

08-19-10 MCMRollout\_8192010

Kathleen Sebelius:

Good morning, everybody, and thank you for being here today. I want to introduce my colleagues on the stage at the outset: Dr. Nikki Lurie, who is the assistant secretary for Preparedness and Response; Dr. Tony Fauci, the director of the National Institute of Allergy and Infectious Diseases at NIH; Dr. Peggy Hamburg, FDA commissioner; Dr. Robin Robinson, the director of BARDA at ASPR; Dr. Tom Frieden, who is our director of the Centers for Disease Control and Preparedness [sic]; and joining us by phone are Harold Varmus and Eric Lander, who were the co-chairs of the President's Council of Advisors on Science and Technology -- PCAST -- and you will hear from them during the course of this presentation.

Our greatest responsibility in government is keeping the American people safe, and to uphold that responsibility, we've always had a powerful military that can guard against conventional threats. But increasingly, the range of dangers we face is widening to include biological, chemical, nuclear, and radiological hazards. Today, we really don't know where our next public health crisis can come from. It could be a dirty bomb set off in a subway car. It could be a naturally-occurring "super bug" that is resistant to all treatments. It could be a biological weapon we've never seen before assembled from the building blocks of life by a terrorist in a lab.

And it was with this increasingly crowded landscape of natural and man-made threats in mind that we released our country's first-ever National Health Security Strategy last December. The principle at the heart of the strategy is that our public health response is only as strong as its weakest link. So, using it as a guide, we've worked to upgrade our entire end-to-end response, from how we assess and identify threats to how we distribute and administer products to counter those threats in cities and towns across this country.

But as we studied the landscape, it became clear that one area is where we needed to put a special focus: on medical countermeasures. Medical countermeasures are the vaccines, anti-virals, antibiotics, diagnostics, and medical equipment. In a public health crisis, they're our most direct and often our most effective defense. To reach our national stockpiles, most countermeasures travel along the exact same path. They begin with discovery in a lab. Then, the discovery gets translated into a useful product and that product gets tested for safety and effectiveness and then someone manufactures it. And if the process works well, there's a steady output of new countermeasures targeted at our biggest potential threats.

But the closer we looked at the countermeasure pipeline, the more leaks, choke points, and dead-ends we saw. So, in this age of new threats, we aren't generating enough products. In a business where delay costs lives, it couldn't manufacture and develop countermeasures fast enough. And at a moment when the greatest danger we face may be a virus we've never seen before, like one that causes SARS, we don't have enough flexibility to adapt to unforeseen threats.

So, we basically had three choices: cross our fingers and hope the worst never happened, pump more money into what we know is a leaking pipeline, or roll up our sleeves and take a hard look at what was going wrong and start building the 21st century countermeasure enterprise we need to keep Americans safe from 21st century threats.

So, for us, the choice was pretty clear, and that's why last December, with the encouragement and strong support of President Obama, I called for an unprecedented review of our entire medical countermeasure enterprise. The review was led by our department's assistant secretary for Preparedness and Response, Dr. Nikki Lurie, and that review drew on dozens of conversations with our own HHS experts, with state and local health departments, with industry groups, venture capital experts, academics, scientists, and bio-tech developers around the country.

As we conducted these conversations, common themes emerged. We needed to focus more on children's unique needs. We needed to work more closely with our partners across government, including the Department of Defense. But most of all, we needed to move toward the report's vision of a nation with, and I quote, "the nimble, flexible capacity to produce medical countermeasures rapidly in the face of any attack or threat, known or unknown, including a novel, previously unrecognized, naturally-occurring, emerging infectious disease." Pretty lofty but pretty critical goal.

Today, we're releasing the report that sums up those findings and you can read it on our website at [hhs.gov](http://hhs.gov). But we're not here this morning just to talk about how we can do better. We're moving forward with a plan that will strengthen our countermeasures pipeline and several key points. So, there are five key areas we are intending to focus on.

Guided by the review, the five areas where we believe we need to act now to make big improvements in our public health defenses are the first level of priorities. First, strengthen the regulatory science at the FDA. One of the hardest parts about getting a product from test tube to our national stockpile is making sure it's safe and effective and meets manufacturing standards, and it's even harder for drugs that target a rare or emerging disease that's often poorly understood.

For too long, we've under invested in the tools, models, methods, and knowledge needed for making these assessments, what's collectively known as regulatory science. Because of this underinvestment, we're often testing and producing cutting-edge products using science that's decades old. So, we're going to give our world-class scientists at the FDA the resources they need to create clear regulatory pathways, analyze promising, new discoveries faster, and help identify and solve scientific problems as they occur. And we're also going to reach out to project developers -- product developers -- excuse me -- early in the process so they know what to expect. Now, the benefits are clear for our medical countermeasure enterprise, but also have great benefits for other drug production to cure diseases.

