The second point I would make is that not all of the professional interests are saying the same thing. And we actually have heard from the academic leaders in the field of otolaryngology and audiology who are actually basically supportive of the recommendations but are asking that there be more of a hard wired availability for this medical evaluation for the red flag conditions. Which seems to me to make a lot of sense. I want to take this opportunity actually to make the following observations. That we have this requirement, the FDA has this requirement right now for a medical evaluation before you can get a hearing aid. The vast majority of people waive, they're allowed to waive that requirement. So if you can think of, you know, maybe 20% of people with hearing loss are actually seeking hearing aids, and then of that, maybe 10% or 20% are actually having the medical evaluation. We're actually missing, if there are all these medical problems, we're missing a lot of them. And what we think this would do is actually bring more people into the hearing health system and allow a whole lot of ways in which we could pick up those problems more. So apologize, I answered two questions instead of one. But gave me the chance to do that.

>>JOHN HOLDREN: Quite all right. Craig Mundie is next.

>>CRAIG MUNDIE: I want to build on your last answer too which is while the analysis we did said the greater good favors getting more people into the system and there are these potential red flags, and some of the comments reflect that, we did spend quite a bit of time thinking about how as these technologies get more sophisticated, particularly tied to things like your smartphone or home computers, that in fact we may in fact be able to learn more about people and even discover they may have a need to seek medical conditions. Even those sort of bypassing the system today may find that. And I thought you might want to comment on that as an opportunity that it doesn't just leave these people out there hanging. That in fact the technology might in fact find more of them.

>> CHRISTINE CASSEL: Right. And we're seeing that, Craig, I'm glad you raised that. We're seeing that a lot more in a whole range of other medical areas. Bio-monitoring and other kinds of opportunities are allowing people to pick up issues that then they can bring to a professional and seek help through a wide range of options. So I think it's quite likely, perhaps even probable, that more people who had red flag conditions would be identified if we opened up the market in this way. Yes.

>>EDWARD PENHOET: And I might add that a number of people are reluctant to keep wearing hearing aids because the technology that currently exists doesn't meet their needs. And we did recommend and do recommend that the changes that we're anticipating would actually drive innovation. But I would like to point out at this point in time that we've actually heard from many potentially new players in this field who are very sophisticated in both well, listening sounds and hearing sounds, et

cetera, who would like to be participants. But many of them have expressed reluctance to enter into the state because of the barriers that exist today. So we think it's not just a possibility that more innovation would occur, but it's actually highly likely because there are a number of organizations already engaged. Startup companies, existing companies that are conducting serious research and development programs in the hearing space that could bring this to market. So it's not a theoretical possibility that innovation will occur. I think there is a sort of a wave of innovation that's already started that could come into the marketplace if the market were more open.

>> JOHN HOLDREN: Seeing no more flags up, and being very close to exactly on schedule, I thank Chris and Ed and the team for their work on this.

Nanotechnology: Anniversary of PCAST Report, and A Grand Challenge is Born

>>JOHN HOLDREN: And we will now move on to our next scheduled topic which is nanotechnology: the anniversary of a PCAST report on that topic, and the birth of a grand challenge on that topic. I think we have Lloyd Whitman from the OSTP staff, and on PCAST I think Michael McQuade, Mark Gorenberg, and Chad Mirkin have been involved. Michael, how is this being orchestrated? We are going to turn straight to Lloyd, or do you want to make opening remarks?

>>MICHAEL MCQUADE: No, I think Lloyd is the show.

>>LLOYD WHITMAN: Okay. Thank you, it's great to be here. I want to start by saying it's quite an honor to serve at OSTP. And I'm also quite grateful to NIST for allowing me to do so. My job is made much easier by the strong support for nanotechnology and advanced materials by Tom Kalil who I work with and Dr. Holdren, and most importantly the President himself and others. So today I'm going to give you a little bit of an overview of what's been going on in the last year. A brief overview of the National Nanotechnology Initiative, and an update focusing on our efforts to facilitate commercialization and launch some grand challenges. So I'd like to start my overview of the NNI with this slide that sort of brackets 15 years of what I call presidential nanotechnology. The NNI was launched in a speech by President Clinton at Caltech on January 21st in 2000, where he asked us to imagine materials with ten times the strength of steel and only a fraction of the weight, shrinking all the information of the Library of Congress into the size of a sugar cube, and detecting cancerous tumors only a few cells in size. And he also met Gordon Moore, more commonly known as Moore's law, and even more uncommon that he knew what Moore's Law was. And remarkably 15 years to the day, this is a coincidence of history, President Obama visited Boise State on exactly January 21st, 2015, and talked about many of the same things. In fact, if you look at the picture, you'll see that the President is holding a model of graphene, which he commented is thinner than paper and stronger than steel. This is one of the Clinton challenges. You will see in the background, learning about the use of DNA in nanotechnology and manufacturing and actually in that discussion, commented about how that could be something that would extend Moore's Law. And in fact that's also one of many materials used in nanotechnology that have demonstrated the sort of storage density required to achieve the Clinton challenge in the Library of Congress in a sugar cube. And also on the table, you'll see some pictures of nanoparticles and

quantum dots in solutions that have been used to label and identify individual cancer cells. In many ways we have sort of met that challenge. And that picture encapsulates a lot of what's going on in nanotechnology. It shows a discussion of Moore's Law shows the importance of this. The semiconductor industry to a lot of developments in nano. In particular, in driving the ways we make and measure things on the nano scale. The convergence of the areas of information technology, nanotechnology and biotechnology in a lot of different ways. So where are we today? So the NNI involves 20 federal departments and independent agencies and commissions, 11 of which have nanotechnology budgets. In 2015, the collective R&D budget was $1.5 billion. And $22 billion has been spent since the beginning. You can learn a tremendous amount about the NNI at nano.gov. You can see our documents, things. A great place to start is our budget supplements. The most recent one out last spring up on the slide. And that serves as our sort of annual report. So it has progress and plans for the different agencies and detailed budget information. I will say a little bit about the budget. This shows the budget trend since the beginning. I'll just make a couple of comments. It's been relatively flat at about $1 .5 billion a year for the last four years or so. Given the budget environment we have been in, flat is actually pretty good. The other notable trend is a significant shift among the agencies such that actually the largest of nanotechnology R&D budget is in HHS, mostly in NNIH. That's actually about 31% now. So along with NSF and DOE, that's about 80%. And then with adding DOD and NIST and those five agencies collectively, about 96%. And there is a variety of other agencies that have smaller efforts. We look at our budget, break it down. And you can see this in the budget supplement. Based on the program areas shown here. I will just comment. One of them is related to our signature initiatives. This is an effort started about five years ago where the government agencies decided to collectively look at are there very specific areas where we are trying to spotlight and focus in and work a little more carefully together, we can make more rapid progress. There's been three areas where we have been working in. Solar energy, excuse me, five. Solar energy, nano manufacturing, nano electronics, knowledge infrastructure, informatics, and sensors the most recent one. The solar energy one is one area where the goals of the regional signature initiative were largely met and institutionalized in a lot of different programs such that the agencies decided we don't need to put a spotlight on that area to make progress. Not that there isn't progress to be made. But the tool isn't needed anymore. We're winding that down and looking at other topics for that. We will continue doing signature initiatives. The other thing worth commenting about on the budget side is if you look at the signature initiatives related to environmental health and safety and you add those in, that environmental health and safety is about 10% of the NNI budget, about $150 million. So the economic impact of the NNI continues to grow. Lux Research, which does a periodic economic analysis of the field, the most recent in 2014, estimates, for example, that by 2018 the global revenue associated with nanotechnology products will be over $4 trillion. It's interesting, this is my personal observation, shared by others, most of the current products really involve what I consider relatively low complexity products. So essentially nano-particles for additives and coatings and things like that. But many of them are quite successful. I highlight three companies here. So one is an Arkansas company, Nano Mech and that is founded by Ajay Malshe from University of Arkansas from NNI funded basic research. They have a variety of nanoparticles and additives and coatings used in things like cutting tools and aerospace and I think in

Formula 1 race cars. And another one which is interesting to point out is QD Vision. This is a spinout from MIT that makes quantum dots used in the back planes of displays. And then a third one, I recently became aware of, a company Titan Spine, making spine implants that have nano structured surfaces that are optimized to reduce inflammation and increase bone growth around those. What's interesting, again, observed, there's many common manufacturing processes, or at least some common manufacturing processes and measurement metrology used in these three different companies. But they're so different in terms of their sectors that it becomes a significant challenge from a policy perspective to figure out how best to sort of encourage the growth of these kinds of companies. So moving on to sort of what's next and what we have been doing on this here. So last October this group had an assessment of the NNI. I won't repeat all the recommendations. But one common thread through much of the report, and this is basically my own perspective, had to do with the sort of overall need to sort of re-energize and re inspire the broader community. That the NNI was sort of there in the background and certainly the federal agencies are very engaged. But sort of the rest of the stake holder community wasn't so engaged in the broader goals of the field. And that we really needed to re-energize and re inspire that community beyond the government and get everyone working together towards exciting goals, and get us the economic development we know is possible. As I put on the slide here, how do we re-energize the ecosystem while promoting commercialization, get the whole community the whole ecosystem working better together, broaden awareness, and get more people participating. And that ranges from the education side to the research and development, through making sure that we understand the environment, health, and safety risks of these materials and products, ethical, legal, and societal issues, and ultimately how do we facilitate commercialization to see the economic benefit. So some of the things that we have been doing to address this question, I'll start with some highlights from the National Nanotechnology Coordinating Office and its support of the federal group that works on this. The Nanoscale, Science, Engineering and Technology Subcommittee. It has been a very active year with a series of workshops and reports on a variety of topics including carbon nanotube materials and sensors and exposure science and environmental health and safety coordination between the U.S. and the EU. Just to give an example, we had a very few hundred people participated in a workshop with the Consumer Products Safety Commission on quantifying exposure to engineered nano materials for consumer products, so how do we do the exposure science to understand how we know what might come from a consumer product with nano materials in it. Also highlight a business webinar series that has been put on. Again, this is a recognition to address the business community. We don't want to, you know, going to workshops, multi day or day long workshops is a burden. We shifted to the webinar model where we can have a shorter attention span, highlight key things. We had a webinar on road blocks to success in nanotechnology commercialization. What keeps the small and medium enterprise community up at night? This is a way to bring in successful small and medium sized CEOs in the nano community and talk about things they have done to be successful as they are. A few other things, I'll point out, we have been trying to be more creative in our outreach. We have had a student image and video contests. In fact there was another contest announced yesterday, with NSF and the U.S. Science and Engineering Fair for high schools to design a super hero based on nanotechnology, enabled super hero properties. And NSF has

