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

>>John Holdren: Good morning, everybody. Let me welcome you all to the 30th meeting of President Obama's Council of Advisors on Science and Technology. Count them—30. This has been, as I've said before, an incredibly productive PCAST. I think we're now something over 26 reports on a wide range of science and technology issues, prepared at the request of the President—all of them available on the PCAST page of the OSTP website, www.OSTP.gov, and the group continues to be very busy with a number of studies currently underway and intensive interactions with each other, with the wider community, with the various departments and agencies in the administration on issues ranging from basic research, bio medicine, advanced manufacturing, biohazards, energy, the climate action plan, and much more. This morning, we're going to have sessions on two topics of great immediate, as well as longer term relevance. The first panel will be on antibiotic resistance, and, just this morning, the administration has released its national action plan for combating antibiotic resistant bacteria. This is the fleshing out of the roadmap, if you will, for taking action in pursuit of the aims of the national strategy on combating antibiotic resistance, which was released some months ago. Then, following the break, we will have a session on Arctic policy. Arctic policy is of increasing interest for a variety of reasons, the United States is about to take over the chairmanship of the Eight Nation Arctic Council in May for a two year term. That means we will have a lot to say about international priorities in the Arctic going forward. Science is an important part of those priorities, but only part. One has issues around the increased opportunities for navigation and resource exploitation in the Arctic, associated with the decline in sea ice. One has enormous issues on the tension between resource development and conversation and preservation. One has issues of the native cultures and engaging them in decisions that affect their well being. So, we'll be hearing all about that in the second panel this morning. I have the pleasure, as of about a month and a half ago, of chairing the Arctic Executive Steering Committee for the administration, which is trying to make sure that across all the many departments and agencies in the administration that have responsibilities related to the Arctic, we have a coordination communication, a coherent set of priorities and effective implementation. So, without a lot of further adieu, let me first call on my co-chair, Eric Lander, to see if he has opening remarks, and then, I think we'll turn very quickly to the panel on antibiotic resistance.

>>Eric Lander: Indeed, we will. So, I just want to echo John's welcome to everyone. It's great having a full room here, and I know we have a lot of people on the web who are joining us and will be joining us, as this is posted and archived. It has remained an incredibly busy period for PCAST, and so, I just want to take a moment to thank all the members of PCAST. There are a large number of studies still in progress, several having been finished up, and much more ongoing, and I just really want to thank everyone for the continued effort here.

**Antibiotic Resistance**

>>Eric Lander: We're going to hear, in just a moment, about the response to one of those studies that PCAST did. The report we did, not so long ago, to the President on combating antibiotic resistance, a report at the request of the President, and one of the things that happened was the President issued an executive order, directing the federal government to produce a national action plan, and it's my understanding this national action plan was released this morning so the timing could not be better, and it might not even be coincidental that they chose to do it when they were showing up to tell us about it. No, actually, it's great to have you. I'd like to invite the panel to come up, who has been working very hard since the executive order was released last fall toward the idea of producing a national action plan. It has just been released, so, in fact, we want to hear about it. We're getting to see this now and one of the things in the executive order was that amongst other things, it was supposed to be explicitly responsive to, that is, considering each of the recommendations PCAST made, and I've had a chance to flip through it enough to see it references those recommendations, but I really want you to walk us through what's going on. We had a great panel up here, which I'm not going to read the full panel bios of because we're on the web. I'll welcome Susan Coller-Monarez who's the Assistant Director for National Security and International Affairs at OSTP, and Michael Stebbins, who is the—where are you Mike?—who is the Assistant Director of Biotechnology at OSTP, and I think they're going to start us off by setting the context, and then, we are going to turn to a great collection of speakers who are going to be able to tell us a little bit about how this interacts with the critical agencies. Beth Bell, Director of the National Center for Emerging Zoonotic and Infectious Diseases at CDC. Joe Larsen, the Acting Deputy Director, Division of CBRN Medical Countermeasures at BARDA, the Biomedical Advanced Research Development Authority. We have William Flynn, the Deputy Director for Science Policy for FDA and the Center for Veterinary Medicine, and I'm sure there will be a lot of interesting questions around that, and we have Steven Kappes, the Deputy Administrator for Animal Production and Protection at USDA. So, having before us all these relevant agencies, and the EOP representative, we're all ears. Tell us about the national action plan. Maybe Susan will start us off.

>>Susan Coller-Monarez: I will. Thank you. First, I want to say, about a year and a half ago, the President did come to this advisory body and asked for specific actionable recommendations to address the crisis emergence of antibiotic resistant bacteria, and over the course of that, the past year or so, the recommendations that came out of this body were tremendous. So, I would encourage anyone that hasn't had an opportunity to read that PCAST report, which was issued by the president last September, to take a hard look at it, and to look at the depth and the detail that came out of that report, and Dr. Lander is absolutely correct. What the President then did was, based on the recommendations in that report, he issued an executive order that tasked the federal government to develop a national action plan that identified roles, responsibilities, milestones, and metrics associated with those actions needed to meet the tenants of the PCAST report and the national strategy for combating antibiotic resistance. I don't want to spend too much more time talking about the context because I want to make sure that we hear from our colleagues from across the departments and agencies that are

responsible for executing the actions that have now been delineated in what the national action plan that was released this morning by the administration, but both Michael Stebbins and I are happy to take questions at the end of their briefing. So, with that, I'm going to turn it to my colleagues and agencies, Dr. Beth Bell from the Centers for Disease Control and Prevention.

>>Beth Bell: Thanks very much. I do have slides. There we go, okay, great. From the CDC, I have to have slides. Thank you so much for the opportunity to talk with you this morning. As you've already heard, the problem in antibiotic resistance is an extremely serious one and a growing one, and at CDC we listed a report about a year and a half ago which estimated at least 2 million infections per year from antibiotic resistant organisms and estimated at least 27,000 deaths. That's sort of not including some of the other growing threats such as clostridium difficile that unfortunately many of you have heard about because it's such a common problem, where we estimate at least 15,000 deaths per year from clostridium difficile. It's—the problem of antibiotic resistance is a complex problem and it requires a comprehensive solution, and that's, I think, from a big picture perspective, is what we've done with the National Strategy and the action plan. We very much appreciated and certainly at CDC, we very much appreciated the input from the PCAST and the PCAST report which did inform, very substantively, the way that we put together our strategy as part of the overall administration's strategy which we're calling the AR Solutions Initiative. An important point, I think, about this problem and the solutions, is that there are certain things that we know can be done now to address this problem. Prevention is a really important component and actually we do know many strategies that we know can work that need to be focused and scaled up and that's much of what we're talking about here. You know, even with the development of new antibiotics, this is a process that takes a decade or more, and there are things in the prevention space, as I say, that we can do now to start to make a difference with presenting antibiotic resistant infections. So, our strategy and initiative here is quite comprehensive with the President's budget reflecting what you see in the strategy and the action plan, and calling for comprehensive tracking, improving detection, faster outbreak response, some insights which might help drive research and innovation, better patient care, and improved prescribing, and what I wanted to do for a couple minutes here is highlight a couple parts of the PCAST recommendations and then tell you a bit about how our strategy and plan fits in with the PCAST recommendations. I'm turning off and pushing the wrong button. Okay, so, PCAST recommendation number two was about effective surveillance and response to antibiotic resistance, and in the PCAST report, you recommended strengthening state and local public health infrastructure for surveillance and response, with state and local programs for detecting AR, for outbreak response, and for aggressive prevention activities across health care and community settings, including enhanced stewardship programs, with a focus also on addressing community AR threats, as well as threats in facilities, and, also, to establish a national capability for pathogen surveillance based on genome analysis, with a national library network for surveillance with a reference collection of sequences and with surveillance in diverse settings through our emerging infections program, EIP, and NARMS which is the acronym for the National Antibiotic Resistance Monitoring system, so let me go in to just a little bit of detail about what we have done. So, for the first component of our response here, we're calling stop, spread, protect people. And what we're proposing to do is

establish state AR prevention programs in all 50 states and ten large cities. I think that because this problem of resistance really is happening in communities, we need a response, which is focused on communities and building real programs in states and localities that can address the problem. There is very solid and growing evidence about the importance of colonized patients being, moving from facilities, from hospitals to long term acute care to nursing homes and back and forth and this kind of interrelationship among many facilities and communities is really a pivotal part of how antibiotic resistant organisms are spread, and, so, we need a real program in states with the state Health Department as sort of the Nexus, bringing together all of the facilities and partners to address this. We are—CDC is part of the National Antimicrobial Resistance Monitoring System, NARMS, which is, you'll hear from my colleagues from FDA and USDA is actually an integrated surveillance system. Our part is about illness and people, and part of our proposal here is to greatly scale up our capacity to test isolates for resistance in food borne illnesses. Right now, we test, for example, only about 5,000 salmonella isolates a year for resistance. That's about 5% of the number of isolates that are collected every year. It's about 40,000, and so, you can imagine how poor a sense we have of resistance in food borne pathogens because of how limited our capabilities are. And we also have some components about gonorrhea and some components about isolate bank, which would help with the development of next generation diagnostics. I'll go into that later if people are interested. We have spent quite a bit of time talking, looking into tracking, which is something that PCAST highlighted, and we are calling for the establishment of a detect network of AR regional labs to actually provide us with the kind of information about what are the most important resistance mechanisms, where are the hot spots, and to be able to have some sense of emerging threats, and some other components that I'm going to skip over, but we also, again to the PCAST recommendations, are calling for the doubling of our emerging infections program sites. This is really gold standard surveillance and provides us with the sort of actionable information that we need to drive prevention strategies. PCAST recommendation number six is about stewardship and overuse and incorrect use of antibiotics in human health care, is one of the most important drivers of antibiotic resistance, and we need to address this if we're going to make an impact. So the PCAST recommendation number six called for improving stewardship in hospitals and long term care facilities, antibiotic use in out-patient settings, measuring antibiotic use and resistance through our national health care safety network, getting a better sense of data on antibiotic use and ambulatory settings and a number of associated recommendations. So, in our initiative for FY 16, there are a couple components. The first is about the data parts, and we need to add capabilities to our national health care safety network. This is the largest network that hospitals and facilities use for monitoring health care associated infections. It's currently in about 14,000 facilities and over 5,000 acute care facilities. We have developed and need to implement, and scale up widely, two additional capabilities. One, which electronically captures antibiotic use in hospitals and the other which electronically captures resistance isolates, resistant organism reports. We need this so that hospitals and facilities can look at their own data for quality improvement. So states can use this data in their prevention collaboratives and for us to benchmark at the national level. We also have a number of strategies for improving use and steward, strengthening stewardship, better data, as I mentioned. With these data, we can set national standards of antibiotic use to improve use and reduce resistance. We have very clear guidelines about what a hospital stewardship program

should look like and we want part of this strategy and the plan is to ensure that all hospitals have effective stewardship programs. Further work on understanding and acting on state by state differences and out-patient prescribing and additional work to innovate and test new intervention strategies through improved prescribing. That's, I'm going to close there, just to let you know that we at CDC see this as an enormous opportunity to really save lives and make a big difference in terms of public health. We have a lot of materials on our website that people can use to further understand the components of our strategy. Thank you.

>>Joe Larson: Good morning, everyone, I'm Joe Larsen. I'm the Acting Deputy Director of BARDA, CBRN Medical Countermeasure Division.

>>Eric Lander: Move your microphone just a little closer there.

>>Joe Larson: Is that better?

>>Eric Lander: Yeah, so people on the web will be able to hear you.