The second area we'll focus on is developing flexible manufacturing. Right now, too

many of our countermeasure facilities are filled with big equipment that's designed to produce just one product over and over again. Now, that works well for seasonal flu vaccine, but it leaves us vulnerable when the countermeasure we need may also be one we don't use regularly or haven't even invented yet. That's why soon we'll announce a solicitation for the new Centers of Innovation for Advanced Development and Manufacturing: facilities that will work to give new flexible manufacturing platforms while giving us a dependable, domestic source of surge capacity for flu vaccine so we don't have to rely on foreign producers, as we did during the H1N1 crisis. And these centers will also serve as a resource where small bio-tech companies with big ideas can get the regulatory and manufacturing knowledge they need to bring their products to market.

The third area we want to move on is nurturing discoveries at their earliest stages. Now, today, it's common for a scientist to make a discovery without realizing it, without realizing it can be turned into a useful countermeasure, or they may see the potential but not know exactly what the next steps are. And that's why we're going to use a wide array of NIH resources to identify and nurture these promising discoveries, including creating new Sherpa teams to help guide them through the development process.

As we conducted this review, we looked at the full range of public health threats. But after dealing with H1N1 and with H5N1, the avian flu looming on the horizon, we naturally put a special focus on our flu response. And that's why the fourth priority is upgrading the way we manufacture flu vaccine, from modernizing potency and sterility testing to speeding up the production of vaccine seed strains. These are the same steps recommended in the new report from PCAST that you'll hear about in a few minutes and they'll ensure we're better prepared for flu seasons to come.

And finally, the fifth area we'll explore is a strategic investment fund for new countermeasure technologies. Right now, there's little incentive for private companies to produce medical countermeasures for rare conditions, like Ebola virus or exposure to non-medical radiation. And yet, in the event of an Ebola outbreak or nuclear explosion, these countermeasures would be critical. A strategic investor could support the companies with ideas that have little hope of making huge profits but big potential to improve our public health preparedness. Taken together, these five initiatives will add more life-saving products to the pipeline, enabling critical programs like BioShield to work the way they are supposed to.

Now, as this review went on, we also looked beyond our labs and factories at what we could do differently right here in D.C. We found that our contracting processes were too rigid, for example. We realized we needed to do a better job talking to the private sector throughout the product development process rather than just when we want to license a product. And we saw that we needed better coordination, not just within our department, but across government. We've incorporated some of these lessons into our response in the H1N1 pandemic last year and we're going to keep working to make sure we're doing our part to strengthen our capacity to respond.

Now, there's an old saying in sports that victories are won on a practice field when no one is watching. In the same way, how successfully we respond to tomorrow's public health crisis when the spotlight is on is determined by how hard we work behind the scenes today to build a 21st century countermeasure enterprise that can respond quickly and effectively to any threat. And that's why in the coming years, we'll invest nearly \$2 billion in preparedness funds to these five key areas. And though our official countermeasure review concludes today, our work to strengthen our public health preparedness will never end.

We know that our enemies are constantly probing for weakness. Every year, new threats emerge and the old ones evolve to become resistant to our known medicines. And that's why we'll continue to look for ways to build not just stronger countermeasure enterprises with the solid base of discovery, a clear regulatory pathway, and agile manufacturing, but also a stronger public health response all the way from disease surveillance to administering countermeasures to people in our cities and towns. Today, we are taking a big step toward a safer America. Tomorrow, the next step begins.

And now, to talk about the new report from the President's Council of Advisors on Science and Technology, I'd like to introduce one of our finest scientists, Dr. Harold Varmus. Now today, Dr. Varmus runs the National Cancer Institute, but he's speaking today as one of the council's co-chairs when they wrote the report. Dr. Varmus.

Harold Varmus:

Thank you, Madam Secretary. I'm sorry I can't be there with you.

Today, PCAST, which as the secretary mentioned, is a council of independent advisers to the president on science and technology, is releasing its report on influenza vaccines, and that report is available to all at [ostp.gov](http://ostp.gov). The report analyzes the efforts we've made to protect the U.S. population during the 2009 H1N1 pandemic and the report identifies several aspects of the traditional egg-based production process that could be improved in the next year or two to increase the likelihood that we will have adequate amounts of vaccine available during the next influenza pandemic. The report also supports more fundamental changes in production of influenza vaccines in the longer term using up-to-date methods. Many of the recommended short- and long-term changes are application to defense against other infectious agents, and hence they're relevant to the HHS report on medical countermeasures that, as you heard, is also being released today.

Why was this study done? As you'll recall, during the H1N1 influenza pandemic of 2009, production of a new influenza vaccine, our most potent defense against severe disease and death during a pandemic, was not fast enough to afford optimal protection. The first doses of vaccine arrived after the second wave of infection began in the fall of 2009 and sufficient vaccine to protect the majority of the population was not available until well after the second wave had peaked in the middle of the fall.