also been doing some high production value videos on nanotechnology with NBC Learns. And I think the first one is coming out soon. And that's actually reaches about a half million students. And we also have short versions sent out to their affiliates. In the area of metrics, the Patent Office did an analysis of global data to assess the impact on NNI on patent output in comparison to other countries. And then finally, Dr. Mike Metter who is the NSI director, who is actually here today, is playing a key role in the OECD working party on biotechnologies, nanotechnologies, and convergent technologies which has a task force on measurement and impact, and they are trying to address the specific questions, what are the right metrics to measure the impact of these areas? They're having an actual meeting in about three weeks. And Mike will be doing the report back out to the working group. So talk about some of the events that we have held at the White House to address the issue of what's sort of holding back these higher value, high complexity products. Back in February, we had a round table where we brought together some fairly senior people from sort of large tier 1 companies in the aerospace and manufacturing with some of the smaller companies that would potentially be part of their supply chain. We sat them down and said what is it that's keeping these things moving into these large products? And what are some of the tools that the Federal Government might use to help with that? In particular, addressed the question, would a manufacturing institute be that right tool? And it was a really interesting discussion. This actually had a couple of interesting outcomes in terms of the questions. Some of the things that particularly interesting, one was something that comes up a lot. Which has to do with manufacturing metrology, how to measure things on the nano scale, on a time scale quick enough to being effective in a manufacturing environment. And the other had to do with the development of a design space. Say you have a material like aluminum, and an engineer can very easily understand if they change the shape or the thickness or the type of aluminum, how that might affect the property of the product and they can design that in. We don't have that design space yet, for example, a composite with carbon nano tubes in it yet. That's worth looking at. Interestingly enough, one of the outcomes of that is some of the participants in this meeting actually formed a group on their own to start talking pre competitively about how they might collectively work better and develop things like that design space. Now in the area of the manufacturing institutes, the sort of message that came across through the discussions was comes back to the slide I had earlier, well, there might be a lot of processes and things in common, there across so many different spaces, it's hard to envision a manufacturing institute led by a mission agency, for example DOD or DOE, that would have enough mission in that one space to warrant an agency led manufacturing institute. But if NIST were to get funds for an industry led manufacturing institute that might be a mechanism for the industry to collectively put together a picture and pitch such an institute that would help with that. But there was some interested in sort of smaller scale efforts, things like manufacturing demonstration facilities that might help some of the smaller businesses scale up and so we're having some discussions with some of the agencies as to how we might expand in that area. We also had a White House forum on challenges to commercialized technology focused on smaller businesses in the spring. That really focused on partnerships. And some other things that came out of that was a commitment to get the business community better tied into things like iCore and things like entrepreneurship through things like Venture for America. Also came out of that is a series of student groups that involves 19 different

schools, that were coupling through something called a Nano Emerging Technology Student Leaders Conference. The first one in June to bring students together with the industrial community. So I want to now sort of wrap up by starting to tell you about our grand challenges effort. That was one of the key recommendations of the report from PCAST. There are many uses of the word grand challenges. But in the administration here we have a very specific one, which is an ambitious but achievable goal that harnesses science, technology, and innovation to solve important national or global problems, and has the potential to capture the public's imagination. And some of the ones that have been launched, they have all been single agency, mission oriented ones such as the DOE sun shot grand challenge or the NASA asteroid grand challenge. So we decided to have a nanotechnology inspired grand challenge. What would that mean? Not every problem can be solved by nanotechnology. But we believe there are some where nanotechnology is very likely to be the key enabler of solving that challenge. So we worked with the federal agencies to come up with some ideas. Ultimately we had a request for information in June, offering the wider community to make suggestions. And we actually put six examples in there so people would have some idea what we were looking for. We did extensive outreach, in fact, especially with the help of some of the professional societies. The ACS in particular had a webinar. They advertised the availability of the webinar to a few hundred thousand people. And we got over a hundred responses which some of which were very, very thoughtful. Some in particular related to electronics led us to look a little more deeply. We had extensive conversations with people inside and outside the government on one particular topic, and ultimately arrived at our first grand challenge related to future computing which we announced a month ago today at the National Strategic Computing Initiative Workshop. We're working on developing other topics as well. Let me tell you the one we announced. It sits as a nexus between the NNI and the NSCI and the Brain Initiative which is to create a new kind of computer that can interpret and learn from data, solve unfamiliar problems using what it's learned, and operate with the efficiency of the human brain. Why is this a nanotechnology inspired grand challenge? Computing for decades has been based on one particular architecture, the Van Namen architecture. And has been implemented for a long time now in transistors and is fantastic at doing numerical computations. And we have made it good at deep learning and image recognition. But it falls short of what we can do in our brain on similar problems, especially when it comes to power consumption. We have a brain that's dynamic, fault tolerant, three dimensional, and it runs at 20 watts, okay? There are many physical challenges that most people believe we will never get a combination of a computer that can do what we do at that power. And there are many applications where that capability would be very useful to move those sensing and recognition problems locally and not having them off in the cloud on a super computer. And that's going to require a lot of different kinds of device work, different kinds of devices and probably different architectures. And we want to get the computer science community and the nano community together to think about that. And that might all be informed by the way the brain works, maybe not. So one of the interesting methods that people have been looking at is neuromorphic computing that might achieve this but there are others in analog computing and spin based computing. We don't want to define the solution. This is about doing that. It's been great, announcing this challenge, there is very strong support from a wide variety of stakeholders in the community. The federal agencies and

program managers working in this area are excited about it. We're having a meeting with that group in about two weeks. There's been support for it from the Computing Community Consortia, the Moore Foundation, IEEE, and the Semiconductor Research Organization, many are organizing meetings. I think there are three meetings alone on this topic related to the grand challenge in about three weeks. So I'm just going to conclude with a quick demonstration of what we're after. So that's a picture of the IBM Blue Gene Q Sequoia Supercomputer at the Livermore National Laboratory. It's now number three of the top 500 list of super computers. It has 1.6 million processor corps, and covers about 3,000 square feet. There's another computer to the left, occupies a bit smaller volume and runs at slightly lower power. One can argue with a lot of computer science people about what we mean by efficient and image recognition. But I'll demonstrate one at 20 watts, and the other one runs at 8 megawatts. How do we bridge the gap? I'll demonstrate this. A small demonstration of single trial learning followed by low power image recognition using a few watts by showing the following picture. And how many people know what that animal is? Well, you saw that. Okay. Okay. So here's our single trial learning. So that's actually an aardvark. It's an interesting looking animal with a long nose and pointy ears and it also has a long tongue, eats ants and termites. It lives in Africa. It's the only member of its order tubulidentata. No living relatives on the planet right now. I'm going to guess you have seen that as an aardvark and you'll be able to recognize one if you see it again, even in a different position. That's something you have done with a couple of watts that we really can't do with computers. So while you look for the aardvark, I will thank you for your attention.

>>JOHN HOLDREN: That's great. And I saw Wanda Austin as the first flag up. Wanda, please.

>>WANDA AUSTIN: Thank you. That's a great, you know, teachable moment there about the difference between the capacities. Congratulations on the progress that you've made in the nanotechnology area. My question is down in the area of looking at, you know, how we can move the ball forward. You talked about manufacturing and design. You know, is there some synergy that can be gained from that? And have you thought about test and qualification? As we adopt new technology, sometimes we run faster at adoption than we do at understanding where the limits are. What's been your experience in that area?

>>LLOYD WHITMAN: So, yes. So that's actually very much related to the design space question, right? Because in order to sort of have that test evaluation, you have to be able to design products and essentially have that closed loop related to that. So what I can say is that's been identified as an area that we need, as we move up the TRL, we need to address. It's an area I think that places like the Advanced Manufacturing Office at DOE works in that space. And they're looking at some of these things. At some point it becomes more of a, I think when you get to that level, it isn't so much a nano problem so much anymore. Hopefully the nano parts are incorporated. I think from the nano community, it's identified as an area we need to work in. And from one of the workshop reports I mentioned earlier, related to the carbon materials. So I think my hope is that between some of the advanced offices and also the industry now working together, that's the kind of thing that they're

looking at. Right? There's that. So my hope is in fact that the industry community can collectively also work. They're the ones that really need to look at that together and understand how to do it.

>>JOHN HOLDREN: Okay. Michael McQuade is next on my list.

>>MICHAEL MCQUADE: Just a comment. I want to take a step back. When we did the NNI report a year ago, you'll recall we described a program that after 15 years of very productive research in fundamental science really had reached a point where the focus on continuing the science investigation and development of technology needed to be coupled with a community aimed at commercialization. We had a number of recommendations related to process and procedures plus a strong endorsement for continuing the EHNS investigation and mission. But our primary set of recommendations really were about how to engage the community more broadly as a community, taking forward to make nanotechnology relevant at scale and the grand challenges were part of that. My comment is to commend Lloyd and the team for really running with the ball in a really aggressive fashion over the last year. The response that we have had to the recommendations report have really been terrific. And I want everyone to know we appreciate that very much.

>>LLOYD WHITMAN: Thank you.

>> JOHN HOLDREN: Thank you. Maxine Savitz is next.

>>MAXINE SAVITZ: Lloyd, really pleased about this re -nergization and the grand challenge. And PCAST has looked at this since the beginning. And this PCAST three times.

>>LLOYD WHITMAN: I've read all those reports having been involved since that time.

>>MAXINE SAVITZ: But you really, and the re-energization is very exciting. My question is, on the international scene, I mean, because particularly as you get into more manufacturing and there's been concern when we looked at the other, did the other studies and on with the Asian, in particular China and Japan. So what is, is America still the leader in this, and what is happening on an international front?