>>Joe Larson: So, thanks to PCAST for inviting me to come here today and tell you about what BARDA's activities have been and what proposed activities are, given the proposed action plan. For those of you that aren't necessarily as familiar with BARDA. BARDA is the government's advanced developer of pharmaceutical products for chemical, biological, radiological, nuclear agents, endemic influenza, and emerging infectious diseases. What's it mean to be an advanced developer? It means we focus on phase one, clinical development, through licensure and approval of products. We include antimicrobial resistance as infectious disease and is part of our mandate. We work with our federal partners to transition earlier stage products, you know, like our partners at NIH and within DOD to transition early stage R&D into products and then pursue their ultimate FDA approval. Our kind of niche is forming novel public, private partnerships with industry to support this mission, but in addition, it's not just simply about giving companies money, it's also about setting the companies up for success and we do that through providing subject matter expertise on pharmaceutical development, but we also have a series of core services to allow for clinical development, nonclinical development, and manufacturing of drug product, all of which will help facilitate, particularly, smaller companies in achieving their aims. Since BARDA's inception in 2004, we've supported over 150 different medical counter measure product candidates, in aggregate across both our chemical, biological, radiological, nuclear portfolio, as well as our pandemic influenza portfolio, and as a result of that, we've now seen, we're now reaping what we've sown and have generated, kind of, we've become seasoned product developers and now have overseen the FDA approval of over 20 products, including one that was approved this last Wednesday, March 25th for the treatment of inhalational Anthrax. Now, the BARDA model exists and the model is supporting product development and providing core services that enable developers to be set up for success, really serves to address market failures. If you look at , right after the Anthrax attack, the fact there wasn't any product developers developing products for those kind of agents, or if you look at our influenza vaccine capacity, to the surge capacity to ramp up in a pandemic, in both of those instances there were market failures, and the causes of market failure are different, but

nevertheless, the BARDA model has been successful in supporting products for both of those areas, with three products now being approved for CBRN agents, you know, a vast majority, more, obviously, being 17 more for pandemic influenza, but we've also resulted in stockpiling 13 products within the Strategic National Stockpile for use during public health emergency. And so, similarly, we view antimicrobial resistance in the market failure that occurs there, occurs for a different set of circumstances, but nevertheless we feel the BARDA model can be successfully applied, and, in fact, five years ago, we established a program on antimicrobials within BARDA, and now, with an aim of really utilizing novel public, private partnerships to incentivize antibiotic research and development, and an ultimate aim of trying to re-engage industry and innovation in this area, and so we're currently supporting seven product candidates, and I'll discuss some of those with you in a few moments, but four of those products have now advanced into phase three clinical development which is the ultimate phase before you submit a new drug application to the FDA, and in the phase three development, one conducts two different registrational trials, two different phase three trials, and two of our products have now hit their endpoints in one of the two phase 3 clinical trials, which is a strong signal that they will be set up for a successful regulatory filing. Here's our current portfolio, and I'll briefly walk through this. I will say up front that all of these programs that I mentioned have a biological terrorism agent component to them, meaning we're evaluating those products against those agents. Recognizing that that's not a focus of this discussion, I probably won't spend a lot of time on that, but, if you have questions, please let me know, but that's part of our core mission, and one that we still are adhering to. We're funding a company called Achaogen to develop a next generation aminoglycoside for the treatment of carbapenem resistant enterobacteriaceae, one of the most severe hospital acquired infections. It's one of the urgent threats deemed by the Center of Disease Control. It's currently in Phase III clinical development, and is enrolling patients in a trial, looking to examine Plazomicin, in terms of superiority over the standard of care right now, which is a very toxic drug known as colistin. We're supporting a company called Tetraphase, which is out of the Boston area, for a drug called eravacycline which is a next generation tetracycline, which overcomes all know tetracycline resistance mechanisms. They're pursuing indications for complicated intra-abdominal infection and complicated urinary tract infection. They current are in phase III clinical development, and have completed their complicated intra-abdominal infection study and hit the primary endpoint of demonstration of non inferiority against ertapenum and are currently enrolling a second phase III clinical trial for complicated urinary tract infections, and they are currently enrolling patients in that trial. We're funding a company called Cempra Pharmaceuticals who's down in the Raleigh Durham area, and they're supporting solithromycin, which is a next generation ketolide antibiotic for the treatment of community acquired bacterial pneumonia. They currently, also, have completed the first of their two Phase III clinical trials to support NDA submission. They hit their primary endpoint of demonstration of non-inferiority against moxifloxacin and are currently enrolling their second community acquired bacterial pneumonia trial for that indication. We're funding a Swiss company called Bazilea Pharmaceutica for the development of BAL30072, that's a novel betalactamine antibiotic that is proposed to treat hospital acquired gram negative infections, including complicated urinary tract infections and hospital acquired, or ventilator associated pneumonia. They're currently in Phase I development. We're supporting a company called Rempex Pharmaceuticals out of San

Diego, they're developing a product called Carbavance which is a combination of a carbapenem antibiotic meropenem, with a novel beta lactamase inhibitor RPX7009. They currently are also in Phase III clinical development. They are pursuing indications in complicated urinary tract infection, and eventually hospital acquired and ventilator associated pneumonia. They're enrolling patients in a complicated urinary tract infection study for Phase III. The last partnership that we have is a partnership we established with GlaxoSmithKline, and I'd like to spend just a little bit more time talking about this one because it's a model that we're hoping to replicate going forward with additional companies as means of sending a strong signal to industry of government incentives to try to reenter into this space, and we established this partnership back in May of 2013, and, in fact, we have previously had a contract with GSK for the development of another product, and we spent about a year negotiating that contract, and then, we got them under contract, and, about three and a half months later, the program failed in phase II clinical development, and we said what a tremendous waste of everyone's time that was, and so, how can we think about ways—how can the government think about ways to partner in a way that accounted for technical attrition and failures that occurred in drug development, which are inevitable, and so, we came up with a portfolio partnership approach, and this is a five year, $200 million partnership with GSK that utilizes a government contracting mechanism that HHS had never used before that we've used for the first time here called other transactional authority, and it allows for governments to partner with industry in a way that outside the constraints of federal acquisition regulations, and the terms of those agreements can be constructed de novo. It supports the development of multiple antibiotics. It has an immense amount of flexibility. Candidate products can move into the portfolio. They can move out of the portfolio. We can adjust the relative level of investment across each one of the candidates in the portfolio, depending if there's a risk that materializes or if there's a programmatic emphasis that we want to focus on a different candidate. These decisions are also made in a very collaborative fashion in a joint oversight committee, where senior officials from BARDA and senior officials from GSK meet approximately every six months and decide how we're going to invest the money going forward so that both parties' interests are best realized, and this has really been an effective model. We currently advanced a novel class of antibiotics into Phase II clinical development, and are preparing to undergo candidate selection for another novel gram negative antibiotic, which is one of the areas of the highest unmet medical need right now. So, , our current funding for FY 15 was $79 million. Our requested budget at FY 16 is $192 million. If we get that, we're going to expand our role into diagnostics programs. We also envision establishing two to three additional partnerships like the ones I've described, with an emphasis on utilizing this other transactional authority as a means of establishing long lasting, you know, definitive commitments that we're engaged in this area. In summary, you know, we feel that a diverse and vibrant antimicrobial pipeline is absolutely required to address this threat, and we're going to continue to put out market incentives for industry to help subsidize the cost of developing these desperately needed drugs. Thank you.

>>John Holdren: Great, thanks. Let's turn now to FDA and then USDA.

>>William Flynn: Good morning. I'm Bill Flynn. I'm with FDA Center for Veterinary Medicine. As you're aware, FDA initiated a strategy back in 2013 focused on making some important changes

to how antibiotics are used in, in the animal agricultural sector, and that's really what I'm going to focus on, providing an update to you this morning as to what the status of that effort is and what we see as next steps as we move forward. There's really three areas that we're focusing on as part of this process. One, as I mentioned, is we're focused on making sure we effectively implement the key changes which I'll briefly talk about further. And we want to make sure that we hit our target of implementing the changes we've identified, outlined in this guidance we issued back in December 2013. Second, that we're, as part of our effort with moving forward and implementing the changes, we understand the critical importance of making sure that we have sufficient information in hand as far as the necessary data to, to enable us to measure the effectiveness of the things that we're doing to affect change in terms of antibiotic use practices and the effect of those practices on resistance issue. And then third, it's really looking forward from here in terms of what, what additional measures do we, do we need to take to further support the idea of appropriate stewardship of antibiotics, and again, in this case, focusing on the use in the animal agricultural sector. So, when it comes to the implementing our guidance, there are two key changes which we think are really important and significant changes to how antibiotics have been used for decades in animal agriculture. One is to limit the use of the drugs that we consider of human medical importance, to limit those uses to the situations in animals where it's really only necessary for addressing the health needs of the animals, that means focusing on using those products only for therapeutic purposes and the meaning of that is that we, as part of this effort, the plan is to phase out the use of any of these medically important drugs for production type purposes that are primarily intended to enhance growth or improve feed efficiency in the animal. Second important change is to bring all these products into the oversight of licensed veterinarians. Currently, these products, as I listed here, there's seven different classes of antibiotics, all of which we considered to have human medical significance. The seven classes are currently used in the feed and water of food producing animals, some of which, not all of the seven there, also have approvals for enhancing growth and improving efficiency. So, the intent, then, by implementation of this strategy is that all the growth promotion, feed efficiency type uses of these antibiotics will be eliminated and all the remaining therapeutic uses that will remain on the label of these products will now be brought under the oversight of licensed veterinarians. When you look across the seven classes of drugs, there's, there's approximately 280 approved new animal drug applications that are affected, so that means that one of those seven classes and are drugs that are currently approved in feed and water. So, all of those products, currently, are available as over the counter products. So, there's no requirement now for authorization from a veterinarian. So, all of those products then as part of this process will need to change as far as their current marketing status from the current OTC status, to a status that requires veterinary oversight and for, and I'll go into this a little bit, for those products that are used in feed, those, that means that they get designated as a veterinary feed directive product which means it effectively does require the authorization of a veterinarian before that product can be used. For the water products that are affected here, those products would be re-designated from OTC status to prescription status. Again, likewise, that would mean that authorization from a licensed veterinarian would be required. So there are 280 products or applications affected. Not all those products are currently on the market, but nonetheless, part of this process means that those underlying applications would have to, would be changed as part of this process. There are 25 companies that are the holders of those