These delays reflected the inherent uncertainty of our current processes for making influenza vaccines. No one was at fault. Fortunately, the virulence of the pandemic

influenza strain remained relatively mild. Still, the CDC estimates that approximately 13,000 U.S. residents died and many others were severely ill. And those numbers could have been significantly reduced by more timely production of vaccine. And, of course, with a different virus, the delays in vaccine production could have had much more severe consequences.

How did this study get done? Late in 2009, even before the pandemic had subsided, PCAST was asked by the president himself and by members of his senior staff to evaluate the current and alternative possible methods for the production of vaccines against pandemic influenza so that we're less likely to face the predicament of 2009 in the future. PCAST assembled a group of experts who systemically examined the several steps that must occur between the declaration of a pandemic by the WHO, the World Health Organization, and the release of the first doses of a new vaccine. Those steps are outlined in the report graphically. We can't project those effectively. Those of you in the room have copies of some of the figures that show these steps. The group also gathered evidence about other aspects of the vaccine production process, about the economics of the vaccine industry, and about other means of producing influenza vaccines other than the traditional method that uses fertilized eggs.

In its findings, PCAST identified five steps in the current process that could be improved over the short term -- the next one to three years -- to hasten delivery of a pandemic vaccine using the strategies that are already approved for making influenza vaccine. These are summarized in the report and in your handouts. They include increased surveillance for pathogenic agents to identify pandemics earlier and give us an earlier start signal for making vaccines. A number of steps in the vaccine process, some the secretary has already mentioned, including making seed viruses for vaccine production in a more efficient way, using faster, novel methods to verify the sterility of vaccines, and better ways to test vaccines for potency. In addition, the manufacturing process that is essential to the final stages of production: Filling and finishing the vaccine vials can be streamlined and expanded. Overall, these improvements could reduce the time required to deliver both the very first doses of vaccine and the last doses from a few weeks to a few months. For each step in the process, PCAST also recommended assignments to federal agencies which will work closely with industry.

PCAST also recommended more fundamental, long-term changes in the production of influenza vaccines. A shift to cell culture away from fertilized chicken eggs is a more efficient and reliable means of vaccine production, and the greater use of live, attenuated vaccines because of their greater potency. We also argued for further development of immunological stimulants -- so-called "adjuvants" -- as components of effective vaccines to decrease the amount of viral material required in the vaccines. We urged that the industry and [unintelligible] the government accelerate the use of modern recombinant DNA methods to produce vaccines to eliminate the need for large-scale growth of the virus, and thereby hasten the production of the vaccine. And we also recommend continued study of the potential to develop a so-called "universal vaccine" that would protect against most or all strains of influenza virus.

Now, implementation of these methods of production could further shorten the time and cost required to produce vaccines. It would reduce the amount of vaccine required for protection, it would improve the manufacturing of vaccine that's used annually against seasonal flu, and would allow production of enough vaccines to protect other vulnerable populations outside the U.S. when worldwide pandemics strike. To achieve this complex set of both long- and short-term goals, PCAST recommends some novel management practices outlined in the report for use by the U.S. government and also recommends a number of ways in which federal agencies can collaborate closely with industry.

PCAST was unable to and not assigned to prepare a detailed accounting of cost at this stage, but did provide some rough estimates that suggest that about a billion dollars of government support would be required for a few years, along with investments by industry to reach the several goals that we've outlined. These cost reviews by PCAST as modest in view of the potential for savings lives during the next influenza pandemic. When the pandemic is over, we tend to forget what had happened during the pandemic, but in a pandemic, there's a life-and-death race between the defense -- that is, those of us who are saddled with the responsibility, along with industry, for getting virus to the public -- and the virus itself, which is always about to return to the population and threaten severe illness and death.

Accelerating delivery of vaccine by even a few weeks can mean saving tens of thousands of lives. In addition, most of the investments that we are discussing would contribute to the nation's defenses against other kinds of biological threats, as described by the secretary in the HHS report on medical countermeasures.

Thanks very much for your attention. I'm happy to take some questions when the opportunity arises.

Kathleen Sebelius:

Well, thank you, Harold. And Dr. Varmus and I would be pleased to answer a few questions before I turn over the conference to Dr. Nikki Lurie.

But I want to end my part of the presentation by just recognizing that this review was an incredibly collaborative effort. Not only did it involve our world-class scientists across HHS, and budget team and policy teams and others, but we had great partners at the National Security Council and the Department of Defense and other government agencies, as well as the private sector who participated. And I just want to recognize that this review is not only critically important, but a great example of an all-government approach, which the president called on us to do to make sure that the safety and security of the American people is our top priority.

So, with that, I'd be pleased to take a few questions.

Yes, ma'am?