>>LLOYD WHITMAN: Yeah, well, still there is significant growth in, I mean, it remains a concern. I think that, you know, the focus of this administration on advanced manufacturing has helped, right? So we now have a whole I think nine manufacturing institutes. And many of which, though, none are nano specific, quite a few of them probably will involve some nanotechnology or certainly advanced materials. So in fact one of the things I, in the interest of time I didn't mention, one of the outcomes of some of these meetings we have had is a much stronger connection between the nano subcommittee and the advanced manufacturing subcommittee. And that's facilitated by the fact that the OSTP, it's that Megan Brewster sits about ten feet from me and we work closely together. And we have had the leadership of the committees talking together. So we've also been looking at, talking to, for example, DOD and DOE who have committed to, as these manufacturing institutes sort of get in place and get set up, to couple them to the nanotechnology, especially the smaller businesses, who might be able to

participate in projects going forward. Because these are dynamic and not fixed by the original initiatives. We are working in that area.

>> JOHN HOLDREN: Chad Mirkin is next on the list.

>>CHAD MIRKIN: Fantastic job. You have done a great job of re-energizing the whole initiative and I think it's very important. On the global front, I have a big concern. I travel quite a bit and see the extraordinary investment in other countries and I'm worried about us losing our position. I'm glad you're thinking about and on top of that. On the grand challenge front, though, I think the grand challenge is a spectacular one. I think it brings together many different fields. But going back to when Clinton announced this and the field really started, it was driven by our understanding of electronics and the importance of miniaturization there. But it's grown to include so much more. And what I want to know is are we thinking about grand challenges that go beyond electronics? Especially in the medical front to also mirror the investment now in the profile that's changed over the course of the NNI?

>> LLOYD WHITMAN: So absolutely. So this is the first and certainly not the last. One of the things, though, you know, it's been a bit of a learning process. Because as all things with nanotechnology, it doesn't sit in one spot. But one of the things that came out of the RFI and the discussions was what I'd like to say, like to describe as finding the topic that will move the needle. Right? So just as an example, we got some comments back from the RFI. One of the examples was related to cancer diagnostics and treatment, for example. But it became clear from a lot of discussions, though that was a great grand challenge, it was so good that everyone would agree vehemently that they were already focused on it. And that therefore though it might bring additional attention, it would unlikely bring a whole lot of additional resources or activity. There's just a significant amount going on, I mean, NCI has a significant program in this area. It's not to say it's not critically important. The challenge is to find the grand challenge that both excites people, but also makes new things happen that aren't already happening because people aren't already excited about that area. And find just that opportunity where there's enough done. So, again, that won't say we wouldn't have one. But I think there's some opportunities we're looking at, particularly in manufacturing and materials, that might actually encompass some of those spaces including regenerative medicine as under a broader umbrella innovative ways to make things, for example. So the quick answer is, yes, we're looking at other ones. But it's more than just being really important and exciting. Because there are a lot of times if it's exciting, people are already doing it.

>>JOHN HOLDREN: Mark Gorenberg.

>>MARK GORENBERG: John, thank you. Lloyd, I want to echo everyone else. It's easy to write reports and difficult to make this happen. You have done a spectacular job. We are all very, very grateful for that. And I have two questions, more specifically the impact on doing this with the grand challenges rather than signature initiatives. One is there's 27 agencies involved, but three are the bulk of the

funding, probably 75, 80% of the funding that goes into nanotechnology R&D. Are you finding the grand challenges are invigorating some of the agencies that have smaller NNI budgets to be part of this? And my second question, as part of that is, also, we talked about the idea of grand challenges having measurable end points. Have you created a set of criteria when you know that this grand challenge will be successful?

>>LLOYD WHITMAN: I'll pick the second question first. Not yet. But actually, actually I'm going to change my answer a little bit. They're coupled, the two questions. To me the most important aspect of the grand challenge is that it not be driven by the federal government. That is somewhat what the signature initiatives are. We want to make sure this is a problem that the external community in this case, the people involved in the electronics industry, really are behind. Because that's what's going it make it last and help the government understand where the investments need to be made. So in fact that's one of the most exciting aspects, we have extremely strong support. The meetings from IEEE, from Optical Society of America is interested, I mean, the (inaudible) Research Corporation, who are really excited and self assembling among themselves to road map this. So they're actually working on defining those end points which then I expect when we get the government people together, I'd much rather have the government people figure out what to do based on that criteria than what they already think they should be doing. That's the process going forward. It was a soft launch. We set out the objective, but without knowing the road map yet and challenged the community to tell us what the road map should be. And they're rising to that challenge.

>> JOHN HOLDREN: Mario Molina will be the last question.

>> MARIO MOLINA: Thank you. Yeah, thank you a lot for the presentation. You mentioned high value, high complexity products. And, of course, you can connect that to grand challenges. We have not yet been achieved. My question is can you give us examples of any such product that, do they exist, high value, high complexity products that employee nanotechnology as the main part?

>>LLOYD WHITMAN: I mean, foundationally, the computer chip industry is one, right? That has nano scale and things like that. You know, some of the, for example, the cancer therapeutics that are being developed, are quite complex in terms of the types of things that, how they are structured and how they are created. But I don't know, someone's going kill me now because I didn't mention their thing. But, you know, if you think about a complicated nano system that has lots of components and a hierarchical system beyond that, in the commercial space, nothing, I don't really think there is anything. Look at Mike, our director. Anything come to mind from you, Mike? So we have a lot of interesting things that are getting close. Things like carbon nano tube based materials and cabling and I things like that. But they don't have multiple components in them.

>> JOHN HOLDREN: We are only three minutes behind schedule. Thank you, Lloyd, for that terrific presentation and Q and A. doing a great job with this.

Private Sector Adaption to Climate Change

>>JOHN HOLDREN: We are now going to move to a discussion and vote on a PCAST letter report on private sector adaptation to climate change. The folks leading that discussion in an order that is not clear to me is Maxine Savitz, Rosina Bierbaum and Michael McQuade. Michael is leading off.

>> MICHAEL MCQUADE: Lead from behind.

>> JOHN HOLDREN: Michael McQuade.

>>MICHAEL MCQUADE: Thank you very much. And thank you to everybody. This is the report, thank you. This is the report on our letter report on actions to catalyze and support private sector adaptation efforts. Recognize the team here so the co-chairs that John went through. So Rosina, Maxine and I. With able help from other PCAST members, Mario Molina and Dan Schrag, and our PCAST co-chair has a passing familiarity with this issue and been part of the conversations and discussions along the way. As it usual at PCAST, we had terrific help from the staff, Marjory, and most importantly Diana Pankevich who has an amazing capacity to keep a lot of balls in the air at one time. And very good support from the ENE staff here at OSTP. In particular Bob Simon and Tammy Dickinson. So really terrific effort. So why are we here? This is a follow on to a PCAST report from 2013. Letter report to the President on climate, climate change. And the chart in front of you shows an opportunity gap. Looking at actions that can be taken relative to climate change by the administration, we have two categories. We have mitigation and we have adaptation. And I should mention in passing that adaptation for us is a simplification of resilience and adaptation. So when I use the word adaptation here and during the report, think resilience and adaptation. How to mitigate the impacts of climate change, prepare for, become more resilient, and adapt to potential climate change or real climate change coming? And the actions that the Administration has launched over the last several years have been really, really quite enormous in three of the four areas. Separated by actions to benefit the public sector and actions to benefit the private sector. Focus on the private sector for just a moment. The clean power plant which is in its birth at the moment. Along with building energy efficiency standards, product energy efficiency standards, the American Business Act on Climate Pledge, which now has over 80 members who have joined into that pledge throughout White House. A whole range of activities to support mitigation in the private sector. But as we began to look at follow on from our report from 2013, it was clear that work could be done on the broad category of how to help the private sector adapt to climate change. There were some places with climate data, the climate resilience tool kit have specific elements that aid the private sector. But really a broad area of opportunity. And in discussions with the President, he asked PCAST to consider how the administration's actions, not the specific actions of the private sector, but what could the administration do to aid the private sector in moving forward with adaptation activities? I will get to a set of recommendations and how we got there. But I would ask you to think, as I go through this, about three broad categories that we have arrived at. One is around communication and education. One is around use of data and by use we mean usability, visibility, access, and applicability of the data. And one around demonstration of measurement of adaptation via public private partnerships and other mechanisms. So we launched into an exploration of the issue. We

conducted over 25 very deep conversations with various stakeholders. We had a total of over 65 different groups and people, individuals that we talked to in the process of the last six months. We looked at reports and peer reviewed papers. We had a number of workshops we participated in, and held a PCAST sponsored workshop with over 35 stakeholders in the private sector, in the government and in the community that sits in between. The NGO community, the sort of public private partnership sector, et cetera. We focused on three specific areas. Not that those, the areas of agriculture, energy and water and insurance. Not that those three areas are exclusive and the only place where adaptation is and should be relevant. But three areas to determine a set of recommendations that were most immediately actionable. And we had, as I said, representation from both the public and private sector. A number of findings, sorry. This is the list of the, all the folks who we have interacted with over the process of the report here. Just to give you an example before I go through the findings of the kind of adaptation examples that we heard about and are trying to enable. So an energy provider who I won't name in the Gulf Coast partnering with the re insurance industry post Katrina to do long term and medium term risk assessments, to identify resilience actions for the commercial and residential building infrastructure, and in the power generation infrastructure in that region. So a set of specific activities from an energy provider in the insurance industry to look at what the next Katrina like event would mean and how to create a set of resilience and adaptation actions to make that a less impactful event in the future. We interviewed a beverage company along the way already in the planning stages for where its supply chain, so its water supply chain, it's sugar cane supply chain, will migrate over time and what it will do about that in response to a changing climate. Therefore moving its supply chain resources further from where it currently obtains those resources. Those are the kind of adaptation activities that we're talking about. So our findings come into a couple of key areas. One is that climate change is undervalued in the private sector. And by undervalued, we mean in the sense that proper and timely response to climate change will lead to, or lack of proper and timely response, will lead to a negative financial impact on the value of that company and its ability to pursue its business. So our findings are that while companies are aware of climate change, 90% of the companies that we interviewed or had access to in various reports would suggest they understand climate change, a very small percentage actually are using it as a future long term valuation exercise in the health of the company. The second is that companies that do focus on what we or they would call climate change really tend to focus on near term impacts. So severe weather events, things like flooding and drought. Rather than long term implications like sea level rise or long term climate that's going to move feed stocks around. Notwithstanding my beverage company example. And few major companies have really incorporated climate data and modeling into their long term decision making. Now part of this is the nature of the horizon on which companies deliver to shareholders and part of this is the way long term risk can or cannot be codified. But it's clear that when companies do generally talk about responding to climate change, they're really operating on a much shorter time frame than some of the adaptation activities that could be relevant to the future value of those companies. It is also clear that better communication is needed for the private sector to understand the long term risks and the steps that can be taking on to minimize the value to the company and also the economic, social, and ecological costs of climate change. Companies rarely report measurements for measuring the success of climate