200 and some, 280 some products. We have gotten written confirmation from all 25 of those companies that they are on board with working with the agency to revise their affected products to align with FDA's guidance by the target date and the date we set is December 2016. A critical element of implementing this overall strategy, because one of the key changes is bringing, and again, a large portion of these products here as products that are currently used in animal feed, so bringing those products under vet oversight means that now come under the umbrella of veterinary feed directive regulation which is in place now, but currently there's a fairly limited number of products that are designated as veterinary feed directed. Clearly, given the number of products we're talking about, this is a significant change in terms of just the sheer number of products in the marketplace that will now be re-designated as veterinary feed directive. So, a critical element of this strategy is also updating our veterinary feed directive regulation to set the stage and facilitate this transition of bringing these products from their over the counter status to veterinary feed directive status, and that has been an ongoing process for us at FDA, to go through that rule making process and to put in place the updated regulation in a time frame that would help facilitate this overall effort. So currently, that, we have already issued a proposed rule, we've received comments on that regulation, and we've now prepared a final VFD regulation and we're now in the final stages of clearance of that final regulation and expect it to be publishing in final form early this spring, and that's, again, a really important step in terms of setting the stage for bringing these products under veterinary oversight by the December 2016 timeline. As we move forward from here, with implementation of this rule, an important aspect of implementation is going to be making sure that we work with our key stakeholders, work in collaboration with our colleagues at USDA, to make sure we get information out to the veterinary community, producer community on, you know, information and education training around these new requirements, so that these changes can be implemented effectively. An important element, as I mentioned at the beginning, as we go forward with these changes is making sure we have sufficient data in place, on both use and resistance, you know, to ensure that we have meaningful and comprehensive metrics in place so we can understand what impact we're having as we implement these changes. So, certainly, as it relates to what FDA's doing under this guidance 213 to eliminate growth promotion and bring products under veterinary oversight, it's important that we have sufficient information in place to support effectively assessing progress that the changes we are, are seeking to implement are effectively being implemented, and, ultimately, that as those changes are implemented, to be able to assess what impact they, in fact, are having in terms of affecting actual behaviors at the farm level, in terms of antibiotic use and that those changes in use practices are actually translating into a positive effect in terms of mitigating resistance trends. Clearly, this is an important issue, goes beyond implementing these changes under guidance 213, but as we go forward with any number of changes that we may be looking to in terms of supporting animal stewardship and the animal agricultural setting, it's important we have the right metrics in hand to be able to assess the effectiveness of those measures and I think Steve Kappes will comment a bit more, also, on the data collection effort. So what we're looking at, as far as data collection is looking at it from several perspectives, one is looking at what data sources we already have and looking for opportunities where that, those existing data sources, could potentially be enhanced. It was mentioned earlier about the National Antimicrobial Resistance Monitoring System or the NARMS program. Certainly, that system

provides a robust source of data that's been available since the late 90s. We're also clearly looking for opportunities along with our colleagues at CDC and USDA for opportunities to enhance the data that's being collected through the NARMS program. One example of that would be a piece of the NARMS program that FDA manages is the retail meat collection arm and program. We're currently in the process of enhancing the numbers of samples being collected under the retail meat program so that's not only increasing just sheer numbers of samples being collected by the current sites that are enrolled in that program, but also, moving forward with efforts to expand a number of sites across the country that are participating in the program, so we can increase the robustness of the retail meat sampling that we're doing. Currently, I believe there's 14 states involved in that program. The effort we have ongoing now to ramp that up would bring the number up to about 21 states. Another aspect of this, clearly, is the effort we have ongoing to collect antimicrobial sales and distribution data. FDA has been reporting out summaries on that, I think, since 2009. That certainly, itself, provides meaningful and helpful information, but it's, again, has its limits in terms of what you can conclude from the sales data. But again, we're looking at the sales data to see, are there other opportunities we can enhance that as much as possible, to make that information as useful as possible. One step we did take was substantially increase the level of detail we're providing in the annual summary that we're now putting out, and the first updated report was published using the 2012 reporting year, and we expect that the report for the 2013 reporting year will be coming out very soon. On this, related to the sales and distribution data, we're also working on rule making and expect to publish a proposed rule this spring that looks at opportunities for providing some enhancements as far as the type of information or level of detail and information we're collecting, related to quantities of antimicrobials being sold for use in food producing animals. And then, looking towards the information that we don't currently have, but we think we need to have, we, we are, right now, working to look for additional data, particularly focusing on gathering additional data on antibiotic use and resistance at the farm level. We're working very closely with our colleagues both at USDA and CDC to develop some approaches that will enable us to collect additional information, again, on both better understanding use practices, how these products are actually being used at the farm level, and, and being able to tie that information more closely with what we're seeing as far as resistance trends. We think that type of information would be enormously helpful in terms of augmenting the information that I already mentioned, that we already have, in terms of the NARMS data as well as sales data, and collectively, we feel that set of information gives us a much broader perspective and enable us to have context around the information. Again, there's more to come on this. We are working to plan a public meeting this spring, likely late spring, early summer, more likely, and again, working with our colleagues at USDA and CDC. And then, lastly, the third, but important area, is really looking at more broadly, the issue of what steps need to be taken with regard to reinforcing stewardship and certainly one element of it is things we need to do around supporting the things I already talked about, in terms of the changes that we're making to the products as far as eliminating growth promotion, bringing products into veterinary oversight into, you know, and all that goes along with that and the training, education, outreach that needs to be done to support that effort. But, I think beyond that, we do recognize that while the changes we're making under guidance 213 are very significant changes to how antibiotics have been used, clearly there's more work to be done beyond that.

Certainly as we move forward implementing those changes, we need to look critically at the remaining therapeutic uses of those products and make sure they're, if there's improvements that need to be made in terms of aligning those uses with, with appropriate stewardship, then, that's an effort that we are focusing on now. Particularly, for example, the issue that I know has raised concerns is the use of these antibiotics for prevention purposes. So those, that is an additional element of our focus as far as how we go forward from here. I think that kind of summarizes what the highlights of what the FDA is working on at this point. Thank you.

>>Eric Lander: We are going to have to move along pretty briskly here to have time for discussion.

>>Steven Kappes: Thank you, Dr. Lander, for giving me the opportunity to speak about what USDA is doing. First, USDA recognizes that we have a very critical and important role in addressing antimicrobial resistance. A quick overview on what I'm going to talk about, we had a stakeholder meeting, we utilized the gaps identified by this meeting to formulate a plan of how USDA was going to move forward. We developed goals and objectives and then I'll also address two PCAST recommendations for USDA as well as the FY 16 budget. The recommendations from our 2000, May 2000 workshop included Ag and non-Ag stakeholders, are listed here. The first one is that we need to have a holistic approach to the entire microbiome. In Ag, we spent quite a bit of time looking at food safety pathogens. We know we need to look at commensals as well as animal health pathogens, and not only do we need to look at what's going on in the animal and what ultimately is in the meat, but we also need to look at the environment, the fate and transport of bacteria that have antimicrobial resistant elements in it. We already had some discussion with both CDC and FDA on the NARMS program. We participate in that and we also look forward to enhancing that with what’s identified in the National Action Plan, and then, the other surveying system that we have in place is called the National Animal Health Monitoring System. This program is led by the Animal Health Inspection Service within USDA, and this program is looking at the major animal species, once every five years, and less frequently on minor farm animal species. So, this is a good system that we can plug into and enhance, but we need to increase the frequency as well as the longitudinal side of this. We also had recommendations to increase research with a long term plan. They recognize that this is not something that we can fix easily in the short term. And also, very critical part is the outreach and indication to enhance stewardship. So the goals that were identified out of that effort where, that we needed to obtain antibiotic drug use information as Bill has indicated, not only do we need to get the use, but we need to know what species and what stage of the production cycle, as well as the purpose of using that antibiotic. Look at the resulting, resistance that's being developed and we need to look at the management practices to see that we can manage the animals in a way that reduces the use of antibiotics and obviously the use of developing resistance. We also need to address the specific knowledge gaps that were identified and develop effective mitigation strategies to maintain the effectiveness of antibiotics for both people and animals and to develop novel approaches that we could exploit to control and mitigate diseases and reduce the use of antibiotics. So, the three objectives that we identified is we need to determine and model the patterns, purposes of, and use of antibiotics in food producing animals, we need to monitor the drug susceptibility of selected

bacterial organisms both in the production environment and through the food chain and also in humans, related to how humans obtain those, those bacteria with antibiotic resistance and then we need to identify feasible management practices and alternatives to antibiotics to reduce the use antibiotic and lower antibiotic resistance in those systems. So, basically, our activities can be broken down into three separate activities. The first one I'm listing here is proposed surveillance. I've already talked about how we have two systems in place in NARMS. We have six USDA agencies that are working together on this, we developed a USDA action plan that is in part, that is very much, is completely aligned with the national action plan for the entire government and the Economic Research Service of the National Statistics Service is ready to conduct surveys. We need to enhance those. Those will are going to be done in conjunction with the surveillance efforts, and I already mentioned the need to do longitudinal studies of NOMES and NARMS. We need to look at the long term effects of production practices and then management of drug use and resistance in the sector. Also, proposed research, we need to identify vaccines and other alternatives, vaccines is one of the areas that doesn't get much of attention, and it is one very logical alternative to antibiotics. We have more effective vaccines and vaccines for more bacterial diseases will reduce the use of antibiotics. We also need to look at feedstuffs and how we can enhance the immune system and reduce the likelihood of getting bacterial infections and also looking at the host genome and looking at identifying animals that have reduced susceptibility to these diseases and then identifying the diseases and seeing how we exploit that in a genetic selection program. We need to look at microbial ecology and find out what's happening in production settings and how we can better control those bacteria. We need to look at management practices we already talked about, and then, with our national institute, and food and agriculture, funding, multi-institutional/multiagency projects that integrate the research education and extension, and the last component is proposed education outreach. Bill already talked about what we're doing with FDA and with the animal industries, with universities, public and land grant universities, and with veterinary, national veterinary organizations and we've already started some of these activities in developing additional materials to communicate the importance of stewardship and the proper use of antibiotics. The two particular PCAST recommendations directed towards USDA, the first one is the funding of a $25 million multidisciplinary innovation institute, was in the FY 15 budget. It was not funded. However, USDA NIFA has proposed an FY 16 budget to have funds for a competitive funding process to address antimicrobial resistance, and the second recommendation was on stewardship education outreach, and NIFA has the mission for education and outreach that can be addressing stewardship, and they can do this with the FY 16 funds in a competitive peer review process in the integrated systems, and APHIS also plays a role along with FDA in stewardship and they're also working on that. So, the FY 16 budget, it would quadruple the USDA budget which is directed towards antimicrobial resistance. We would go from $20 million to $77 million, and the way that's broken out, if we were funded at that level, $65 million would be for research and $12 million for surveillance. Part of the research is directed towards the surveillance side and on NIFA's funding research there will also be some surveillance in there. So, here's three websites that identify a report from our workshop that I talked about, our action plans that fits in with the National Carve Action Plan, as well as our explanatory notes on our budget. Thank you.

>>Eric Lander: Great. Well, thank you, and thank you to everybody, I know we have six people up here, but happily you left 25 minutes for conversation. We have until 10:35, I think, so there's a good chance to discuss. Before we do, I wish to remedy an oversight on both John and my part. PCAST has a new member. We have already introduced this new member to PCAST and have been talking with her and all that, so we were kind of taken for granted. This is our first public meeting since Wanda Austin has joined the President's Council. We're incredibly excited for her appointment by the President. She's the President and Chief Executive Officer of the Aerospace Corporation, which is leading architect of the nation's national security space programs. She brings extraordinary expertise, both in science and technology, and experience from the private sector, and we could not be more thrilled at the President's appointment, and you're joining us here for this meeting and I apologize that we were already taking you for granted because we have been talking with you, which is the case with PCAST members. It gets down to work, but I did not want the occasion to go unnoticed, so, welcome to Wanda. [applause]

>>Eric Lander: Now, let's dive in. Our practice is to stick flags up, and I've got mine up preemptively, and then I see Chris Chyba, who is the co-chair of the PCAST report, which you are referring, has his flag up, and I suspect other flags may rise as well. The issue we hear an awful lot about is this agriculture issue. Are there many people who are concerned that the use of antibiotics in agriculture is a significant contributor to the overall problem? So, I want to just go back over what was said and understand where we are and what it says in the National Action Plan, because I think it's really important. So, first, let me make sure I've got it right. These FDA guidances, 209 and 213, will do the following thing: As of December 2016, and correct me if I'm wrong, it will be illegal to use those antibiotics. Illegal. Not like a suggestion, but when the manufacturers withdraw that from the label, as they said they'll do by December 2016, it becomes illegal to use them for growth promotion and to use them without veterinary oversight. That's the first part. I'm assuming you just get a nod.

>>Steven Kappes: That is correct.