Female Speaker:

[Inaudible]. Thank you. I had a question about the \$2 billion. Where will that come from? How much of that will be directed toward industry itself, like, to the bio-tech companies? Will any of those funds actually go toward the bio-tech companies? And then for your -- the new Center of Innovation: Where will that be located and how will you fund that as well? Will that be funded by the \$2 billion?

Kathleen Sebelius:

Now, that's sort of three questions, but --

[laughter]

-- let me see if I can take them in order. The \$2 billion -- the bulk of the \$2 billion is money that is already allocated and directed to HHS for preparedness. Much of it comes from the 2009 supplemental funding for the pandemic response, and so we are re-purposing, redirecting those funds to these five initiatives.

The Centers for Innovation and Advance Manufacturing [sic] will really be competed for in RFPs that will be released hopefully in the near future. They are being developed right now, but there are a number of interested entities around the country, a number of creative ideas for flexible -- much more flexible manufacturing that could be used for multipurpose, which, really, we lack right now, in addition to additional manufacturing capacity. So, those are the two goals.

And in terms of the money directly to the industry, I would say the funding for the strategic investor that we are anticipating -- and we will go to Congress to ask for this authority -- really is the kind of not-profit, venture capital ability. What we know is that some of these great ideas are going to come from very small companies who don't have the capital and the wherewithal to get a product from microscope to market, so the investment early in that pipeline can really not only ensure that the great idea actually becomes a product, but will help spur that development. BioShield will remain as the entity for purchasing a developed product, but what we know is that a lot of products never get to the point where they can be purchased because the process stops at some point along the way. So, part of this effort is to make sure that pipeline continues to flow.

Yes, ma'am?

Female Speaker:

Hi. Megan [inaudible], NPR News. I was wondering about -- you talk a lot about the manufacturing process, but when you get a lot of vaccines together, do you think the current distribution system is going to be all right for in the case of a pandemic?

Kathleen Sebelius:

Well, what we've found in the H1N1 vaccine situation was that we were able to, with great partners at the state and local level, to develop a significantly enhanced and robust distribution system very quickly: identified the PCAST (correction: ACIP), the scientists

sat on the president's advisory council, identified the target population. Our state and local partners then identified the specific sites that were best to reach that population. And we significantly enhanced what had been in place as the children's vaccine distribution methodology and made that considerably more robust and also used school-based clinics and a variety of strategies, knowing that that was a target population that isn't typical in the flu. I think that is a step forward.

What I think is a considerable concern -- and we're going to continue to work on everything from surveillance to distribution. I mean, this particular report focuses today on the development production and stockpiling of medical countermeasures, but what we know is that we need faster, more nimble, better ways to do surveillance and we find what is going as early as possible, whether it's here in the country, or around the world. And we need, at the other end, to make sure if we get a product and we have an identified target population, we need a better and more robust distribution system. So, we'll continue to work on that.

I would say of great concern is the, really, decimation of the public health infrastructure around the country due to the economic downturn. A lot of states have severely cut public health officials, emergency preparedness officials: the kind of infrastructure that's needed in this country which is the backbone of the first responders. So, the preparedness funds that are sent by the federal government to states, the kind of partnership that was developed during H1N1 by Dr. Frieden and other colleagues to work very closely with state and local partners, I think we will need to continue to make sure that's a robust infrastructure because that's really the heart of our distribution system.

With that, I think I will turn over the program to Dr. Nikki Lurie, who led this response. Dr. Lurie.

[applause]

Nicole Lurie:

Well, thank you, Madam Secretary, and thanks, Dr. Varmus. I'd like to extend a special thanks to PCAST for lending their expertise here. We were conducting our reviews concurrently and we had a huge amount of back and forth and exchange and I think it was very productive.

To get to the really root-cause issues that were at the, sort of, heart of this medical countermeasure enterprise and the leaky pipeline and the road blocks that you've heard about and to come to some really novel, creative, and very realistic solutions. As I think you heard from the secretary, we talked to all kinds of people around the country and, frankly, around the world: scientific leaders from our federal agencies that develop and play a part in this enterprise, including colleagues at the Department of Homeland Security, various components of DoD, and as you've heard, the components of HHS, whose leaders are represented here today.

As well, we spent a lot time -- to the previous question -- talking with people at state- and



local-level health departments. We consulted with colleagues in academia, in industry. We were conducting this review, and some of the heart of our review, actually, was going on when we had those lovely blizzards that we had in Washington and we had to cancel and reschedule advisory committees and workshops a couple of times. And I particularly want to thank colleagues at the Institute of Medicine, who hosted a workshop for us that had to be rescheduled, and colleagues from our advisory committee, the National Biodefense Science Board, who really did the same.

And we talked with industry leaders, as you heard from the secretary, people in the venture capital world, people in the investment banking world, all of whom are involved in one place or another in this complicated pipeline that gets us medical countermeasures at the end. I want to take a moment and just say a huge thanks to people inside and outside of government, really all over the place, who stepped up, provided their time and insight. All of their feedback was just of tremendous, tremendous value in helping shape our review and the path forward.