adaptation initiatives. Part of that is because there's not a lot of it going on. Partially, it's hard. It is hard to measure. There's not common standards or best practices for dealing with and measuring the impact of adaptation activities. And you'll see in our recommendation this is a task we need to get after to help here. The relevant tools and information from the federal government are large. There is a lot of information that's available. Much of it I talked about as its relevance to the public sector does have relevance to the private sector. But it is difficult to locate in the opinion of the people that we talked to. And it is not easy to use. And in many cases it is not precisely tailored enough to the specific user needs. We'll talk about this in the recommendations. But this is a broad theme. There's an overwhelming call for easy to use single point entry process to actionable information. And we will talk about that in the findings. Our recommendations fall into three key areas as I said before. Communication, usability of the data, and access to the data, and demonstration. So here are the six recommendations that are in the report. And I'll enunciate them and go through each one. One is around education and communication. The second is around enhancing adaptation, science, research and technology and demonstration of adaptation activities. The third is to close the information gap to available stakeholders. The fourth is to unlock additional investment capitol relative to both the private and public sector. The fifth is to use public private partnerships. Either existing or new public private partnerships to motivate adaptation activities. And the sixth is to use specifically an existing city based project that's under way to launch a pilot program. And as usual when I go through these, as is usual PCAST practice, we tried to ensure there's an owner for each of the recommendations so we can track progress going forward. Recommendation number one around education and communication. So the Council on Climate Preparedness and Resilience, co-chaired by OSTP, OMB, the National Security Council NSC, and CEQ and others should develop and implement a broad and robust strategy for private sector education and communication. Specifically the four areas in the report are to ensure, explain that the critical need for adaptation planning and actions by companies and organizations, and the value of that. Bring attention to the fact that the nature of such efforts will often extend beyond short term planning horizons, and communicate in the language that the private and public sector can understand. The difference between how a city makes a long term bonded investment and a company makes decisions relative to its shareholders and meeting quarterly results. So there's a communication effort there. How to integrate private sector efforts with adaptation work currently going on in the public sector. And also, as we talked about yesterday, ensure people understand the critical nature that insurance and insurance regulation plays in both motivating adaption activities and dealing with how those activities work or do not work. And as we said in this recommendation, the council should specifically ensure this is not a government effort, but a government effort to involve the private sector as an integral part of that activity. Our second recommendation is around adaptation science research and technology research. This is not the data. This is the research that helps drive the recommendations for what the private sector can and should do. So the U.S. GCRP, the Global Change Research Plan, which is the research arm of 13 federal agencies who participate in climate change adaptation and research, has a global change research plan in the second iteration now and is in the process of being updated. The sort of 2012 to 2021 version is in the process of being updated right now. And our recommendation is to ensure that update include the development specifically of a

research strategy around adaptation. How scientific modeling should be used to identify adaptation activities and estimate the impact. And identify how we should measure, project the measurements and identify the measurements and report the measurements on adaptation activities going forward. And as we said in the previous recommendation, the Council on Climate Preparedness and Resilience should create an interagency working group to develop this plan on technology development and demonstration to go in conjunction with the research plan that we have in place. Our third recommendation, the broad area of the information gap. The subcommittee on global change research. A subcommittee of NSTC's committee on environment, natural resources, and sustainability in consultation and close working with the private sector, and others who have a stake here really needs to take charge of improving the availability of, access to, and usability of data. This is a very broad statement. It is easy for people to come to a table and say, I don't know where the data is and you need to make it easier for me to get to data. The question we're asking people to address here is much broader than that. This is a question of where is the data, what kinds of data do we have, what is the right way do get access to the data? What's the right way to make the data live and update it over time? What's the right way to understand what the community wants from the data? This is not just we need a new database to go to. This is a broad statement about an integrated methodology, architecture and availability of data to assist the private sector in knowing what's out there from the data point of view, what modeling capabilities exist and what programs exist to help the private sector as it looks at adaptation activities. We point out in the FY17 R&D priorities memo jointly issued by OSTP and OMB, this by them, this area of commitment to data and data availability and modeling and resource availability is mentioned. So there's a precedent here for the recommendation. The fourth recommendation is about unlocking investment capital. We ask that the National Economic Council in conjunction with OSTP, OMB and the Department of Treasury create a task force specifically to recommend public private partnerships to create new public and private investment capacity for adaptation. The, not the complication, the added issue here is to understand how these kinds of investments are evaluated. What metrics should be associated with the adaptation activities, the success of the adaptation activities, how one scores these kinds of investments given the long term nature and the, long term nature and the preventive nature of the investments. So there is a need for significant new investment capital to aid both the public and the private sector here. The fifth recommendation is around expanding public private partnerships. And in this recommendation the idea here, or the recommendation here is to build on at least one existing public private partnership and potentially launch at least three others we identify as examples. The first that exists already is the DOE's Partnership for Energy Sector Climate Resilience, a partnership between the Department of Energy and 17 energy producers in the United States, which is currently already looking at adaptation activities in the energy sector. We recommend that this continue, obviously continue, but to build on that to make sure that best practices and lessons learned from the adaptation element are shared broadly beyond the partnership to the broader community. And also to develop incentives for adaptation activities based on the learning in the areas not specifically related to adaptation. Things like rate recovery mechanisms, things like investment capital. How do we lever those from non-adaptation activities into a broader private sector adaptation? That's an existing program that's under

way. And then we identified three potential new public private partnerships. One I have actually already talked about. Which is the creation of a public private partnership that OSTP has been encouraging to deal with this issue of climate information, best practice sharing data, et cetera, and how that's applicable for private sector adaptation. We recommend that the interagency council continue its dialogues with insurance and reinsurance leaders specifically to include lenders, rating agencies and the financial banking sector in identifying new capital and new methods of evaluating the deployment of capital. And finally we recommend that the interagency council convene an additional work stream as part of the state, local, and tribal leaders task force on climate change that works together with representatives from the private sector to implement its recommendations, but implement those as they may be applicable to an integrated public and private sector set of activities related to climate adaptations. And then our final recommendation, sorry, is to launch a pilot program. So we have the public private partnerships that we've announced. Would like to see action quickly and identifiably, so we recommend a very specific action to take an existing city's program. And the one we have chosen as an example is the Strong Cities Strong Communities Initiative. Our recommendation is to take three of the SC2 cities, they might be Detroit, Fresno and New Orleans. And essentially what we're asking is that we layer into that existing city's partnership specific activity to bring the private sector adaptation activities into the public partnership that's already in place. So understanding information needs that the private sector would have. Test adaptation efforts that align with the other recommendations in the report. Identify opportunities where public and private sector adaptation can be co executed and jointly undertaken for the benefit of both sectors at the same time. And to continue as always in these pilot programs to ensure that the data and the results of the public private partnership are made available, ubiquitously, and lessons learned are translated as quickly as possible. So in summary in the report, find, sorry, significant opportunities for the U.S. government to catalyze private sector moves. At the end of the day it is the private sector has to execute the adaptation activities, but the government can play a role in helping catalyze that. And the recommendations outlined in the report specifically leverage public private partnerships to bring focus and commitment to all stakeholders on what should ultimately be private sector activity in adaptation. Let me stop and turn it over to I think Rosina and Maxine for comments.

>>MAXINE SAVITZ: Just a few comments on the front end. I want to re-emphasize, this was just looking at several industries. And also the supply chain. And the supply chain are often smaller vendors. So they have less access to the data than some of the bigger companies who do have it and develop their own models when building bigger and new facilities particularly with the energy supply group and the utilities. The other thing is that the idea that they may be, the private sector may be aware of the of climate change, particularly in the near term, but they don't frame it in the terms of risk, which is where they manage when they're concerned about their future and their bottom line and also the long term risk. Much more framed as a hazard, where it does not need to be managed. And the insurance industry, of course, is very concerned about this. In fact one person told us that, it was appropriate, because we also heard about the aiming today, that aging and climate are their biggest sources of risk that concern them for future liability. So that really raised to that. And just that mentioned that there are two other studies that were going on at the same time and the workshops we did participate in.

GAO on their own initiated a look at adaptation and the private sector and what they were doing. They issued their report yesterday. Has a lot of the same findings. They make no recommendations. But really the same things that we did. And the Center for Climate and Energy Solutions has been looking at this and has some interesting case studies from various people. And they also have very similar things. So it's getting, so to get attention, and we're hoping that this will even accelerate and particularly have more public private partnerships. Turn it over to you.

>>ROSINA BIERBAUM: Thanks. As the non-private sector co-chair, I would be happy to answer questions about information or research mainly. But I wanted to say that this is really timely, I think, for at least two decades people have been thinking about the mitigation side or how emission reductions could be accomplished. And we ran into many companies disclosing their carbon emissions and set targets and are working to reduce emissions. But I would argue that adaptation in general, both in the public and private sectors has been under attended to for almost two decades. We have a lot of catch up work to do now. And I think it's clear that the pace and magnitude of climate change means that you need both as much mitigation as you can get and adaptation to cope with the changes we're already seeing at the global average increase of 1.4 degrees Fahrenheit to date. And some of the new research coming out, the statistics that show some of the heat events and some of the drought events that are so improbable. A five sigma event in an unchanging climate have really brought attention to the public and private sectors to learning how to cope with this and fast is quite necessary.

>>JOHN HOLDREN: Well, thank you very much for that good account and for all the good work behind it. Let's open it up for questions. Mark, I think your flag is a holdover. But I've got, I've got mine up. And closely followed by Bill Press. So in the course of this work, obviously, as you have related, you spoke to a lot of companies. And as Rosina has just noted, a lot of companies have shown a lot of enthusiasm, a lot of initiative on the mitigation side. How would you characterize the welcome you got in raising these issues with the private sector? What is the level of enthusiasm or lack of it for working with the government on private sector adaptation and resilience?