>>Eric Lander: That is correct, because I often hear this described as voluntary something. The voluntary part was that the manufacturers voluntarily took the FDA suggestion to withdraw it. Once it's withdrawn, it's now illegal to use it that way and I want to get that out. So, that means you have removed growth promotion as allowable use, or will have by December 2016. Kudos to you. Now, another concern people have is, okay, growth promotion will no longer be an allowable use, but using it for animal health still can have a fuzzy boundary to this. Folks may say they use it for kind of prevention, kind of broadly, how do I really know? One of the issues we had on the PCAST study was a feeling that it was not the kind of data that we needed to know how much of the resistance that arises on farms comes into the human health care system and being able to know that might put us in a position to say okay, it's not actually a major contributor or it's a huge contributor and we have the scientific data to perhaps make the hard decisions that further restrictions might be made on the use of antibiotics, even for some of these prevention or health uses, but that we were concerned, and I got to say, frustrated that good enough scientific data didn't exist. So, I of course, open the action plan and

immediately went to that section to try to understand it, and the action plan commits the U.S. government to, as I understand on page 33, within one year, developing a plan to enhance these efforts to monitor the occurrence the drug resistant zoonotic pathogens in food animals on farms and water, got to have a plan within a year, and then, then in three years, what will be implemented, if I understand correctly, is the USDA will implement routine susceptibility testing of veterinary diagnostic isolates and report its findings, and will expand the surveillance for antibiotic resistance. So that, if I understand correctly, is designed to produce the kind of data set to give us the situational awareness of exactly what's happening. Now, I'd be very much happier if when you make this plan, it's very clear you're going to be sequencing those bugs because by sequencing the bugs, their genomes, we're going to be able to have enough information to know whether something you saw on the farm is the same as something you saw in this hospital, knowing the rate of antibiotic resistance won't do, but having all that extra genetic variation information will make it really clear whether the transmission is from farm to hospital, from hospital to farm, there's evidence that that might occur. And by the way, also from hospital to hospital, the sort of thing that CDC is doing. So, maybe I just said what you said and said what the action plan is, but I want us all clear and on record, because it's the first morning this thing's come out that you are committing to the American people to collect the data we need for a real science based policy and that data is going to be rich enough to answer these questions. You can both jump in on that one. You can all jump in. CDC can jump in too, but I know that's just an issue of concern to lots of people, so I didn't want to pussy foot around about it.

>>William Flynn: Yeah, so, I guess, one comment, too, you sort of mentioned the concern about the month's gross promotion to remove the sort of fuzziness around remaining uses and how they'll be used. Certainly, that is one of the key reasons we felt it was critical as part of this effort to bring those products under the oversight of licensed veterinarians, which now puts a responsibility on the shoulders of veterinarians that they're, they're part of that decision making and in terms of authorizing those products and making sure that it is, you know, it is an appropriate situation.

>>Eric Lander: So, if they played fast and loose with those rules, they'd lose their license.

>>William Flynn: Well, again—.

>>Eric Lander: Potentially.

>>William Flynn: There's an obligation there from the standpoint of there is the legal obligation that the products now can only be dispensed with a licensed veterinarian. There are then practice obligations, as far as the licensure of veterinarians at the state level, in terms of meeting, you know, appropriate standards of practice as a licensed veterinarian.

>>Eric Lander: Okay, most veterinarians are quite ethical about what they are doing.

>>William Flynn: The data point, completely agree, and I think we are, you know, this is a clear priority for us at FDA as well as USDA, and I'll let Steve comment, but, you know, we are working collaboratively on this. It is a significant undertaking, and our goal is to try to pull together, you know, again, it's a very complex issue, you know, pull together as comprehensive, this set of information and to look at information collectively, because it's hard to really make this, you know, there's no one single data point that's going to answer the question for us. Again, NARMS data is, is valuable information, and the sales data is valuable information in and of itself, but we do feel there's more information needed. Where I think where we're going is to get this broader context of having a better understanding and better granularity of what is happening at the farm level. What's being used for what purposes, and be able to track that overtime and tie that back to what we're seeing in terms of resistance trends. So, I'll let Steve comment on that, but I think that's what we're working on now, is to map out how those different data streams can be pulled together and to provide a comprehensive, a more comprehensive picture.

>>Steven Kappes: You all did a very good job explaining it. One thing I would add, is that yes we'll be using full genome sequencing, so we have the ability to track it. One of the critical things is, not only do we need to take samples from certain farmers and ranchers over time to see the impact of these things, but we also have to follow those animals through the production chain into the meat case. So, we know what's happening through that whole production chain, and then, once you have the sequence information, you can follow that back.

>>Eric Lander: Great, and Beth, I know you wanted to jump in on this as well.

>>Beth Bell: Well, I'll just say that I think from the CDC side, where we're actually monitoring and tracking infections in people, as I mentioned, we have very concrete plans, you know, with our FY 16 initiative to basically increase by 20 fold. The number of salmonella isolates, for example, where we need to know what the resistance patterns are in people and that sort of information is the kind of information that these guys need in order to start to target what are the most important places to focus their studies. I think, as everyone said, it's so complicated. We need a way to prioritize, and I think the way to prioritize is to focus on the, what is causing the most problems in human health. The other comment I'll make to the point of sequencing is that, you know, we actually have already started a number of projects, not about antibiotic resistance, but sort of proof of principle, there's something we've called the Listeria Initiative, which is a collaboration between ourselves, FDA, USDA, and NCBI at the NIH, where we're sequencing Listeria isolates from people, from food, in real-time, and we've already seen NCBI does the bioinformatics. We post the sequences. We've already seen how we've been able to detect Listeria outbreaks more quickly, bind, sort of, clump things in ways that make more sense it's already, I think, actually, having an impact. So, it's a prototype, I think.

>>Eric Lander: So, big data is going to drive all of this. We'll have enough data to see what's coming from where to whom? Let me turn to Chris Chyba who co-chaired the PCAST report.

>>Chris Chyba: Thank you, Eric, and I was very pleased to see the idea of One Health, my question is related to Eric's question, but I think it's at a higher level. I was very pleased to see the idea of one health mentioned explicitly in the National Action Plan and this idea that there's a very close connection between animal health and human health. It's commonly remarked that those communities are not in sufficiently close contact, that there's not enough cross talk. So, broadly, I'd like to ask the panel what are your plans as we go forward to try to ensure that the animal health community and human health community are, in fact, in regular close conversation with each other?

>>Beth Bell: I think, to sum up the examples that we just, that I was just talking about, I think are good examples of this, where we've already been kind of collaborating I think on projects that have demonstrated impact and I think we have a lot to build on, you know, I think that we have kind of been working together and also, maybe sometimes, not so much together for some time, but we have a lot to build on. I'll also mention the development of this action plan has been a long process. We've been at this as the federal government now for over a year, and the process of developing the action plan really involves some very serious work, collaborative work, among all the various agencies. So, from the CDC side, I can say that a lot of these work around what is the research that's needed to understand the contribution of antibiotic use on the farms to human health. The CDC has been, you know, very involved in thinking about what are the best ways to do that. So, I think, you know, we have a foundation, and we have examples where we're already doing this and it's providing public health impact, and I think it's a matter of continuing to move forward on sort of the role that we've already started upon.

>>Chris Chyba: I, I hope to hear from the whole panel, but let me just ask a follow up. With respect to outbreak surveillance, are we in a better place now than we were say a decade or 15 years ago? Is that going to continue to improve? With respect to cross talk?

>>Beth Bell: Definitely. Definitely and I don't know whether FDA wants to comment, but—we have, now, essentially, I would say, certainly between ourselves and FDA, and USDA, depending on the outbreak, really pretty much a seamless method of doing outbreak investigations. There's a group at FDA that's in charge of foodborne outbreaks that we work with all the time, and I have been at this job now for several decades and having actually started my career with a Jack-in-the-Box outfit with e coli ON57 20+ years ago. I can tell you personally that this is a completely different landscape than 20 years ago or even 10 years ago. We clarified who does what, when. We share information. We have some of the legal things in place because they're regulatory agencies that allow us to get some of the data that we would need to help us with our part of things and of course while nothing's perfect, I think that as I say, for foodborne outbreaks, we're in a very, very different place and a much better place than we were a decade ago.

>>Eric Lander: Great. I think—can we turn to the next one? You want to get further feedback, Chris?

>>Susan Coller-Monarez: Yeah, I just want to make one quick point. The recognition that we needed an interdisciplinary approach was a priority when we wrote the executive order, and in that executive order, called for the establishment of two bodies that would, that would foster this interdisciplinary approach. The first is a federal task force that will comprise these departments as well as others that have a primary stake in, in ensuring that the implementation plan is effectively implemented and the second is the President's Advisory Council, and we're pleased today to announce that the Office of the Assistant Secretary for Health and HHS has posted the charter for that group and also soliciting nominations, so for those in the community who want to lend their voices and contribute to the government's understanding and processes in addressing this critical issue, there's an opportunity to, to take part in that.

>>Eric Lander: Great. Let's underscore that point, that there will be a federal advisory group, and you're taking right now, suggestions, nominations, to be considered. Very important. Mike? You want to jump in on this point?

>>Michael Stebbins: One of the things that we're announcing today, in conjunction with the National Action Plan, is that there's going to be a follow-up or supplementary plan that's going to be specific to TB. So, there'll be a TB action plan that will also be done. That will be completed by September of this year.

>>Eric Lander: So, like this more general carved action plan, there's going to be a TB action plan?

>>Michael Stebbins: Correct.

>>Eric Lander: Excellent. That was also a topic that came up in the PCAST report, and I'm sure we'd love to hear more about that, but I see flags up.

>>Michael Stebbins: There was one other thing. You guys also made a recommendation that we haven't addressed here which is on economic incentives. We have a second task force, or a sub—a working group of our task force working on economic options as well, and we hope to be able to discuss that with you in, perhaps at a future meeting.

>>Eric Lander: Okay, so you're going to bring that back? I noticed we had a whole chapter on economic incentives, this exciting chapter, five, I think.

>>Michael Stebbins: It didn't go unnoticed.

>>Eric Lander: Okay, good. I didn't want to, you know, get in the way of other folks questions, but it's good to know that you've not forgotten chapter five. I appreciate it. It's a complex one, but you have a working group on it. That's great to know. So, I'm going to turn to Chris Cassel, Jim Gates, Craig Mundy, and Ed Penhoet, which might, or might not, be the order in which the flags went, up, but it's my best recollection, so, Chris?

>>Christine Cassel: Thank you Eric, and thanks to the panel and all the people who have gone into making this action plan and all of the work behind it. My question, and this may, I appreciate Susan's announcement about the advisory council. I know there's a lot of interest from my world, which is the medical care world and so, I just wanted to tee that up, much as, you know, there's this, CDC has a huge agenda and obviously in the agricultural area, but there still is a lot of progress to be made, even within the walls of hospitals, but more broadly within prescribing world. And so, CMS isn't here, but I assume that obviously that's one, because as I skim the report, there's some mention there. I just wanted to also suggest that in the private sector, professional leadership groups, there are a number of medical organizations that really have been very leaning forward on this issue and want to do more and have been eagerly awaiting this day. And so, I urge you to take advantage of that because I think that that's another lever that's ready to really help.

>>Eric Lander: Jim.

>>Jim Gates: Thank you, Eric, and also, I'd like to associate myself and my colleagues' comments on the defined briefing, as well as the amazing work that's been done. This whole issue of taking antibiotics and moving them from indicated to more medical status, to be prescribed by veterinarians is huge, so, I want to probe a small question that was raised by Eric's technical term of the fuzzy boundary. So, the question is, in medical practice with humans, when doctors prescribe drugs, one of the things that is part of the monitoring process, that doctor has to have a DEA indicated number in order to get the prescription filled at a pharmacy. And so, in this fuzzy boundary area, is the idea that something like this might be implemented for veterinarians as prescribed uses of these, of these materials?