And while we're seeing agency leaders here on the stage, many of my colleagues here in the audience, many unspoken and unsung heroes in putting this together; there are a lot of people who are instrumental in putting this together.

I want to particularly thank Dr. George Porch [spelled phonetically], who is sitting here, who is really my right-hand person in leading this effort, and as well, Stef [spelled phonetically] from the National Security Staff, who worked in a really intrepid way collaboratively with us throughout this, and they were ably led by Heidi Avery, who is sitting here as well. Similarly, other colleagues who are not on the stage who were involved in this include Andy Weber from the Department of Defense, who is also here. It was just a terrific collaboration, lots of very thoughtful and dynamic exchanges we worked this through.

So, let me just, I think, review for a moment what the secretary told us about why this matters. You know, an infectious disease doesn't really care about economic conditions, doesn't really care about rich or poor countries, doesn't really care about how it got here. And so, as we know that we can't predict when the next pandemic will occur, we can't predict when we will see another act of bio-terrorism, when people say to me, "What's the most surprising thing to you since taking this job?" My first answer is, "How many earthquakes there are in this world."

[laughter]

And my second question is, "How many reports I get about new and concerning infectious diseases," including continued cases of H5N1, the avian flu, that come across my Blackberry on a pretty regular basis. And it reminds us on a day-to-day basis why it is that we need to be prepared. And this --

Operator:

Once again, for the parties on the phone that would like to ask a question, please press \*1.

Again, to ask a question, please press \*1. Thank you.

Nicole Lurie:

-- in the face of a public health threat we've never seen before, whether it is a naturally occurring one or whether it's man made. And so, many of the actions we're taking are really aimed to address that.

But one of the things I also want to point out is that we expect that many of them -- and I think you can probably tell from listening to this -- ought to have applications be on the medical countermeasure arena to help us deal with other emerging threats and other neglected diseases, both through new scientific breakthroughs, through some of the regulatory innovation you've heard, through helping companies get other kinds of products to market. And we're really quite excited about, you know, having come through H1N1 and seeing these recent reports of these scary new super bugs, we all have a tremendous sense of urgency to get this done. And I think all of us here carry with us a tremendous sense of responsibility to do this; this is really our job in government. And so, the approach that we have announced today with all of its initiatives and enhancements really reflect that sense of urgency designed to build a better system.

The other point I just want to make really quickly is we haven't waited for this announcement to get going. Already -- in fact, even as this review was going on, we started working across federal agencies to put a lot of changes in place. We've now conducted the first of reviews of major product portfolios for things like smallpox, anthrax, radiologic and nuclear products, and soon, again, another look at our flu enterprise.

In the next few weeks, as you heard, we'll be releasing the [unintelligible] solicitation for the Advanced Development and Manufacturing Centers of Excellence, we're establishing an HHS regulation for the use of other transaction authorities so the secretary has the full use she needs in new contracting methods, and we're instituting a five-year budget planning process so that we can really systemically think about this from end to end, because, as you know, some of it begins and ends with the science. It all begins and ends with the money.

[laughter]

And inside, we've implemented already a number of ways to do our own work better and smarter, including things like shortening the time of a contracting process, et cetera.

I think all of us are really pleased and excited to be here today. I think for all of us it's been a long road getting here. It's been an exciting process, but now, we are actually at a new point, beginning a lot of really exciting work, a lot of hard work. It's going to continue to take our focus and determination to take this report, which looks lovely and glossy, and implement these initiatives and plans and get the job done for the American people. And I think we're all very excited about taking on that challenge.

I'd like to introduce to you my colleagues and the leaders who helped make this report possible, and I think each of them is going to speak for a few minutes, beginning with Dr. Tony Fauci, I think known to all of you as the director of the National Institutes of Allergy and Infectious Disease; and Dr. Robin Robinson from BARDA; Dr. Peggy Hamburg from the FDA; Dr. Tom Frieden from the CDC; and then we'll take any additional questions you have.

So, we'll start with Dr. Fauci.

Anthony Fauci:

Thank you very much, Nikki. It's a real pleasure to be here with you this morning.

You heard the secretary outline for you five major initiatives that emanated out of our intensive medical countermeasure review that we undertook over the past several months. Each of these individual five initiatives impact to a greater or lesser degree on virtually all of the sister agencies that are involved in this process, including our collaborations with the Department of Defense.

What I'd like to do over the next two or three minutes is just to very briefly outline for you two of these initiatives which have a particular importance for the NIH efforts, but also in great collaboration with a variety of others that you'll hear from today.