>>MICHAEL MCQUADE: So at the risk of saying it's a biased sample, the nature of the people we talked to were people who were willing to hear a strong message. I think that by and large I would say two things. One, when providing information around how adaptation can and should a strategy beyond mitigation. There was good appreciation for it. Obviously lots of conversation about how that fits into a long term investment stream. What adaptation might mean. Adaptation in place versus wholesale pick up and move. But also very strong communication on, as Rosina said, the small and medium enterprises on really needing help to understand what resources are available to execute. So bottom line answer to your question, I think strong. I think strong appreciation that adaptation was something that should be on the radar screen. Varying capacity on the ability to execute against that.

>>MAXINE SAVITZ: And I would just amplify that, that the public private partnership that was started at DOE in April at the time that they issued the first part of the quadrennial energy review, which looked at infrastructure, and they no trouble finding 17 utilities who represent 25% of all the consumers. And some of their participants were at our workshop also. And they really are looking to the government to

help share the best practices and they themselves, you know, are building facilities that are around for 30 and 40 years. And so it's of big concern to them. And they also want this rate of recovery for adaptation that now occurs in their rate structures for efficiency and renewables. And that's one of the things we're suggesting that DOE follow up on.

>>MICHAEL MCQUADE: I would just add one other comment. Really doesn't show up in detail in the report. And really in its infancy. But I was struck by the interesting, eye opening viewpoint of companies on what adaptation will mean from future business. So there's adaptation, what should I do to protect my company? But many companies are beginning to think about what will this mean for new markets being developed for me? So the movement of my customers from one location to another, the movement of infrastructure projects from one location to another. So there is an element of this which is positive future business, other people have to adapt to it and I will play a role in how they adapt.

>> JOHN HOLDREN: Bill Press is next.

>> WILLIAM PRESS: Thanks, John. So this is one of these, I am not an economist, but questions. I understand that many companies will have this barrier to action because of a certain short term viewpoint against a long term risk or another way of saying that is they have to figure out how to discount to the present value. The time value of money and so on. But it seems to me the insurance, reinsurance business is in a unique different space because they have to think long both on what they're insuring against, and how they invest their premium stream against that. And I wonder whether in that sector, which both you and Maxine mentioned, there is a kind of thinking about how will climate change affect at the very macro level, what their investment returns are in this long period in which they're in a sense banking or investing premiums. Because I think climate change could be a depressor on investment returns, or it could enhance investment returns. Any thinking along that line?

>>MICHAEL MCQUADE: I think among the folks we talked about, and maybe it's what you're saying, I would suggest the insurance, the large insurance industry is very sophisticated on this issue. And the comments about availability of data, use of data, use of models, the insurance companies are already very sophisticated. The challenge in all cases to determining whether this is long term opportunity, long term risk, which way the discount calculation is going to go has to do with the (inaudible), and the (inaudible) are regionally specific, as is the portfolio, makes it a complicated calculation. I think this is the place where it really does come home to roost most directly. This is what they do for a living, right? If they get it right or get it wrong, it's an existential question. Right.

>>MAXINE SAVITZ: They also are concerned about the people they're insuring that the return's going to be there. So therefore they encourage things like building codes that look at what, how you might adapt those for adaptations. And not just fire and safety and others for energy. Because that will help reduce the risk. They are looking for public policies that will also help to minimize their risk.

>>JOHN HOLDREN: Good. Ed Penhoet is next.

>>ED PENHOET: So recommendation, you have articulated the subject matter that should be the part of the National Global Change Research Plan. But much of the adaptive research can be characterized as essentially practical in nature or applied in nature. So you don't articulate who would do this research in your recommendation. Could you fill that out a little bit more with the discussion of who will do it?

>>ROSINA BIERBAUM: Yeah. So I said that I thought, thinking about adaptation itself was quite nascent. And when we finished the National Climate Assessment which Congress mandates, and we finished the third one a little more than a year ago. For the first time we included adaptation activities of sectors and regions and cities, et cetera. What was really clear is all sectors and regions are vulnerable to climate change, but how to respond is not so clear. And as you might imagining the devil is in the details, and you might have urbanization, habitat fragmentation, invasive species, and climate change. And so you want to think about things that will not make it worse trying to combat climate change. But we also realized there are basic research questions that we need to answer. So, for example, we know the world is getting hotter. We know we're having an increase in droughts and floods. In some planting seasons already it's too wet to plant. Maybe we need different crop varieties that may be able to tolerate more heat, more rain, more drought. Not the crop varieties we have been using since 1970 that might be optimized to an unchanging climate. That's a basic research question. I think, you know, garden clubs of America are greatly terrified because if you look at the shift in growing zones in the next 50 years, about 120 miles will, planting zones will have shifted north. Now what does planting native mean? Cities like Ann Arbor, my own city, we plant city trees to be there for shade. What kind of trees can persist this rapid changing? That's a research question. Every one of the federal agencies put together a report that says how climate change will affect their missions and mandates. Whether it's to protect human health or reduce pollution or preserve species, et cetera. But if you have the climate map moving at a rate that we know to be four to ten times the rate at which plant species have moved historically, you're really ripping apart ecosystems and parts that fly and swim and crawl are dispersing moving at different rates. SO what would a large land management entity like the Department of the Interior or Forest Service, how do they make sure they're having intact forest with species with ecosystem services. Those are researchable things, and I could go on and on. It's easier to think about what kind of infrastructure that you need to withstand the new 100 year flood and what is it in your region anyway? So those are a lot of the basic research questions, and we would argue that the Global Change Research Program, the entity of 13 agencies that does $2 billion of research each year should be addressing those basic research questions for the nation. The second part of that recommendation too was it's more than basic research. We've got to begin to start demonstrating and deploying activities. So that we expanded, oh, I'm sorry. I like to talk about research. But there are experiments being tried now. And so if you talk to a group of Mayors and the Resilience Task Force the President set up had some amazing recommendations from them. They are trying things now to deal with changing floods and droughts. Assembling those best practices and distilling in things that can be transferred across communities and sectors and to the private sector is something more than the research group. That's why we put it in the purview of the four part council.

And the science and technology council. So, you know, assemble what you have today and get it out there. But make sure you're answering the questions you really need to answer for tomorrow.

>>JOHN HOLDREN: I don't see any more flags up. Do the leaders of the study want to make any further comments before we call a vote? Michael or Rosina or Maxine?

>>ROSINA BIERBAUM: I want to come back to the first thing you said, Michael, which is that this builds on the report we gave to the President on climate change back in 2013. And I don't know, I think it was recommendation 6C. But I think very, very importantly we had asked that there be this interaction between the public and the private sector to both identify problems and identify solution sets. And so I think this way of bringing the public sector, the private sector into a dialogue that was very rich with the resilience task force that included Mayors and tribal leaders and governors is an important missing piece. So I think we are actually coming back to a recommendation that we hadn't quite crystallized in 2013 with this report.

>>JOHN HOLDREN: Chris Cassel.

>>CHRISTINE CASSEL: Thank you, John. I wanted to thank the working group for I think a really strong and important report and move approval.

>>(PCAST MEMBER) I'll second that.

>> JOHN HOLDREN: Approval has been moved and seconded. Any further discussion before we vote? If not, all those in favor of accepting this report as usual subject to final edits, raise your hands. All those opposed. Abstentions. The report is unanimously approved. Again, my thanks to the leaders of this extraordinary effort. And to the staff, who so ably supported it. This takes us to the end of our pre-break activities. So we will now go on coffee break, resuming at 11:00 sharp for a sure to be fascinating session on academic research, make sure the rules of the road don't stop the traffic. See you at 11:00.

Academic Research: Making Sure the Rules of the Road Don't Stop the Traffic

>>ERIC LANDER: All right. We're going to resume for the second portion of this PCAST meeting. And we have a session on academic research. Making sure the rules of the road don't stop the traffic. Which is a nice statement about the issues involved in regulation in academic research. The National Academy of Sciences has a committee currently working on a topic called Optimizing the Nation's Investment in Research: A New Regulatory Framework for the 21st century. It's already released at the end of September part one of its report. And everyone is eagerly awaiting part two of the report which is expected in the spring. And who knows, maybe the committee will decide to make this an ongoing serial with parts three and four. Although I think not. It's really a very interesting and provocative report that was released and we are lucky enough to have the chair of the committee and a member of that committee who will be able to brief us on the report, and although they can't tell us what the next chapter of the report is going to say. The National Academy does not allow those kinds of spoiler alerts and things. But we would like to engage in a broad discussion about this topic and where they are

broadly going. So we have with us Larry Faulkner, the President Emeritus of the University of Texas at Austin serving as the chair of this committee. And Barbara Bierer, professor of medicine at the Harvard Medical School and a colleague of mine up in Boston. And thank you for coming and talking with PCAST about this important topic on optimizing our investment in academic research.

>>LARRY FAULKNER: Thank you, Mr. Chairman. It is a pleasure to be here. It's an honor to be here. And I think Barbara and I are eager to talk with you about the report. Which has come about in a little bit different way. As I will discuss. Let me draw your attention first to the title which is Optimizing the Nation's Investment in Academic Research. There is pretty broadly extent in the country now a concern about the total amount of time that investigators in scientific and other kinds of research are directing away from the actual performance of research toward the administrative and compliance functions that are associated with research. The committee views that load as one that draws away from the nation's funding. The irreplaceable asset, which is the researcher's time and insight, and puts it on a really a second level function. But at the same time regulatory activity is essential. And it serves to protect absolutely essential interests of the public and indeed of the researchers themselves. So how do you balance properly and where is the optimum? That optimization is central. But also central to our consideration is the idea of efficiency trying to maintain an efficient regulatory system that allows us to proceed in a responsible way into the future. But in as with as much researcher time dedicated to actual research as possible. The committee's roster is a strong one. I won't go down these names. I just put them there for you. And it does have representation from various aspects of research, but also from government and from experience in the process of regulation. They, I draw your attention to this comment from Howard Shelanski over at OMB. Now he is essentially echoing the message that I just gave that there is a concern, there is a risk, that the regulatory load has become so great that we're not getting as much for our research money as we should be getting. Because people can't spend the time that they need. This is more elegantly stated, but I'll leave that to you. The committee was charged by Congress, charged the Academy was asked to undertake the study by congressional request. And we have been asked to examine all aspects of regulation. But let me just draw your attention to that last paragraph. That the committee will develop a new framework for regulation at research universities in the 21st century that addresses the needs of Congress, federal agencies and the broader public. That has meant in the committee's mind that part of our charge is not just to look at individual regulations, or how to lighten the load in this area or that. But it's to look at the process and apparatus by which regulation arises. And to think about whether there is a different configuration, or a different approach that might be applied in the future. One of our recommendations bears on this issue. And one that I'll dwell on as I talk with you here in a moment. These are elements from a statement of task. I won't go down all of this. It's the kinds of things you would expect to look at regulations with significant impact and to gather information on how effective they are and what they cost. And I just won't go down, as I said, that. I do want to draw your attention back to seven. Seven is develop a framework and supporting principles for federal regulations for research universities in the 21st century. That is part of the task I was talking about just a moment ago. Now this study was, as I said, charged and organized, it was thought that it would be an 18 month study. But just a few months after we got started, Senator Alexander came to us and said, you know, we really need a list of things to work on by mid-September.