>>William Flynn: Well, veterinarians are, you know, required to be licensed, you know at the state level, so they need to have a valid license, you know, in the state or states that they're practicing, and that would be basically a requirement for them to be authorizing you know, the use of a prescription or VFD drug.

>>Jim Gates: But in the case of medical doctors, if I remember correctly, it's actually one step more.

>>William Flynn: There, you may be referring to, for certain controlled substances. The same would apply to veterinarians that would be handling controlled substances, but of course, we've not yet designated antibiotics as controlled substances.

>>Eric Lander: Good to know. Craig Mundie.

>>Craig Mundie: Thanks, and my question is really directed at Bill, but it was sort of reinforced by Beth's last comment. There are two things on the slide we talked about, data collection, I'll also say it surprised me, not being an expert in this field. On this, you said, well, we've got 14 states now going to 21, is that all there are that need to report or are there some that are outside of that?

>>William Flynn: That's with respect to the retail meat component of the NARMS program, where we've enrolled, engaged the states across the country to participate in the program in terms of actually collecting samples, you know, in their region. Certainly, our view right now is 14 is not enough, in terms of getting a broad enough picture. So, we are using the increased funds we have available for FY 15 to expand that, with what we have, we think we can expand it to 21 and get to a much better place in terms of representativeness. We, there's probably still some room there to improve on that, in terms of getting a bit further. It's been a funding issue, but again, we're looking, you know, as much as opportunities where we can to expand that. I think, obviously getting up to 21 gets us in a much better place in terms of the robustness of that sample. I think we feel if we can get closer to sort of the 30 area, that that's probably getting us in a, in a better place, but, I think, we're making progress to get the retail meat component, you know, as robust as possible.

>>Craig Mundie: Well, the next thing that surprises me is you talk about releasing the 2012 report, about to release the 2013 report, like with the Listeria thing, the near real-time, you know, analysis seems to be really effective. So, why is there a two year lag and is that something that is going to get remediated?

>>William Flynn: Yeah, I mean, that's a great point and certainly something we've been working towards, not only that, I was referring to the sales data we put out. We put out annual reports in sales data, and that's a relatively new program that we first got that requirement when it went in place in 2008. So, our first report came out in 2009. The significant, I think one of the reasons for the significant delay, recently, was we did a fairly substantial reconfiguration of the format of that report, substantially increased the level of detail in that report between 2011 and 2012. So there was a fair amount of lag time because we actually did go out and put out a public notice and get comment on suggestions for how we can improve the report. So, our hope is now, like I said, the 2013, our goal is obviously to get, improve our turnaround time on that. Now that we have a new format in place and our better, you know, have our, are better familiar with how to pull that data together, we hope to improve that frequency. The 2013 report should be coming out pretty shortly.

>>Craig Mundie: And finally, as you get to the, I'll say approaching the real-time analytics, I was just curious, do you have programs now to move more things like machine learning and predicted modeling as a way to forecast where we're likely to see outbreaks, as opposed to, you know, just catching them after the fact?

>>Beth Bell: Certainly this is something that I think we would aspire to. At CDC, we have this initiative that Eric is very familiar with called Advanced Molecular Detection, which is about bringing the benefits of next generation sequencing bioinformatics to public health, and part of that is some of the sort of the predictive modeling that you're talking about. We have been really focusing on trying to build partnerships. For that, I think there are parts of this where the road for example, and other institutions can help us, if we have the right kind of data with the right kind of information. So we're sort of working towards that. I think in this area of antibiotic

resistance, we really don't have enough data yet to get us there. The amount of information that we have is, certainly on the human side, is really quite limited, and we certainly would hope with regional lab network and really increasing the amount of sequence information we have, that we can move towards doing some of that sort of work.

>>Craig Mundie: Thank you.

>>Eric Lander: Finally, Ed Penhoet gets the last word.

>>Ed Penhoet: A couple quick questions for Joe. First of all, do you have some sense of what fraction of the total development activity that fall within this spectrum of your funding? That you guys actually fund? Today in this country? Is that a small fraction? Large fraction? Second question, related one, is many of the compounds that you're supporting are enhancements of existing classes of antibiotics and there are very few novel targets represented there. Can you give us some perspective on what you, what your view of the earlier pipeline is in terms of developing truly novel antibiotics that address different modes of action than the ones you put up and showed us today. Not that those aren't important, but I think the earlier stage pipeline is something I'd like to hear your thoughts about.

>>Joe Larsen: Yeah, thanks for the question. So, the first part, first of all, a proportion of costs on a micro level, many of the programs we fund we actually share the cost of development, and typically, it depends, but on average, it's about a 50/50 cost split, for every dollar we put in, they're putting in a dollar which is a situation we like because, we like to have our partners have equal footing, equal skin in the game, if you will. In a larger macro sense, in terms of the companies out there, yes, we are investing in, I don't want to put a specific number on it, but I would say a substantial portion of the biotech companies that are out there, that are still developing antibiotics, the number of large pharmaceutical companies that are still developing antibiotics that have active R&D are very, very small. GlaxoSmithKline is one, but there's been many that have been trying to shop around their portfolios, as of late, and there's some science of re-entry back into the space, which are promising and we're hoping to engage with those companies as well to ensure that it's a comfortable environment for them to reengage in, but we are making a significant impact in the market, I think. In terms of novel targets, yeah, I mean, the number of novel targets that are prepared to enter into my spectrum of development, I can certainly count on one hand, if not less. There was a huge emphasis in the 90s and early 2000s in the wake of the genomics area, everyone thought that they were going to be these new novel targets, and everyone thought we were going to be able to screen those targets and get all these new compounds and really getting compounds past the gram negative envelope, the gram negative outer membrane has proven to be a significant challenge, and the industry now is taking a look at going back and pursuing what we refer to as non-traditional therapies, things that historically have not been thought of as an antimicrobial therapy. Whether it be monoclonals, phage, whether it’s microbiome modulation as a means of re-bolstering the pipeline, as well as looking at novel targets, but frankly there’s just not that many out there. So, our colleagues at NIH, they do need the funding that they are proposing to get, to

increase the early stage pipeline and increase the number of candidates that are going to be positioned to eventually transition to BARDA support.

>>Eric Lander: Great. We have come to the end of the time. I just want to thank everyone who's has been working on this National Action Plan. It's a lot of work. This thing is a 59 page response to the President's executive order that we have a national action plan. It lays out specific deliverables at one year, three year, and five year timeline. There's still going to be a tremendous amount of work to be done within it, but there's now an interagency process to be able to coordinate this. There's an external advisory being set up to do this. I wouldn't be surprised if PCAST continues to express interest in wanting to keep an eye on this too, if you don't mind having another set of eyes over the whole thing, but what is remarkable is the federal government never had a plan like this before. This has been a growing and growing problem, and I think we're all pleased that the President to initiate this out of a sense of real concern and that there's something very concrete to point to. We're going to have hold, collectively, all of our feet to the fire to make sure this gets done. You know, some of it costs money, a lot of it costs money. It doesn't cost that much money, all things considered, but it costs money. We've got to be sure it's there, but it's as much a commitment to the agencies, and so, I'm glad in public session, we're getting to read out a first look at this national action plan. I hope there is a public discussion that emerges from it, but I know how much work people put into it, so right now, what I mostly want to say is thank you to all of you, and everybody at your agencies who have contributed to it. Thanks.[applause]

**Arctic Policy**

>>John Holdren: It is a great pleasure for me to introduce this panel on Arctic issues. We really have an amazing group. I will start with Beth Kerttula, who is the Director of the National Ocean Council which carries out the responsibilities under the President's National Ocean Policy which he rolled out in July, 2010. That council is co-chaired by myself and the CEQ chair, but Beth Kerttula really runs the operation. She was formerly at Stanford's Center for Ocean Solutions and she served for 15 years in the Alaska House of Representatives where she served as minority leader for a large part of that time. Fran Ulmer is Chair of the U.S. Arctic Research Commission, an extremely important entity that she will undoubtedly tell us more about. She's also been appointed by Secretary John Kerry as Advisor for Arctic Science and Policy to assist in the U.S. Chairmanship of the Arctic Council which, as I mentioned at the beginning of the morning, we take on in May of this year and will serve two years. The United States will serve for two years as the Chair of the Arctic Council. So, that's another important responsibility for Fran. She has also been the Lieutenant Governor of the State of Alaska, and the Chancellor of the University of Alaska in Anchorage, the largest public university in Alaska. Brendan Kelly is the Director for Conservation Research and the Chief Scientist at the Monterey Bay Aquarium. He was previously Assistant Director at OSTP for Polar Science and before that had corresponding responsibilities at the National Science Foundation, and Mayor Reggie Joule is the Mayor of the Northwest Arctic Borough in Alaska. He was born in Nome. He has served on the task force of state, local, and tribal leaders on climate change preparedness and resilience,

reporting to the President, a task force that produced over 100 recommendations for what we could do in the federal government to improve preparedness and resilience and help states, communities, and tribal jurisdictions improve their preparedness and resilience and he has also served as a representative in the Alaska State Legislature, so, representing a large part of the Alaskan Arctic. I just cannot imagine a more qualified and distinguished panel to inform us about Arctic issues. So, Beth, I'm going to turn it over to you to lead the thing. I think you can tell us what order you've decided upon.

>>Beth Kerttula: Thank you, Dr. Holdren, and thank you, everyone in PCAST for having us today. The order that we decided on is Director Ulmer, then Dr. Kelly, then myself and then Mayor Joule, and with Mayor Joule and myself, to help us with our slides, is Patrick Sebinlist our NARC office. He is or intern there, so with that, I'm going to turn it back to Director Ulmer. Thank you.

>>Fran Ulmer: Good morning, everyone and thank you very much for spending some time focusing on the Arctic this morning. The way we've decided to do this is I'm going to do a very brief overview, sort of setting the stage of what is the Arctic, what are the issues we confront in the Arctic, a little bit about the national agenda, about the international space, the Arctic Council, and touch on science, and then, my friends and colleagues will take a deeper dive into all of those areas. So, that's the way we are going to proceed this morning. So, my remarks will focus on these four areas, just a general introduction, a bit about the National Arctic Strategy and the other things that our federal government is doing, touch on Arctic Science Cooperation and the Arctic Council U.S. chairmanship which is about to begin. Now, I know most of you are very familiar with the Arctic, but I think it's important to start with what it is and what it isn't. It is not like the Antarctic in many ways. The Antarctic is land surrounded by water. The Arctic is an ocean surrounded by land. The Antarctic has penguins. We have 4 million people, and there are eight nations that have significant national interest—security, economic, cultural, et cetera—in what happens in the Arctic. There's no overarching treaty governing the Arctic, the way there is in the Antarctic. Instead there, are a variety of relationships, bilaterals, multilaterals, et cetera. But, it is a place of tremendous change. I might just note that in the United States, we have defined the Arctic a little differently to include the Bering Sea, the area south of the Bering Strait. The Arctic Research and Policy Act of 1984 defined it this way because of the significant connections, ecologically and biologically, between the Bering Sea and the Chukchi and the Beaufort, which I believe Brendan will talk a bit more about later. But, I think what's really important today is to just mention how much this region is changing. Change is the operative word. When you think about the Arctic, don't think slow change, think rapid change, in terms of retreating sea ice, and glaciers, in terms of thawing, permafrost, significant warming temperatures, and all of the change that is impacting human activity, both from the standpoint of things that people think might be possible there for shipping, mining, gas tourism, fishing, but also the extent to which its impacting the 4 million people who live in the Arctic—much more international interest, much more media coverage, all of those things, largely driven by the fact that it is warming so dramatically, probably twice as much as any other region in the world, not only in the winter and in the summer, but, I mean, really, we couldn't even start the Iditarod Sled Dog Race in Anchorage this year. We had so little snow we had to move it to Fairbanks. So, it's a dramatically changing place, and I would say that, even though