The first is what the secretary mentioned, what we're referring to as a "concept acceleration program", and what that really is is fundamentally a nurturing program for scientists who come up with concepts so that they really do not have either the expertise or even the realization of the potential impact of a scientific discovery or a concept, how it might be translated into something that's a definable product as a medical countermeasure, be it for a deliberate threat or for many, many of the naturally-emerging challenges that we often face.

The underlying principle of this program is to not leave any promising concepts on the vine. I'll give you an example of what happens virtually every day in science. Many scientists are fundamentally focused on developing a concept or a basic science discovery, and we like that; that's the fundamental creativity that gives us the seeds for developing the important products that we need. However, more often than not, once they publish their paper in Science or Nature or what have you, it could essentially stay there as they go on to the next concept as opposed to realizing what implications that discovery might have.

What we have been doing, but we're going to do now with much greater intensity with this new program, is to serve as a guide or a Sherpa for these individuals not only in getting them the experience, which they don't have, and how you deal with the regulatory agencies, how you deal with BARDA, how you deal even with the NIH to get further money for grants, but also to supply for them access to our reagent repositories, our animal models, our Clinical Trials Network, and above all, the expertise that we have. We have a number of examples of these which we have been doing even prior to the

official launching of this -- individual program.

The key issue in this is really staff time and the expertise that we have. We've been doing this, as it were, on our spare time, if you can say there's such a thing as spare time in this business, but now, we are going to launch this in a much more organized and much more intensive way.

The second issue that relates very closely to what the NIH does is what the secretary mentioned as a "strategic investment fund". This really is a 501(c3) nonprofit organization with an independent board of directors, and as the secretary mentioned, we will require authorization for this. But the fundamental principle of this is that individual companies, be they bio-tech or what have you, if they are involved in public health, they are often in a precarious situation. They're really an endangered species, because there is not a lot of incentive to develop issues that have to do with public health, particularly threats that are potential that have not yet even occurred.

So, what we're going to be doing is that we're going to be serving as a -- similar to a venture capital but with investments in the companies themselves, not necessarily investing in a particular product, but to ensure the viability of companies to make it more attractive for them to get into the business that we find so important for the protection of our citizens.

So, with that, I'll close, and as Nikki mentioned, I'd be more than happy to answer questions with others after they have finished. Thank you.

Robin Robinson:

Thank you. I'm Robin Robinson from BARDA, and BARDA will work collaboratively with other HHS and DoD agencies to cross all of these initiatives and from a medical countermeasure review and also from PCAST's report. And we'll lead three specific areas. I want to outline those.

As mentioned by the secretary and Dr. Lurie, the first is flexible manufacturing, advanced development, core service partnerships. As HHS is committed to developing new, nimble, and robust ways to manufacture medical countermeasures that is flexible and multipurpose manufacturing, BARDA will lead the HHS effort with DoD to support the establishment of U.S.-based Centers of Innovation for Advanced Development and Manufacturing as public-private partnerships between the U.S. government and experienced pharmaceutical companies and academia.

This initiative primarily will support the construction and operation of new facilities and/or the renovation of existing facilities in the United States to provide, on a routine basis, core, advanced development and manufacturing services to medical countermeasure candidates of small bio-tech innovator companies under contract with the U.S. government using flexible manufacturing and plant-form [spelled phonetically] technologies.

These core services from the Advanced Development and Manufacturing will be coordinated with other core services that are already provided by the NIH by [unintelligible] animal testing and clinical testing. Additionally, these U.S.-based facilities will serve as a commercial skill manufacturing sites for pandemic influenza and for emerging infectious diseases as the need arises. This program builds on previous HHS investments, which have included the building of a new cell-based influenza vaccine manufacturing facility in North Carolina and in retrofitted manufacturing facilities in Pennsylvania and California that provided vaccine during the H1N1 pandemic. So, that's the first one.

Secondly, following on what the PCAST recommendations and from the medical countermeasure review with influenza, we will be improving influenza vaccine manufacturing. And this will be an effort that will be with JDC, FDA, NIH, and BARDA to bring about the first and last doses of pandemic vaccine sooner. Therefore, we'll look at every step in the manufacturing process to build efficiencies into the systems and sharpen our scientific understanding for both current and new vaccine technologies. These agencies will work with the vaccine manufacturers and we will shorten the influence of vaccine manufacturing cycle by weeks and make the first and last doses of pandemic vaccine available sooner and in larger amounts. Three areas that will receive the most attention will be optimization of virus seeds, potency assays, and sterility assays.

The third and last area that BARDA will be leading is with advanced development of new technologies. We will continue to improve vaccines, anti-virals, and diagnostics for influenza and other threats with support of advanced development. These will include more influenza vaccine candidates using recombinant and molecular technologies that are not vulnerable to the slow-growing viruses, as we saw with the H1N1 pandemic. Secondly, anti-virals that are targeted against novel targets such as host and viral seeds. And secondly, this will spin the emergence of drug resistance that we're already seeing with our anti-virals. Third, with CDC, we will work to develop more sensitive and easier to use point-of-care and high-throughput diagnostics for influenza and other respiratory pathogens.