He pushed hard for an early report rather than a later report because he has a belief that this fall represents an opportune moment for some progress. As a consequence, the committee worked really hard. And the staff, led by Anne Marie Mazza who's right over here, worked really hard. We produced a part one of the report, not a usual procedure for an Academy committee, in time for Senator Alexander's deadline in mid-September. That part one has been made available to you. It is said on the cover that it's a pre-publication copy. However, it's been all the way through the Academy's review process. And it is formally released by the Academy. It won't be rewritten in part two. The committee is, has not fulfilled all of its elements of its statement of task and is therefore continuing on. We are doing additional work this fall and by the end of the first quarter or so in calendar 2016, we expect to issue a second part. But that second part will deal with items that we did not get to in the first part. It will not be a reiteration and expansion or revision of the first part. We have said what we're going to say on those items. The second part will cover things that we haven't talked about in full detail, human subjects, export controls, and some other topics that have not been addressed. Now, let me ask Barbara to go ahead and discuss the overarching findings. You want to control the slides?

>>BARBARA BIERER: Sure. Sure. Thank you. The overarching findings are summarized in the next few slides, and really do not detail the extent of work that went into those findings. There's more in your report if you wish to review it. But basically we never took the position that effective regulation is not necessary. Rather that effective regulation is essential to the overall health of the research enterprise. Protecting both the national investment and the various parties in the partnerships. That the expansion of the federal regulatory system, however, and its growing requirements are diminishing the effectiveness of the research as Larry has described. Now, most federal regulations, policy guidance, rules, funding requirements, et cetera, are efforts to address accountability and performance. But those well intentioned efforts are really undermining the research that can get done. And undermining the nation's investment in research. And these regulations really do not address the diversity of the research enterprise as we know it today. Further, many of these regulations are inconsistent, duplicative, unclear, marginally different, one agency to another, without being substantively different. And therefore there's an enormous investment in compliance with these individual regulations. And universities therefore increase the requirements for each of the investigators to comply universally across these funding agencies in order to protect themselves and to ensure that there is a compliant framework from which they work. And it would be different if academic institutions received funding from one agency, and had one agency's regulations to comply with. But that is not the way that current universities are funded, and we all deal with multiplicity of sponsors for that research. And the lack of harmonization is crippling the research institutions. Some of the basis of this may be that universities failed to respond appropriately to actions that have been inappropriate by their investigators. And there is an effort to really enhance the controls and the environment to discourage both the individual and institutional level behaviors that are in conflict with the norms of the community. There is a section here addressing the inspectors general. Since academic institutions may be audited by those inspectors generals, each from different agencies, many of which have very different approaches. Which may even be incongruent with their cognizant agency. And, you know, our relationship in the research environment has been a partnership between the funding agencies and the institutions.

That's been in existence for seven decades or more. But there's no formal entity, no structure, no mechanism or process by which we stakeholders from both partners, and more dedicated to fostering, sustaining, and strengthening the enterprise, can consider the effectiveness of existing research policies and review those policies with the name to being efficient, dynamic, and effective. And that conforms to some of our recommendations to follow.

>>LARRY FAULKNER: We're going to present the recommendations, thank you, Barbara, present the recommendations going over one, two, three, quickly. And dwelling on four and then coming back to consequences of one, two, and three. There are actually only four recommendations that the committee has made. They are, however, large in scope in some cases. So let me go quickly through them. Recommendation one calls for the regulatory regime comprising not just laws and formal regulations, but also rules, policies, guidance, and requirements. Governing federally funded academic research should be critically re-examined and re calibrated. Now under this, there is a large list of specifics. Some of which I'll come back and dwell on as we come, we go further. Recommendation two is a recommendation to the academic institutions themselves. It says that institutions must demand the highest standards and institutional and individual behavior. That it can only be achieved if the universities foster a culture of integrity among all the players. And that they meet out appropriate sanctions in instances where behavior deviates from the ethical and professional norms of the institution the research communities. Universities that deviate from or fail to enforce norms should be sanctioned. And the committee recommends that possibly the research policy board that I'll talk about in a moment could have a hand in this. And recommendation three is about the inspectors general. Saying that the inspector general responsibility should be rebalanced to provide appropriate consideration to uncovering waste, fraud, and abuse. And to advising on economy, efficiency and effectiveness. Both of those columns of responsibility are in the legislative charges to the inspector general. But in our observation only the first column really gets attention. And then I'll come back to that slide. Recommendation four is that the committee recommends the creation of a new mechanism to include an active public private forum with a designated official within government to foster a more effective conception, development and harmonization of research policies. This is the recommendation that is responsive to the element of our charge calling for us to look at framework. Let me just say that I think the committee believes that what we have, which is we believe and have judged to be to be, an overburdening regulatory environment is the natural evolution of this complex picture of two dozen funding agencies and other agencies having a hand, plus hundreds of research entities, all working in an environment with no focal center. And on an operational point of view, we believe I think that if we were to make a fix, a one-time fix right now, that it wouldn't stay fixed. That evolution would continue to manifest itself. And that we can see coming down the road, spheres of scientific progress that will give birth to new regulation. We can see that in big data, we can see that in genomics, we can see it in other areas. So the burden is going to grow. And it could grow paralyzing if we don't actually look at the framework thoughtfully. So as we go forward, the recommendation is this in sort of a graphic form. It's to place a body called the Research Policy Board into the picture. And I'll say more about how that Research Policy Board might be constituted. But we view it as being connected to the academic research institutions and the funding agencies. And the associations that exist already. But also

formally connected to OMBOIRA and OSTP. We recommended that an associate director of OSTP be designated not just to be the liaison with the Research Policy Board, but to oversee or to look out for the operating health of the research partnership. There is no single official in government that, who works every day thinking about the operating health of the research partnership. Yet it is a $65 billion enterprise with a great many moving parts. And lots of connections to multiple agencies. We're recommending that all happen. Now, let me talk about the Research Policy Board itself. The model that we have recommended follows the example of the Financial Accounting Standards Board, which is a federal it's a federally related entity. It's actually a private sector entity that is formally linked to and overseen by the SEC. It's funded by mandatory assessments on public companies on the things regulated by the SEC. It's been functional and effective since 1973. And it's organized and financially able to undertake relevant projects on a current need or anticipated need basis. That's the model that we've looked at. Obviously there's a great gulf between financial accounting standards and what we're talking about doing here. But we believe that the apparatus that has been chosen in that sector might be relevant for the sector we're talking about. The concept is a private sector entity that would be formally linked to and overseen by OSTB and OMB using a governance basis to be determined. We haven't been too explicit about membership and how it would be managed and all of that. Our view has been essentially that if it were to come into being, it would come into being through a negotiated process involving all the players and perhaps Congress and the people in the administration and there are different models. We're not, we haven't tried to cover all the details of how it would formulate, members would be chosen and it would work. But we're talking about this as a structure. That it would be funded by mandatory assessments of research institutions. It would be organized and financially able to undertake relevant projects on a current need or anticipated need basis. Enabled to work flexibly with the associations. The mission would be to improve and maintain a regulatory environment conducive to optimal performance of their search partnership. We envision maybe nine to 12 members from the academic institutions and six to eight liaisons from federal agencies, all designated through formal processes. That it should become the primary policy forum relating to the regulation of federal research programs and academic institutions. Now, because it's a private entity, not actually formally part of government, though reporting to government, its responsibility would be to recommend regarding conception, development, and harmonization, through good information, through studies that it could conduct, that it could organize with government agency participation dealing with prospective or existing regulations. It could look at negative or adverse consequences. It could look at the overall load. We were asked in our process to quantify the load. And we weren't able to actually to do that. Now, there's no tool. There's no information that an Academy committee can make access to give you an answer to that question. But it's a question that ought to be thought about on a regular basis. An organization like the RPB could have it as part of the charge. It should be future oriented, cognizant of needs, of trends affecting overall regulatory needs. Anticipatory based on future technological demands, scientific demands. And it should become a more systemic, integrated, meaning formally tied to government, and an effective operational forum on research related matters than any or all of the historic professional associations. That's the lay out for the RPB and for the recommendation that we have made regarding the creation of an associate director of OSTP to be

focused on the operation of the research partnership. I don't think I need to go further into detail now. There are many specific recommendations. I think if you have a copy of the slides you'll have a set of slides that I'll just say is an appendix that gives you the specific recommendations. Let me go back to this slide right here. And just now say, this is what one to three addresses. Actually mostly this is one. But there are several areas that we have recommended get early attention by OSTP, by OMB, by agencies themselves. First in that list is proposal preparation. There is a vast quantity of investigator time that is now soaked up by the lack of harmonization across agency lines in what's expected, that proposal submission time. Many investigators prepare essentially the same proposal for multiple agencies. It's a restructuring job. We believe that lots of investigator time could be saved by harmonizing in that area, and also using more effective, more effectively the provisions or the ideas that already exist in the community for just in time submissions of information that is not likely to be needed from the 80% or so of unsuccessful applicants. We, there are many pieces of the proposals that go in now that could be given just in time, and we made a recommendation for wider use of that. We have similar kinds of comments on conflict of interest. I might ask Barbara to comment on that. I might ask Barbara to comment on human subjects and also on animal research. But these are three other areas where we believe that there's a great deal of resonance across the community that early and creative attention could save quite a lot of effort. Barbara, you want to comment on any of those?