we think of it often in the climate change arena, I would want to remind you, again, the people who live in the Arctic are living with this change, this very dynamic space, in a wide variety of ways. The thawing permafrost and the coastal erosion that comes with increased storms, eating away at the shorelines, so communities like Noatak, Shishmaref, Kivalina, which Reggie will talk about, are facing imminent disaster, and, in a number of cases, they're planning on moving. It's impacting their foods, their subsistence foods, and it is also creating economic opportunities. So, let's talk a moment about the changing economics, driven by global demand for resources, driven by the fact that there is a lot of oil and gas in the North, and driven by the increased accessibility and the opportunities that, in a way, the technology and the climate change makes possible. Much of that is in the context of oil and gas. Oil and gas, and particularly since the USGS came out with the estimates in terms of the increased amount of oil and gas that is available in the Arctic, and again, I want to point out, this is throughout the Arctic. The darker the area, the more likely that billions of barrels of oil will be found. But, as you can see, it's really spread around the Arctic. That has created a phenomenal amount of interest, and in some cases, moving forward with exploration and development. Shipping is the other thing that Beth will talk more about in terms of its impact on oceans and what we are talking about here, largely is the Northern Sea route above Russia and the Northwest Passage above Canada. The Northern Sea route is seeing the most increased traffic, even as we speak, for a variety of reasons. Less ice, but also because the Russians are promoting it. They have put in place not only ice breakers, but are building facilities to accommodate the increased shipping, again, a whole other hour long lecture on that, but let me just say, whether we're talking about oil and gas, tourism, shipping, fishing or whatever, really, in order for nations to step up to the challenge associated with this increased human activity, there's a lot of work to be done in terms of charting and mapping, in terms of navigation aids, in terms of adopting some of the existing international protocols like the Law of the Sea Treaty, which all of the other Arctic nations have adopted, and over 150 nations, but our Senate has not yet ratified, unfortunately. So, there's a lot of work to be done, and again, we'll be talking a little but more about all of that. The United States government has recognized that this does require us to step up as a nation, step up in terms of our focus and our activity, and our willingness to engage all of the federal agencies that have some responsibilities in this area. So, in 2013, the national Arctic strategy was released. It has three principle areas, advancing security interest, Arctic region stewardship, and international cooperation. I might just note that all of the Arctic nations have Arctic strategies and they're all very similar to ours. If you picked up the Arctic strategy for Russia or for Finland or Canada, you'd see many of the same basic three principles in terms of what our interests are, but it's not just the National Arctic Strategy. The U.S. has also adopted, in 2014, an implementation plan, and in 2015, an executive order, which created the Steering Committee which John Holdren now chairs. So, there's been a lot of activity, including in the area of research, the Interagency Arctic Research Policy Committee, IARPC, came out with its comprehensive Arctic Research Plan two years ago. I could go on and on about many of these. I won't. Suffice it to say that there has been a considerable step up of activity, focus, and, I hope, at some point, additional financial resources to be able to support these efforts. Let's switch gears now to the Arctic Council. What is it and what is it not? The Arctic Council is not a treaty based entity with authority. It is, instead, the eight Arctic nations that have come together to work together in a cooperative way on things that, really, they have shared interest in, and two

principle focus areas since the Arctic Council was created in 1996 have been the same. Arctic Ocean stewardship, Arctic environment stewardship, and promoting sustainable development in the Arctic, really, all of the activities associated with Arctic Council work are around those two themes. The important thing to remember here, even though it's a very complicated structure, is that most of the work of the Arctic Council takes place at the working group level. There are six working groups that produce reports, assessments, scientific analysis, recommendations, best practices. That's the work of the Arctic Council. But at the ministerial level, which is at the John Kerry level, they meet once every two years, and that meeting will take place in Canada next month that will signal the passing of the gavel, so to speak, from the Canadian chairmanship to the U.S. chairmanship. The senior Arctic officials meet twice a year, the working groups, more than that, depending upon their focus areas. Over the years, they have produced many excellent reports, and here are just a couple of examples. They are pretty much all around science, better understanding of the region, better understanding of the challenges facing the region, and how the countries can work together to address those challenges. So recently, the Arctic Ocean Acidification Overview, all the work that they've done on climate impact assessments, more recently on black carbon. These products are excellent. They are well done. They are international in scope and they really provide to not only the nations, but to the people of the Arctic, useful information. Recently, the Arctic Council has done something very different. They have adopted two agreements. Actually, they haven't adopted it, because as I said before, it's not a treaty based organization. So, it can't formally adopt anything, but they've agreed to these things and went back to the eight Arctic nations for formal adoption. One on search and rescue, one on responding to oil spills in the Arctic region, and right now they are negotiating a third which deals with international coordination and cooperation for scientific research, that it is expected that this third agreement will come to fruition under the U.S. chairmanship. So, what is the U.S. going to do under its chairmanship in the Arctic Council? It has three main themes. The three main themes are Arctic Ocean safety, security, and stewardship, improving economic and living conditions of the people of the Arctic, and addressing the impacts of climate change, and under those three broad umbrellas, the U.S. has proposed a number of specific projects. The senior Arctic officials, even as we speak are kind of negotiating the fine points about those specific projects, but again, they will be formally agreed upon and released at the Arctic Council ministerial meeting that will take place in Canada in a few weeks. Secretary Kerry has also indicated that he wants to use the U.S. chairmanship for two additional, broad goals: 1. Strengthening the Arctic Council and its governance structure, and 2. Public diplomacy. What does that mean? What that means to him, to us, to, I think, all of us, is raising the understanding level of the fact that the United States is an Arctic nation. Now, in all the other Arctic countries, they self-identify as an Arctic nation. Canada does. Russia does. Finland does. The US—not so much. So, the hope is that during this Arctic Council chairmanship, we can raise the awareness level of what is the Arctic all about, what are its challenges, its opportunities, its responsibilities as a nation, and as a result of that, get a little more attention, not only to big picture issues like climate change, but more specific needs like additional ice breakers. A moment on the science coordination piece before I pass the baton—the 1984 law that I mentioned that was the one that created the map that included the Bering Sea, created the Arctic Research Commission that I chair. It also created the Interagency Arctic Research Policy Committee, which is a federal agency coordinating

mechanism for federal Arctic research, and it kind of put in place this process where the commission identifies broad goals, IARPC takes it to the next level of a research plan, and that theoretically informs OSTP, OMB, and Congress, in terms of how to spend money. Sometimes it works that way. Sometimes it doesn't work that way. But, that is what Congress envisioned when it passed the 1984 law, and it is in rough approximation of how the system works, and we are supposed to do a budget cross cut. Actually, John Holdren is initiating that as part of his steering committee product, in terms of doing a gap assessment and better understanding where we're spending money and how we are achieving our goals. The goals report that the commission produces, we're about to release our new one in a month, and it will focus on the six broad categories that we describe as the most important areas of emphasis for Arctic research investment. The commission is a presidentially appointed commission. I was appointed to be chair by the President, and we serve for specific terms. We have a very small staff, both here in D.C., and in Anchorage, Alaska. I just want to end by putting in a pitch, which I probably don't need to pitch to this group because I think it's where you all come from, but investment in Arctic science is incredibly important, particularly right now, as we face all of this change and all of the pressures that are associated with the collisions of values that people have about how the Arctic will be used and managed. Everything from identifying resource potential, to making certain that the needs of Arctic residents, whether it's in food security, or adapting their infrastructure, to inform the decision makers at the public and private level, at the global, international, national, state, regional, and local level, increased investments in science is incredibly important, even as we speak. My final pitch is to just direct you to the website of the Arctic Research Commission. The Arctic Research Commission website which is Arctic.gov has a variety of publications as a result of workshops and other systems that we have used over the years to identify high priority areas for Arctic research, but you can also sign up for a daily electronic newsletter which we produce on all things Arctic. It gives you a snapshot of Arctic research, Arctic investments, Arctic statements by elected officials, upcoming events, and conferences that can be of use to you. If you go to Arctic.gov, you could do that. You can also find there, something that we have recently done, Why the Arctic Matters, and for those of you who are in the audience, there are copies of this as you leave today. You might want to pick one up. I will stop there and simply say thank you very much for the opportunity.

>>John Holdren: Well, thank you, Fran, and let me just say, we're going to hear from all of the panelists before we open it up for questions. So, let's just go right through.

>>Brendan Kelly: Thank you, Dr. Holdren, and members of the council. Early in my career, I learned three dozen Yup'ik words for sea ice from Konrad Ozeva, a native hunter on Saint Lawrence Island on the Northern Bering Sea, and I, I recently—is this advancing here? The top button? Thanks. So, I recently looked at my notebook from that period and realized that some of these terms refer to types of sea ice that are rare or non-existent today, that some of those Yup'ik terms, which were probably used for thousands of years should become obsolete in a few decades, attests to this very rapid change that Fran has described and it also tells us about the great impacts on the people who live in the region and depend on the ecosystems of the sea ice, and indeed—let's see here—we seem to be out of order. Let me back up a little bit. Yeah, well, any case, indeed, one of Conrad's neighbors actually referred to these rapid changes

taking place in the Arctic as the Earth is faster now, and that, in fact, became the name of a volume on indigenous knowledge of the Arctic. Model forecasts of sea ice also indicate a faster Earth, and the observational data in recent years indicated more rapid ice loss than most models predicted. Before the end of the century, in the summertime, the Arctic will be nearly ice free. So, what you're seeing here from Julienne Stroeve's work is, on the Y-axis, the area covered by sea ice in the Arctic in September, the year on the horizontal axis for two scenarios in red and blue, and then the black line represents the observational data. Well if the impacts of these changes were limited to ecosystems and People north of 66 degrees, 33 minutes, it would be sufficient motivation to understand and respond to changes, but the impacts of changes in the Arctic are, in fact, global. So, asking the right questions at the right scale is a challenge, I believe, is inadequately met in Arctic research. Governmental and nongovernmental organizations have been making progress at getting at the right questions and scale, but a great deal remains to be done. We need help, I believe, in prioritizing, in light of limited resources, and we need help in asking questions at the appropriate scale. Before elaborating on what I think we're not doing adequately, let me briefly review recent successes in organizing Arctic research. The academic community, and the federal government, both are making significant contributions to orchestrating the efforts. I shall then end with some comments on where I think further work is needed. Fran has already described the important work of the Arctic Research Commission. We also have a great deal of intellectual talent in the academic community focused on observing, analyzing, and modeling Arctic change. One of the early efforts to organize a holistic study of the response to changing Arctic came in the form of the Study of Environmental Arctic Change or SEARCH, a bottom up effort, driven mainly by scientists in the academic community supported, primarily supported by the National Science Foundation, but also with support from NOAA. They continue to organization the scientific community in ways that help focus our overall efforts. For example, SEARCH organized a network improving our ability to forecast sea ice conditions, enhancing our collective knowledge of permafrost degradation and in many other important areas. The Polar Research Board of the National Academy of Science has made significant contributions by bringing together experts on particular topics. A notable example was an especially insightful workshop on predicting the future of Arctic sea ice. The report does an excellent job of laying out the need to sustain ongoing observations and ongoing conversations between user groups, modelers and those collecting observational data, and through SEARCH, the IARPC continuing conversation is happening. Another example would be a workshop hosted by the Polar Research Board on the proposed connection between Arctic sea ice loss and extreme weather in mid latitudes. Those workshops have been an example of science working at its best. The proposed linkages are being vigorously debated within the atmospheric research community and those debates are focusing on ongoing research. On the federal side, the work of IARPC was considerably enhanced by bringing it in the National Science and Technology Council structure within OSTP. The Arctic research plan that IARPC produced articulated seven research areas and the federal agencies involved in meeting objectives in each area. Unfortunately, we were not able to prioritize those objectives. Completing the research described in the plan also fills one of the four objectives in the stewardship line of effort for the national strategy of the Arctic that Fran mentioned. Much of the intellectual content of the IARPC research plan came from the hard work taking place outside of the government in SEARCH, in the Polar Research