In closing, BARDA sees this as a new era to improve the mission of providing medical countermeasures to the public when it needs it.

Margaret Hamburg:

Thank you very much, and it's a real pleasure to be here this morning.

I have been working on issues of bio-security and public health preparedness for many, many years now and so it's very exciting to see this degree of commitment of collaboration and real progress in a field that's so important to the health of the nation. Together, we can and we will build a safer America.

We're all here today because we're committed to doing more, and we must. We live in a rapidly transforming world, and biological, chemical, radiological, and nuclear threats pose a unique and growing challenge. Developing and evaluating medical products to

protect against these threats is a complex, time-urgent requirement.

And that's why the FDA has participated closely and actively in this department-led review. And because FDA evaluation of product safety and efficacy so significantly impacts the course of product development, as the secretary indicated, the review identified our agency as fundamental to the success of the overall enterprise. Already, the FDA conducts activities to increase access to and availability of safe, effective medical countermeasures.

This initiative will enable us to take our actions to the next level. We've developed an FDA action plan that, once implemented, will allow our agency to do its part in helping to strengthen and to transform the medical countermeasure enterprise and this will have very broad implications for health and for safety.

Specifically, the plan has been designed to address in three major ways some of the key challenges we face as an agency and as a nation in the development and availability of medical countermeasures. First, FDA will support enhanced review of new products and novel manufacturing approaches for the highest-priority medical countermeasures. We'll work with developers and government partners from very early in the development process and in a highly interactive manner to define viable regulatory pathways, speeding progress towards product approval by helping to anticipate and resolve bottlenecks, and to identify and address scientific issues as they emerge.

Second, FDA will advance regulatory science and improve countermeasure development and evaluation pathways by strengthening our own scientific capacity and building scientific research collaborations with governments, academic, and industry. This emerging science will support the development of needed, innovative tools and standards to better assess the safety, efficacy, and quality of new medical products. This initiative will allow FDA to identify and help solve the scientific challenges that hinder countermeasure development and, without solutions, result in unacceptably long delays in getting the products we need.

Third, and finally, we'll work with HHS and other government partners to conduct an examination of the legal framework as well as regulatory and policy approaches toward medical countermeasure development and availability to assess adequacy or improvements needed to properly support preparedness and response.

Ultimately, our mission at FDA is to do everything that we can today to ensure the safety, effectiveness, and availability of medical countermeasures tomorrow. We cannot afford to wait until an emergency to discover that a product is too risky or that it doesn't work and we must do our part to expedite the development of promising products and identify those that won't make the cut as early as possible in this process, as well.

So, we are very excited about this new initiative and the opportunities that it represents to improve health, safety, and security for our nation and, frankly, for the world. So, I'd like to close by thanking everyone at the FDA who's worked so hard throughout this

review to maximize our agency's contribution to the effort, our friends and partners at other agencies and outside with whom we've collaborated, and finally, Secretary Sebelius and Dr. Lurie for their excellent leadership and unwavering dedication to an issue of such critical importance to our country.

So, I wish all of us good luck in the tasks ahead. Thank you.

Thomas Frieden:

Thanks very much. I also want to thank the secretary and Dr. Lurie for their leadership in this process, for PCAST for a very thoughtful and helpful and insightful review, and our many partners at the Department of Defense, State, USAID, throughout the U.S. government, and also globally, as I'll discuss briefly in a minute.

The investments announced today will help us have vaccine sooner for a future pandemic. CDC is involved in several ways, as have been mentioned, and I'll just outline them very briefly.

First, we will tweak the vaccine production methods. We all hope for game-changers. Game-changers would be a universal, long-lasting vaccine or a recumbent vaccine, which could be produced very quickly in large quantities. And we are investing more, the government is investing more in that, announced today. But in addition, we can use existing tools to cut days, weeks, even a month or two out of our current vaccine production methods without any concerns about new products or the difficulties of getting those to market.

That's possible by first optimizing the way we make seed strains, so finding seed strains that will grow quickly. One of the fundamental problems with how the response to the 2009 H1N1 pandemic vaccine production progressed was that the seed strain grew too slowly. There are ways in the laboratory of optimizing that, and with additional investments from BARDA, we think that is achievable in the next few years.

Second, and achievable, we think, even sooner, in collaboration with the FDA and with support from BARDA, are enhancements in potency testing. Currently, to see whether there is enough vaccine in a vial takes an extraordinarily cumbersome and inaccurate, potentially, technique. Studies done in CDC laboratories outline a pathway to do that much more quickly and much more accurately and we hope to have that actually in place, with the support that is being announced today, relatively soon. We also, as Dr. Robinson mentioned, will promote modernized diagnostic tests, so that ultimately, we would hope that in the doctor's office, diagnosis not only of flu, but the specific type of flu or other lung infections could be made. These are all critically important and can make an enormous difference.