>>BARBARA BIERER: Sure. So on the conflict of interest policy, there are separate policies for many of the different funding agencies. Different thresholds, different expectations of when to report, what to report. And we have recommended harmonizing the conflict of interest policy across the federal agencies so there's one set of expectations which we hope would in fact enhance compliance if everybody knew for every proposal what they had to do and what they didn't have to do. For human subjects research, it's one of the places since the NPRM for the common rule has come out since this part one of the report, that we do intend to go back and not change our recommendations, but potentially annotate the explanation behind them and then to enhance that. For instance, with further consideration of HIPPA issues. But the four recommendations for human subjects research is, one, to introduce a re stratified human subjects review so that would reduce regulatory burden on minimal risk research while preserving review and attention to that research which is of higher risk or consequence to the participant. That Congress should require single site review for multi-site research, but only after there's appropriate infrastructure to support that single site review and communication pathways. So an infrastructure both in terms of IT as well as policies and processes. Otherwise one risks having a patchwork of interactions that actually will make this process worse rather than better. That the Congress should direct agencies to align and harmonize their regulations and indeed even their definitions for human subjects research in order to know whether one is depending on the funding agency. How one defines a human subject. What the review expectation is, what the exceptions are, et cetera. Should be, again, harmonized across the agency. If one looks at the human subjects protections from the point of view of participant, the protections, indeed, should not differ. That we recommend that Congress amend the FDA's authority so as to allow the FDA to waive informed consent or modification of the requirements of informed consent, something that they can only do right now in very limited instances. And finally that Congress should instruct HHS to work with

other agencies to allow that research involving bio specimens is eligible for a waiver or modification of informed consent, so long as it meets the definition of minimal risk research. In animal research, we actually did a fairly deep dive, and I'm just going to show you one graph which you don't need to read. You just have to appreciate that depending on the funding agency. The expectations are completely different. And if you take the point of view of sitting as an animal, one would not expect the protections to any animal to depend on the funding source. So this is a good demonstration of how these kinds of regulations consume an enormous amount of time for both investigators and their institutions. So do you want to take over for inspectors general and audit?

>>LARRY FAULKNER: I think I won't. What I wanted to convey here, really, is the early attention that we're recommending in those four main areas. Proposal preparation, conflict of interest, human subjects' research and animals. The audit climate is the subject of our third recommendation. It is a complex issue. In some cases we've seen examples where there are policy disputes between auditors, excuse me, the inspectors general for an agency and the agency itself on the policy promulgated by the agency. They get fought out on university campuses. This is a federal dispute. It should be settled in federal offices. And not using universities as battle grounds. But more generally, if you look at the record of recoveries from auditing by inspectors general, you will see that there's not that much that comes out of the world of research. That this seems to be a place where inspectors general could make a greater contribution using the efficiency and effectiveness column of their charge as opposed to the waste, fraud, and abuse column of their charge. And we're simply recommending a rebalance in their attention to make positive contributions more likely. Compensation for personnel expenses is about payroll certification versus time and effort reporting. In the recent uniform guidance, the payroll certification method has been accepted. It is okay, according to uniform guidance, but there are disputes still between audit figures and agencies over that. We've simply asked for a higher level affirmation that payroll certification is indeed okay. So that universities feel the latitude to actually adopt those procedures. Right now they're afraid to adopt those procedures, even though they're said to be okay. The remaining things that we have in uniform guidance are there. They're significant. But they're not, I think, necessary for being reported to you today. So we won't talk about those. Barbara, you have anything else you want to add?

>>BARBARA BIERER: I think this would be a good time for questions.

>>LARRY FAULKNER: Yes. I think we are done. So thank you, Mr. Chairman.

>>ERIC LANDER: Well, thank you for that really great summary of this report. It's our practice at PCAST that we raise our flags when people want to ask questions. And Susan Graham's flag is up.

>>SUSAN GRAHAM: So I want to thank you very much for all the effort that you've put into this report. I think that anybody who's ever done funded research has their horror stories about the problems with the present system which are only getting worse. I'm a believer in evidence based decision making. And so let me say first, we have a summary of your report, but not the whole report. And so it's very possible this is in your report. But I have two questions about evidence. One is, research universities

are increasingly accused of bloated administration. That we're hiring more and more administers, and the money should go for faculty and so forth. And it's our belief that a certain amount of that bloat comes from hiring people to do compliance. And so my first question is whether there's any studies, any quantitative evidence of that phenomenon and the increase in compliance officers and the like over time. And the second question is from the point of view of the regulators, are there any measures of the effectiveness of the regulations in accomplishing the avowed purposes of those regulations. In other words, do they actually do the job for which they're intended?

>>BARBARA BIERER Yeah. So I think that what both comments reflect a sense from the committee that very little data is available. And that would be one of the principal, or a function of the RPB, to collect that kind of data. We did hear from individuals, but that's all anecdotal, about that bloat and the rise. I'll say two things about that. One, the number of compliance officers, or the number of people in compliance, severely underestimates the number of administrators that are there to ensure compliance at the transactional level. So I think that would be a potentially one surrogate to look at, but not really the impact that you're looking for. And I'll also say that we heard that in institutions, because they have this patchwork of regulations with which to comply, raise the level of expectation of all research to the highest compliance threshold in order to ensure that they're compliant regardless of which funding agency there, you know, a specific project is funded with. Because it's almost impossible to ensure that if you do a project by project, dollar by dollar. Again, not a lot of data there. And as far as we know, I don't think we've heard any data about from the funding agencies themselves about the efficacy of the efforts, particularly with the instruction of new regulations. It's one of our recommendations is to essentially review new regulations periodically, say in five years, with the expectation that answer would come in. We can look at a conflict of interest, for instance. And there has been a good study now from the AAMC on the cost of the implementation of the NIH conflict of interest with very few important new conflicts being exposed, but enormous resources for the research institutions to comply with that regulation.

>>LARRY FAULKNER: There's not any doubt that institutions are hiring people to address the compliance matters, and that there are some increases. That has to do with the broadening scope of federal regulation. One statistic that we had, I can't quote is exactly at this point, but the rate of instruction of new federal regulations has substantially increased since the early 1990s. And there are certainly reaction to that. We have had declarations by individual institutions which I have no doubt are accurate, that they are by policy trying to unload, or to relieve, faculty members from having to deal with compliance issues that have historically been done at the investigator level. And they're having to hire people to do that. So there certainly is some strategizing being done by institutions that is leading to hiring. But Barbara's right, we don't have comprehensive numbers.

>> BARBARA BIERER: Here I am Vanna White showing you the data. This is the introduction of regulations. This is only regulations, not guidance. And this is over time. And this is, for instance, one of these dots is HIPPA. So this is by no means an overestimate of the kind of regulatory climate we're facing.

>>LARRY FAULKNER: Those with quanta, not sizes of quanta.

>>ERIC LANDER: Chad Mirkin.

>>CHAD MIRKIN: First of all, thanks to both of you for taking on this very important topic. It's one that's really bothered me for quite some time and many of my colleagues. I'll start by, I guess, connecting to the first for the question just asked, if you do a cost analysis, right? Investment versus what we gained, how does it bear out? An enormous amount of money, not just time, money, has gone into implementing all of these. And over my career, over 25 years, it's increased dramatically. I would guess that the amount of money saved, or the problems found have been fairly minimal. So the question is, what are we get out of this from an investment standpoint? And the second one, I have a very different experience from what, Larry, you referred to in terms of institutions hiring people. I found that universities have been hiring people to deal with these, but to deal with them from the university's perspective to make sure that they are covered. And in the process, over the last ten to 15 years, they have shifted a tremendous amount of responsibility to the individual PI who is not staffed well enough, does not have the background to really deal with them. So you've got a real tension created because of these. And I was curious if the committee's looked into dealing with that.

>>LARRY FAULKNER: The committee hasn't looked into that issue. And I have no doubt that story plays out differently in different institutions. There are institutions, I think, that have made a conscious effort to try to unload investigators. And, you know, I've seen that, and can testify that there are such places. I can't say.

>> BARBARA BIERER: And I can testify to the reverse.

>>LARRY FAULKNER: Yeah. All right. But you ask another question, really, Chad. The question was essentially what do we get for, you know, in kind of, if there's a dollar quantification, there is no data that can tell you what we're getting for the, and it's not even easy to put in dollar terms what the diversion is.

>>CHAD MIRKIN: Don't you think we should try? Because the cost is enormous.

>>LARRY FAULKNER: I don't disagree. And one of the things we say is that the Research Policy Board should have that as one of its mission to try to quantify cost and benefit. But in the end, what we're diverting in my mind, the most important thing it's diverting is not financial resources, its diverting investigator imagination and attention of that investigator to the issues that we're paying for. That we really want that investigator uniquely to address. And we're taking that capability and putting it into a much lower order of activity.

>>ERIC LANDER: Let me call on Mike McQuade.

>>MICHAEL MCQUADE: Maybe sort of a two part question and it relates to public research universities. The first part of the question, you refer to this Research Policy Board as a private entity. Are there any subtleties associated with the fact that there's a significant amount of government funded research

that occurs in public universities? So does that create any sort of subtleties at how you looked at this? The second question, the broader question is, are there overlapping issues between regulatory framework imposed on public universities by states that are in play here at all? Or is this solely a federal research funded sort of view of the landscape?

>>LARRY FAULKNER: I come from Texas where the state doesn't regulate much.

>>BARBARA BIERER: And I come from Massachusetts where it's not quite the same. So we did not specifically address all of the state regulations in our deliberations to date. So I cannot say that we took that into account. And how the state regulations would interdigitate with the Research Policy Board is something we should take back to the committee and discuss. Thank you for that.

>>LARRY FAULKNER: Your first question was about the word "Private." The model that we have recommended, I mean, it's not the only model for a research policy board. It could be a purely governmental entity, if Congress wanted to create such a thing. What is attractive about the FASB model is I think the flexibility that it has to do anticipatory project work. It has the ability to forecast what's likely to be important, to organize teams flexibly to go do that. And because the financial basis for it is outside the federal budget, it is not as constrained as the federal government is in organizing teams or even advisory bodies of any kind. So what we see is the greater flexibility for an RPB that is separately funded, outside the federal budget, is worth that distance. But you're always trading, of course, I mean, by creating distance you create less influence, I mean, in some sense. So, I mean, you have some trade off there and people who have talked about this think we could go different ways. In the end, as I said earlier, my belief is that if we as a nation go towards some structure like this, what exactly it becomes will get argued out and won't be settled at the National Academy of Sciences.