Board, and other venues. We, therefore, worked very hard to find a FACA compliant way to coordinate all the research talent working on those issues. The answer was the creation of what we call the IARPC collaboration teams. 12 teams of federal and nonfederal scientists meet regularly to share science in their specific area, and meetings are limited to federal employees only when they are spending the government's money, or talking about regulations. The collaboration teams represent the community of researchers, federal and nonfederal, who conduct science that IARPC organizes, but a weakness of the IARPC research plan was that it wasn't written with sufficiently broad input from the indigenous or academic science communities. Therefore, at the urging of Simon Stevenson, the IARPC passed the hat. I'm getting ahead of myself, or, behind myself. They passed the hat and funded the Polar Research Board to produce a report laying out research priorities for the coming decades. Simon, now the Assistant Director for Polar Science in OSTP, had the foresight to request this report that indeed will provide important broader input to the next inter duration of the IARPC plan. This final report, the Arctic and the after scene was well considered and laid out questions in novel ways and the authors avoided the trap of producing a laundry list of projects that merely reflected the author's particular interests. Like IARPC, however, they too, issued prioritization. This inability of the agencies or the broader science community to prioritize our research efforts makes it difficult for us to reconcile the disparity between important research needs and available resources. We are rich in intellectual talent, but not in research dollars, and we have not figured out a way to prioritize. Perhaps PCAST is in a position to get us beyond plans and reports that leave out the hard prioritization. The barriers to prioritization include, of course, inter nation competition between agencies, and the challenge of deciding what is the appropriate scale. So, let me highlight the problem with examples of, from emerging research questions from the Polar Research Board report. The dozens of questions put forward in the report were clustered in four main areas. The first cluster was entitled the Evolving Arctic. Here are two questions discussed under Evolving Arctic. Clearly, both are worthy questions, but agencies and researchers have no guidance on how to rank the importance of these questions. It also seems clear to me that these questions are addressing issues at very different scales. So, as the mayor of the Northwest Arctic Borough, Mayor Joule, understandably, might be interested, primarily, in the first question, but the second question might be of interest to every mayor on the planet. Under the heading Managed Arctic, the Polar Research Board report listed several questions, including these important questions that, again, are on very different scales. Nor was the PRB report alone and struggling with this question of scale and prioritization. The IARPC five year research plan included as one of its seven themes, development of an Arctic observing network. The NSF leads the collaboration team meant to realize that huge task and they are an agency that has a specific budget for Arctic observing. I've argued, however, that the academic and federal research efforts on observing have been approached too much like a discovery research problem amenable to bottom up organization. We need to choose, probably in a top down fashion, the most critical observations that can be sustained at an appropriate scale and duration. We do not have the resources to make all the observations that would be interesting, and yet, the pace and scope of environmental change in the Arctic argues loudly for firm decisions and commitments to sustain the most critical observations. On a global scale, the U.S. group and Earth observations employed a waiting approach to extract from the community the most vital observations for what they bend as sustained observations and experimental

observations. The national plan for civil Earth observations, however, probably did not await Arctic observations sufficiently, and we have initiated a plan to rectify that in subsequent iterations of the plan. The Earth, indeed, is faster and the Yup'ik language of Saint Lawrence Island will, I fear, suffer further atrophy of its sea ice vocabulary. PCAST has, of course, dealt with many great challenges. I think you could play a critical role in helping us focus our scientific responses to rapid change in the Arctic, resulting in feedbacks on the entire Earth system. The pace of change, it seems to me, creates a greater urgency for answering some of these questions than others. Thank you.

>>Beth Kerttula: Thanks. My name's Beth Kerttula, the Director of the National Ocean Council. It's a pleasure to be here with you. I had the honor of presenting to you on National Ocean Policy last year, and while the National Ocean Policy, I'm proud to say considers the Arctic and one of the first places were Arctic policy was starting to be coordinated. I'm not going to focus on that today. I'm also very proud to be here with my fellow Alaskans and Arctic residents. We've all known each other for a long time and there are elements of each other's speech that I know we could give for each other. But maybe, the most important factor in my being able to be here today and present to you is that I'm a third generation Alaskan. My grandfather, Oscar Kerttula was stuck in the ice at Nome in 1918 and he liked to point out that he was not the captain of that ship, but, you're going to see another ship that was caught in the ice going up to Nome in a few minutes. So, my presentation is going to focus on three things. And in a way, I think this is working out even better than I had hoped because you'll see, maybe, the narrowing of the broad governmental, governance element that's starting in the Arctic and of course the incredibly important science and all of the pictures of ice. I'm narrowing it down a little bit on some of the major ocean issues, and then Mayor Joule, with whom I have the great pleasure of serving in the legislature is going to bring it home with a real picture of what life in the Arctic is like. So, I'm speaking about the community, changing conditions, and threats to the Arctic Ocean environment. Arctic communities—I'm not going to go into great depth because Mayor Joule is going to be able to speak much more eloquently and personally, but I don't think that you can talk about the Arctic without focusing on the people who are there. I want to take a very brief look at culture and subsistence, some of the challenges, and then something that I find to be one of greatest challenges and most heart rending in some ways, the communities exploring relocation. Culture and subsistence. Mayor Joule lives in this culture and can speak about it much more eloquently and personally, but I want to make the strong point that the survival of the ocean and the survival of the animals are critical to the survival of culture in Alaska and the Arctic. Subsistence, while defined by the state of Alaska is a noncommercial customary and traditional use of food and wildlife, it is about more much more than food, although, obviously, that's a critical part of it. Subsistence is a deeply profound and spiritual way of life, and when that connection is threatened by sea level rise, oil development, ship traffic, climate change, relocation, the culture, itself, is threatened. Brendan mentioned a little bit about local and traditional knowledge, that's part of the subsistence way of life and it should also be part of any decision making in the Arctic. Challenges. All right, here's one challenge: energy, and energy costs in rural Alaska. The cost of living, in general, is tremendous. One of my favorite pictures, I'll say it, I didn't bring it, but it's a photo of Senator Lisa Murkowski holding a box of Tide, and it was a big box. $50, $50 for a box of Tide laundry detergent. You know, a

gallon of milk can be $9 to $12 a gallon, and Arctic residents can spend up to half of their income on energy costs. We still use diesel. We still use the oil based fuels and there's a lot of work on renewables, but not enough yet, and the cost of living is an incredible challenge, even with a subsistence lifestyle. This is the REMDA on your left. It's a Russian tanker, and, to your right, is the coast guard cutter, the Healey. In 2012, the city of Nome wound up not getting its last fuel shipment because of a major storm. So, they contracted with the REMDA to bring it up with fuel. It's a success story at the end of the day, but we had to bring in the Healey to cut the ice so that the tanker could get there, and, ultimately, it made it. The citizens of Nome got their fuel. It was the first time we saw the transportation on the sea to bring in fuel to a western community in the winter. But, it points out the difficulty of even getting the fuel into communities in rural Alaska. And the great challenge that presents. This is not going to be a sustainable method of developing and bringing that fuel in. Relocation. Even the word, for me, is a very loaded one and presents so many different issues for the communities themselves, for the people who live there, for families. Just think about what it would be like if you were forced to leave your home and go somewhere else. It's only two decades ago that, I mean, two generations ago, sorry, that many of these people were nomadic and not in communities. Some of them, like the King Islanders were relocated a number of times, but the communities, in these areas, are all looking at having to move, the coastal communities because of erosion and because of exactly what Brendan showed you, the change in sea ice, which then, of course, causes greater waves, greater storms, and the erosion. This slide is from a GAO report in 2009, and to quote that report, "the villages of Kivalina, Nutaaq, Shaktoolik, and Shishmaref will likely need to move all at once and as soon as possible since they continue to suffer flooding and erosion and have limited emergency evacuation options." That was 2009. The challenges to the residents, of course, are not just financial, or even moving, it's sense of place, sense of community, and sense of culture all being threatened. This is a great website, and it points out the fact that the issues that are being faced by the communities in Alaska are not just Alaskan issues. These issues are going around the world in terms of threatened communities, but this is a picture of Shishmaref, and there are some very powerful statements made by some of the youth there on this website, and I really recommend you take a look at it to see just how important the issue is. As one Alaskan youth says, did you ever lose your home? Have you been homeless? We are about to lose our homes from erosion. We know from research, most notably Dana Kingston and Elizabeth Moreno, when communities move, they need to move together. To spread people across regional centers and into larger cities is a death nail to culture, social organization, and language. And the Arctic, as I mentioned, is only the tip of the iceberg. In 2008, the Organization for International Migration predicted there will be 400 million climate migrants, worldwide, by 2100. Thank you. Now, I'm going to switch to the changing marine environment. Fran mentioned it a bit. Some major impacts in increased vessel activity, oil, gas, and mineral development in the fisheries, so, I love this slide. We all tend to use it. But it's kind of a success story of one man, guy named Ed Paige, Captain in U.S. Coast Guard, that actually started going in and putting tracking systems on vessels, and using them to show the increase in the traffic. The Bering Strait's the only route between the Arctic and Pacific Oceans, and it's becoming increasingly vulnerable to maritime casualties and this map shows ship transits from 2009 to '14. The Northern Sea route, first commercial ships made the transit in 1997. By 2011, just four ships completed the passage, but in 2012 and 2013, traffic

rose with 46 and 71 commercial ships, arcing over Russia, between the Atlantic and Pacific Ocean. In 2014, 440 ships went through the Bering, twice the rate of 2008. Both the international community, through the International Maritime Organization and the United States, recently, with the Coast Guard proposed rule for the Bering are starting to react to this increase in shipping, and the consequences of any kind of accident in those areas are very, very serious. Next slide. Next issue, which leads me to one of the greatest debates in the Arctic, and it's development of oil and gas. With decreasing sea ice, diminishing onshore oil production, further increase of oil and gas exploration, it's going to happen, and the question is, how? 95%-98% of the State of Alaska's revenues come from oil and gas development, and we struggled with that in the legislature and it's a very great difficulty not to have a more diverse economy but the focus on this development is intense and it's going to remain that way. Hard rock minerals, also very important production, the Red Dog Mine, which is in Mayor Joule's community, provides tremendous jobs and tremendous opportunity for the region as does oil and gas, but the considerations are tremendous. Recently, United States had a couple of important decisions on oil and gas development in the Arctic. There's withdrawal. The President issued setting aside certain areas from that development and also, the Department of Interior has just come out with proposals for recent, for exploration and some very important pieces of that, a relief rig to be right on site so that if there is an accident, at least we have some opportunity. Although, and go ahead to the next slide. Really, the challenges are, again, tremendous, and this slide shows Alaska overset on the United States and it has the picture of our one U.S. Coast Guard. There are two ice breakers, but one is going to go to Antarctica and not stay in the Arctic, and you can see how difficult it is when you've only got that one ship that's serving the whole area. The challenges: no deep water ports, the lack of infrastructure, you're talking about small villages and while we do have spill response located around the Arctic, whether it can get there, whether it's enough, those are tremendous questions. One friend of mine calls the tyranny of distance, just the distances alone, and, of course, the oil spill pollution response capability, equipment and the, really the reality, as I heard, one leader of one environmental group say yesterday, the fact that you cannot pick up oil on ice to any effective extent. Fran mentioned search and rescue. There is an international agreement now. But, whether you can reach someone who has a problem in the Arctic Ocean quickly enough is a tremendous question, and finally, the data and information gathering, not having the baseline information that we need to be able to make the decisions is another big issue. The fisheries I'm just going to be very quick about, but one of the greatest fisheries in the world, probably in the Arctic, right now, there's a moratorium, and before any major decisions are made about that, we need to have better scientific evidence, information to be able to make reasonable decisions, and, of course, we're not showing it, and some, some areas don't, I mean, some maps won't include it in the Arctic, but you have the world's largest natural run of salmon in Bristol Bay which was just protected by the President. I've got one last one. I can't stand to end without putting out the bear. We're seeing the decrease in the polar bears and, of course, we have, you know, other threats for other mammals, but for me, the polar bear is the harbinger of change in the Arctic. There are bears coming onto land and adapting and they are resilient animals. But, nevertheless, we, we watch the bears and I worry about them greatly, so I had to end with the bear, and to say, the Arctic is a place where we hope for adaptation and resilience,

but one thing, which you've heard the two previous speakers note, what we do know about the Arctic, it's a place of rapid change, so thank you very much. That's it. Thank you.

>>Mayor Reggie Joule: Good morning, everyone. I'm the Mayor of the Northwest Arctic Borough, and the red is the part of the state that I call home. It's the part of the state that makes up the Northwest Arctic Borough, most of which is above the Arctic Circle. In the 16 years that I served in the Alaska State Legislature, my district went all across the North Slope from the Canadian border, all the way over to Little Diomede when I first got elected, and you know, maybe 15,000, 16,000 people, and the one thing I want to emphasize here, in much of the Arctic, there are no roads. No two communities are connected by roads, and if you go to the next slide, please, in the Upper Kobuk which is to the far right, there is a little bit of an, well, there is an inner tide between the Shungnak and Kobuk. These are the 11 communities that make up the Northwest Arctic Borough, and this little spot of real estate is about the size of Indiana, and the people who reside there, the indigenous people, are Inupiaq people, which I happen to be one of. I was born in Nome, as it was mentioned a little earlier—not by choice. I wanted to be close to my mother. [laughter]I'm sorry. I couldn't. I will, however, mention that my family, on my mother's side, comes from about 100 miles north of Kivalina which is the community on the coast and so, my blood lines, even though I live where I lived, my blood lines run across the North, on my mother's side. On my father's side, my blood lines are mixture. I come from, or, my ancestors on my father's side come from the Fish River, which is around Nome, but I also have some German, some Jew, some Norwegian, a little of mixture, a blending of different things. Next slide, please. This is the hub community of Kotzebue. It's about 30 miles above the Arctic Circle. As you can see, the community is only on the north of the run way. Next slide. As was mentioned, subsistence is a big part of who we are, and it isn't simply hunting and fishing. Subsistence is about economy. Subsistence is about meaningful contributions to family, to community. Subsistence is about science. Subsistence is about knowledge. Subsistence is about doing. Subsistence is about understanding our universe and our place in it, and having the ability to share that knowledge with your children and grandchildren and the younger generations of the community. Next. It is a source of food security. And because of the rapid changing of the climate, this poses some different challenges, new challenges, if you will, to the things we used to consider normal in harvesting and gathering for our families and for our communities. Climate change certainly plays a role. There's some concern about the health in the animals. We see it in sea mammals. We see it in fish. We see it in terrestrial. If we could get to the next slide. Here's an example. The western Arctic caribou herd goes from the North Slope of Alaska, through our area and down to around the Nome area, and over the last less than ten years, or about ten years, the western Arctic caribou herd, the first dot, went from a high of 490,000 animals, and is currently at about 235,000. So there's a rapid decline in the caribou, which provides much of the sustenance, and the Teshekpuk has gone almost in half also. Now, you know, we also harvest from the oceans, and, and the fishing and at least up to this point, the sea mammals, the changes are certainly occurring, and it's—I'll tie that in a little bit later. We started a Research Steering Committee program through a local grant that we received from Shell, an oil company, and we put together a Steering Committee that is made up, out of 15 members, seven local knowledge holders from our area serving with many, eight others, from the science community. There to

promote community based research, starting from the bottom, working your way up. How do we get, and this for us, this is a larger question that we're answering, in fact, but it is a challenge. The Inuit people, because of our lack of formal and western education, we're anecdotal people. We're not Masters, we're not PhDs. We just live in the area. But, along the way, and after a few generations, we picked up some little tidbits of information, and how do you get anecdotal people and western science to work together and recognize the importance of each other? One so that, you know, scientists and data collection, it's almost like an invasive species and, and people get over that after you spend probably at least ten years in the area, and people have a sense that you're looking to do more than just know about something, but to understand it. Understand what it is you're learning and knowing. If we can move on, please. So, these are some of the things that we're currently doing in and around the Kotzebue Sound. There's a cooperative effort with the North Slope Borough Science and Research Group, doing research on beluga whales, bearded seals, and their ability to hear, and we're also doing some ambient noise monitoring. We're doing village surveys where we are going out and talking to all of, to the people who are residents of the community, to determine what are some of the things that should be priorities as far as gathering research. Move on, please. This is some of the drama, if you will, in climate and erosion. We have coastal communities and in one community there's certainly buildings falling over, over the edge as the permafrost is melting. The picture on the right with the arm of the excavator is trying to reach into the ocean to put up a sand barrier for protection, prior to a revetment wall being put up. The bottom picture is in Kotzebue. What you see there is, is a wall that had to be built. It has sheet piling, and it was built out, and that actually serves as a protection. Some of the kinds of things that is needed to protect the people from harm in coastal communities if they're not going to just out right have to move. Next. The village of Kivalina and you saw that in one of Beth's earlier slides, it was just that little community that stuck out there. It's on a, it's on a, I guess, an island, if you will, a barrier reef, barrier, whatever it's called. I have a lagoon in front, a Chukchi sea in front, the Lagoon in the back, and when it gets violent, the 400 residents of that community, because there are no roads, have no access to safety, and there is no system, or very little, for planning. We have tried for some time to get an evacuation road for the community and the residents, for their safety. That has yet to be accomplished, and sometimes, and I think it's necessary to say this, you know, you might ask the question, why do people live there? And that's because the United States government said you had to. When you put in churches, and you put in schools, and the laws that came with them said your children had to go to school, and now you have permanent communities. Prior to that, the people were nomadic, and they lived where the food resources were, and the cost to addressing some of these is going to be high, and what we've seen so far is that if there's so few people and high costs, indecision seems to be the order of the day, and it sometimes is very frustrating. I just might add that in the area of Kivalina, they've had to evacuate, out of the community, physically, once, and on two other occasions, they evacuated to the school, and in the heights of those storms, the waves that hit the revetment rock at the beach splashed right onto the school building. Eventually, that's going to change. So, if we could move on, and I might add, just as an afterthought, Kivalina, while it's one of the communities that, it's imperative that something get done. Along the communities and river systems, some are faced with the same river erosion, permafrost melt, the changing of the climate and all of that that is, that either is river erosion or coastal erosion,

and there are, I would say most of our communities are impacted, if not all of them, one way or the other. This is about resource development. What you see here is a picture of the Red Dog Mine. It is located 70 miles north of Kotzebue, about 30 miles north of the village of Noatak and the Noatak River. It is the largest open pit, lead and zinc mine, for sure in the United States, and I think it's second in the world. If you could go on. The Red Dog Mine, for all that it is, for all the disturbance that it causes, was not a project that was taken lightly. The land is owned by an ANCSA, Alaska Native Claim Settlement Act corporation. The land is owned by indigenous people. They went out and found an operator and somebody to, to develop this mine. That was back in the 80s, late 80s. Yes, I started out by saying subsistence is important to our people. There's a 52 mile road from the pit to the, to the dock that you see there. Where, where barges come in and they take the oar and load it onto ships, and they're able to move in excess of 1 million metric tons of ore a year, and they only ship during the summer months. They store the oar during the winter months when the ice is there, and I say this because, yes, subsistence is important, and when you do development in a way that takes into account the renewable resources, and because it was a native owned resource, natural resource, the minerals, we were probably able to dictate a little bit more, and we've had a, they've done a good job of finding the balance of development and preserving the economy and preserving the renewable resources in a way that the people are satisfied with. Constant water monitoring, because of the village of Kivalina is just down river, about 50 miles, so, if we can go to the next slide. In the coming years, oil and gas, well, actually it's here. Oil and gas. It's been talked about for years, but it looks like Shell will get the go ahead to work their leases this summer and it's out in the Chukchi Sea, while not specifically in our waters. The seals and the beluga and other sea mammals all work their way through there. They're not stationary, they're migratory, and so, we're impacted by that, and that has caused us to have some really vigorous discussions/debates about whether or not this is something that should be done. Whether we support it or not, and quite frankly, I'm at the point that while I have some concerns about how the continental shelf, exploration and development, the regulations put in by our government, that's going to be mandatory for an explorer like Shell is going to mean they're going to have to have the necessary equipment in place to be able to respond to anything they may cause. Now, exploration, that is going to resume this summer is not new. In the 80s and early 90s, there were over 70 holes that were drilled as part of exploration. And there was no fanfare, there was little publicity about it back then, and probably a whole lot simpler in terms of permitting, than what a company like Shell or any future company will have to go through, and to my knowledge, there hasn't been anything of any major concern. I will say, however, that in the 2000s, the increase in marine traffic, and you saw the maps from Beth's earlier slide, and I'll show it again here, is going to be become an issue. And because—

>>John Holdren: Mayor Joule, I apologize for interrupting you, but our lease on this room expires in five minutes.

>>Mayor Reggie Joule: Okay, we'll just move on. We'll go on here. You saw some of these—the only point I want to make here is marine traffic is a concern, and there you have that, go on. So, this is, this is where we're at with, or maybe not at, when you take a look at some of the global preparedness for the Arctic in terms of marine traffic. There's one thing that I want to mention

in term of our people, and I, in the challenges and opportunities, adaptation is going to be a big issue. It is, and, so, I'm really happy for the, for the time that I was able to spend here and apologize for maybe taking a little bit too much time. But, you know, when you're boots on the ground and you look at opportunities of potential employment, you look at challenges of the environment, and you try and find a balance, and the word comes from 7,000 miles away, what gets done, or not. The whole opportunity, I think, for, for consultation and dialogue with the people of the area, becomes even more increasingly important and I thank you for the opportunity.

>>John Holdren: Well, thank you. Those were—[applause]

>>John Holdren: Those were all terrific presentations. We officially have three minutes remaining in our session. That's probably time for one question and one quick answer. Would anyone like to offer that question? I think the presentations have left PCAST members uncharacteristically speechless. We really do appreciate what all of you have contributed to this very important set of issues and certainly, it's been illuminating for PCAST and I know for the wider science and technology community represented and watching on the web. We really are most grateful to you. We have no public comment today on the schedule. We have received none. My distinguished co-chair has corrected that formulation. We of course would not suppress public comment if we received any, but we didn't receive any, and that brings this 30th meeting of President Obama's Council of Advisors on Science and Technology to a close. Thanks, again to everybody involved and, above all, our incredible staff who support the PCAST operation, and without whom, such a complicated set of arrangements and meetings could never be pulled off. We'll see you all next time. [Applause]