>>BARBARA BIERER: But just to address the question directly, there's no intent to exclude public universities from this effort. How the assessment gets dealt with, and whether they're private funds in the public universities, which there are, or another mechanism, a waiver for those funds, we didn't address. But there's no expectation that they wouldn't be part of it.

>>MICHAEL MCQUADE: No. My question.

>>BARBARA BIERER: In the same way, we haven't defined the membership just, you know, there could be industry representatives. They're part of the scientific enterprise, et cetera. And we need to think about that further.

>>ERIC LANDER: Good. Very good. My Co-Chair John Holdren has a quick comment as well.

>>JOHN HOLDREN: Yeah, I just want to first of all thank Dr. Faulkner and Dr. Bierer and their colleagues for what obviously has been and continues to be an extraordinary amount of work. I'm very impressed by the detail you have gone into, the way you have parsed the different parts of the problem. I think this is going to be extremely useful to the Administration as we continue to struggle with this issue we are aware of it. I myself spent 40 years in universities and research institutions of other kinds since my

Ph.D. before I became a government official. So I spent a lot more time on the receiving end of these regulations than I have spent on the dispensing end. And I'm extremely sympathetic. And I know that Howard Shelanski is as well. I'm glad you showed the quote early on to indicate that there are folks in the administration in key positions who understand what a big problem this is. But I think your report is going to be a tremendous help to us as we move ahead aggressively. So thanks again.

>>ERIC LANDER: Let me add my thanks as well. We're very much looking forward to seeing the second part of this report. And really seeing the impact that you're really detailed. And that's the best kind of recommendations are detailed recommendations we'll have. On behalf of all of PCAST and on behalf of tens of thousands of people at universities across the country, thanks for taking on this problem.

>>ERIC LANDER: Thank you.

Public Comment

>>ERIC LANDER: So in the remaining part of the meeting, we're going to turn to our public comment section. And we have four public commenters here with us. And I'm going to turn to one of the PCAST Vice Chairman, Maxine Savitz, to lead the public comments section of today's meeting.

>>MAXINE SAVITZ: Thank you. I'm pleased, what he said, we have four people from the public today. Two related to the report on hearing technology, and two related to nanotechnology. The first one will be Alicia Spoor, the treasurer of Academy of Doctors of Audiology. And thank you for coming forward. And we have a two minute rule that you have two minutes and at 90 seconds, there's a light up there that will turn orange and you know you have 30 seconds to go.

>>ALICIA SPOOR: Fantastic. Well, on behalf of the Academy of Doctors of Audiology, thank you for the opportunity to comment. On November 12th we published a letter to the President providing qualified support for all four of the recommendations contained in the PCAST report. We emphasize that the provision of quality audiologic services is critical to successful patient outcomes. We want to make sure that that fact is understood by this Council, particularly considering the broader initiatives for improving access to affordable care for older adults. Professional evaluation and treatment are vital in remediating a patient's communication disabilities. Better hearing cannot be achieved through a device alone as its one component of the successful treatment. We recommend that over the counter hearing aids and PSAPs have a strong recommendation that a consumer get an evaluation from an audiologist or physician. We foresee confusion in the report's terms of the word class and category. Due to FDA recommendations and definitions, we recommend that the report only use the term category. We also recommend that PSAPs carry labeling that clearly indicates they are not FDA registered devices. We encourage the development of PSAP standards by ANSI. For the record, we are opposed to online diagnostic testing. We are very supportive of online hearing screening tools. From a clinical standpoint, there's a clear distinction between testing and screening and those terms are not interchangeable. The federal government must do more to ensure that older adults have access to audiologic care. We have included several recommendations to bring Medicare in line with today's best practices. Finally we believe that awareness is the greatest barrier to diagnostic and treatment for

hearing loss. We asked that the CDC be directed to prioritize hearing loss as a significant public health issue and encourage efforts that promote greater attention to this issue by primary care physicians. We are pleased to see governmental recognition of hearing loss and the focus on hearing impairment, specifically related to hearing technology. It's critically important that the same level of attention and emphasis be directed towards ensuring patient access to high quality care. We look forward to continued dialogue on these issues and would be pleased to assist. Thank you.

>>MAXINE SAVITZ: Thank you. Our next speaker is Dr. Neil DiSarno, Chief Staff Officer, Audiology, American Speech Language Hearing Association.

>>DR. NEIL DISARNO: Thank you. On behalf of the American Speech Language Hearing Association and its more than 14,000 audiology members, I am speaking in concern and in opposition to the PCAST recommendations that focus narrowly on the price of a hearing aid. This narrow focus does not represent cost effective, evidence based practice of hearing healthcare. A hearing aid alone is not enough to overcome a hearing disability. Treatment for hearing loss, even mild to moderate hearing loss is complex, particularly amongst seniors. Audiologists provide an individualized assessment of a person's hearing needs that goes well beyond the measure of pure tone sensitivity. This includes consideration of listening and background noise, specific tests of middle ear and inner ear function, and the important cognitive and psychological factors that impact a person's ability to use a hearing aid. The council made a common but serious error in assuming that hearing is analogous to vision, a misconception that was evident in the PCAST report is that amplification alone will enable a person with hearing loss to hear and understand fully in the same manner that glasses restore vision. Even the most advanced hearing aids cannot restore hearing to 100% in the way that prescriptive glasses or some over the counter readers provide 20/20 vision. A hearing aid makes sounds louder, but not necessarily clearer and will not restore normal hearing function. A hearing aid alone cannot address the consumer's disability. It is the audiologist who has the focus on your parents or your grandparents need to hear and communicate at work and with family and friends. It's the audiologist with scientific, evidence based methods of evaluation and rehabilitative treatment who will ensure that the consumer, and that could be you, your gets value and benefit from a device used to amplify sound. We respectfully request that this Council takes a view that addresses hearing disability rather than focus simply on the cost of an amplification device. The council should make recommendations that consider evidence based hearing health care practices that improve affordable access to these services. And thank you for the opportunity to provide this statement.

>>MAXINE SAVITZ: Thank you. Very much. Our next speaker will be on nanotechnology. Jim Herd, Director, Green Science Exchange.

>> Thank you. I'll be skipping a few paragraphs from the written version due to time constraints. Nanotechnology is absolutely fundamental to a majority of all non-digital products sold in the United States today. Semiconductors, defense applications or consumer products. As I have said for years, when we entered the micron era 40 years ago, naming a company micro or soft was the last thing you wanted. But a company named Microsoft became one of the most important companies in the entire

world. 40 years later, nano is having the same fundamental impact, but very few people in the general public are hearing about it. We are in a nano enabled world. My battle cry to empower the average person is, quote, manage your own molecules. End quote. Whether it's your biological molecules or the valuable physicalogics you use in everyday life. And many of our biggest U.S. corporations have dramatically reduced talking about nano tech in their products over the last ten years. Intel does not talk about its nanotechnology like it did in 2004. IBM talks less about it than it did ten years ago. DuPont does not talk nearly as often as how powerful its consumer products are enabled by nano scale features. GE used to talk about nano as one of the five areas critical to its R&D future. Cosmetics companies have taken the nano label off some of its cosmetics. Clothing sold across the United States that had nano coatings to stop spills is not labeled that way nearly as much as it used to be. Many of these companies have cut back due to threat of litigation from consumer groups who fear nano scale products can affect the cells of their skin and tissue, and also from EPA litigation and compliance issues, if the word nano is used to describe the benefits of their products. Countries like Russia, China, and Korea, do not have the litigation from consumer groups and from environmental regulation that the U.S. has. Now nanotech is primarily done by large U.S. corporations. As a result, investors have run the other way when the word nano is pitched to investors. Make no mistake about it. This is a serious problem. And our brightest young minds are attracted to make digital apps, not breakthrough materials innovations. Thank you very much.

>>MAXINE SAVITZ: The next speaker is Caroline Trupp Gil, Director for Federal Relations, the American Chemical Society's Office of Public Affairs.

>> CAROLINE TRUPP GIL: Good morning. My name is Caroline Trupp Gil, and I'm speaking today on behalf of the American Chemical Society and its more than 158,000 members and in particular, ACS President Diane Grob Schmidt. The ACS would like to commend the Obama administration for prioritizing investments in nano science and to affirm the OSTP's nanotechnology grand challenges. As you heard earlier this morning, the field of nanotechnology has seen enormous advances since the inception of the NNI. The interdisciplinary tools and technology enabled by nano science have the potential to benefit society in many ways, medicine, energy, water, food, materials, and electronics to name a few. Breakthroughs in nano science touched virtually all aspects of the chemistry enterprise. The mission of the ACS is improving people's lives through the transforming power of chemistry. And nanotechnology has demonstrated how truly transformative chemistry, and indeed all of science can be. Looking ahead, the scientific community must now address the realities of moving promising research out of the lab to the market. Many basic nano material applications are already in the marketplace as product enablers. But high volume manufacturing of more advanced and sophisticated materials remains a challenge. And as with all new advances, meeting that challenge in an environmentally safe and responsible manner, must be an integral part of the plan. For all of these reasons, ACS believes the National Nanotechnology Initiative continues to play an invaluable role in providing support, coordination, and focus. ACS applauds the OSTP nanotechnology grand challenges effort which will ensure that nanotechnology's enormous potential continues to be developed for

societal good. And finally ACS looks forward to continuing to partner with OSTP and the National Nanotechnology Initiative to encourage our members in meeting these challenges. Thank you.

>>MAXINE SAVITZ: Thank you. And I want to thank all the speakers from the public. We do encourage the public to come forward and give us their views at each of our meetings.

>>ERIC LANDER: Well, thank you Maxine. That brings us to the end of the agenda for today's meeting. I want to thank everyone from the PCAST, everyone in the room, and everyone including our public speakers who have spoken and who led the sessions before, and everyone watching on the web. And I am going to turn back to John Holdren for any closing words.

>>JOHN HOLDREN: As usual I think this has been a full and very interesting meeting. We have had a number of important issues before us. Have approved a new report. And have, I think, a clear path forward on a variety of critical issues for the science and technology future of the country. So, again, I can only add my thanks to Eric Landers, to all of the members of PCAST, the OSTP, staff and the wider community who has been with us in all of this. Thank you very much indeed.

>> Adjourned.