As the secretary highlighted, we are focusing today on that middle section of developing, producing vaccines, biologicals, treatments, new drugs. There is also a need to improve both ends of that process. The detection of new pathogens or new pathogens in new areas around the world and in the U.S., and the CDC is investing heavily in this with

people, with capacity building, with laboratory development. After all, if we had known two months sooner that the H1N1 virus had been spreading in Mexico, we would have been able to start vaccine production two months sooner and have it available two months sooner.

And second, at the other end of the process, we are dealing with the challenges that Secretary Sebelius outlined very clearly: that state and local governments are facing often unprecedented fiscal crisis which are putting great strains on the ability of the public health system to detect and respond. In that context, we are doing what we can to strengthen the ability of governments to respond, to optimize systems, to enhance collaborations between the health care and public health systems, to use the electronic health record initiative to make it easier to reach out to and vaccinate or treat patients as needed.

And finally, as Dr. Lurie said, we're already working on implementing this plan. The plan is carefully constructed, it has taken some time to get right, but it has not resulted in the delay of research and initiatives, such as the potency testing and other projects that are already well under way.

Fundamentally, with this response, we as a society need to determine what's needed and when, we need to decide what to make and how much of it, and we need to make sure that it gets to people using systems that they are familiar with from their everyday life, and today's announcement and initiatives will make that a reality much sooner and much more securely for Americans. Thank you.

Nicole Lurie:

Thank you. And as we're talking about new technology to make all these medical countermeasures, I gather we have moderately new technology that brings Dr. Eric Lander, the other co-chair of PCAST, on the phone to us from, I believe, Turkey.

So, Dr. Lander.

Eric Lander:

[laughs] Well, it's not that advanced technology, but it is a cell phone --

[laughter]

-- and I hope it will work.

I think much has been said. I would like to express my thanks both to the secretary and to [unintelligible] Lurie and to everybody throughout HHS. It has been a tremendous pleasure for PCAST to work together with HHS, and I have got to say I am and I think PCAST as a whole is tremendously excited by the commitment and the coordination expressed in this report on medical countermeasures.

There is no magic bullet with respect to medical countermeasures; it's a systems problem.



And that's why the kind of coordination expressed today, the kind of thinking that ranges all the way from small tweaks and optimizations and improvements to looking ahead to discovery, occasionally swinging for the fences, is very important to have that whole portfolio covered.

PCAST was given a particular assignment in looking at influenza. It's just one specific threat, but it's often very valuable to look at a specific case, because it is a case in which we actually do have a countermeasure and it does work. We do know how to make a vaccine. We have an industry that already creates vaccines. The only problem is it takes a bit too long, a couple of months, sometimes, too long. And the truth is, that's just fine, the amount of time it takes to produce a seasonal influenza vaccine. It's predictable; we can produce it; the only problem is in a pandemic. So, influenza is, in a sense, the perfect test case. It doesn't require a tremendous amount of new invention of vaccines that we don't know can exist. It requires a systems optimization, and as has been expressed already by all of the speakers, that system optimization is already well underway from improving the efficiencies of surveillance, improving efficiencies of production with new production methodologies and potency testing and sterility testing. Two, as was discussed in the PCAST report, recent and exciting scientific data that suggests that it may someday be possible to even produce universal flu vaccines that wouldn't require an annual immunization when new seasonal or pandemic flues arrive.

So in all of these ways, flu is a test case. I think the ways of working with industry, the ways of streamlining regulatory approvals and really advancing regulatory science, as the FDA has really focused on it now, will be wonderful models for perhaps the more difficult cases in medical countermeasures.

So, I simply want to express my tremendous enthusiasm for both the specific five measures that were laid out and more generally for the bold and coordinated spirit that everyone at HHS has engaged the problem with and say that PCAST stands ready to help in any way as the work moves from creating a plan and a blueprint to actual implementation. So, thank you very much.

Nicole Lurie:

Thank you. So, tried and true technology, huh? Brings him here.

Eric Lander:

It worked. I hope it worked.

Nicole Lurie:

Yeah, it does. I'm impressed. Well, that's great.

You know, the old adage, "The system is perfectly designed to get the results that it does," I think really applies here. And as you've heard, we really took a step back, took a systems approach to looking at the whole medical countermeasure enterprise problem and I think came up with systems solutions.

I want to stress that each of the initiatives and enhancements that we've talked about today are intended to work together, and as you heard from the secretary also, intended to work with Project BioShield and the special reserve fund. It's -- this is not that we've put a bunch of things on the table that you can be a kid in a candy store and pick the candy you like the best and just do it and expect to get the results. We believe that we need to do all of these things and to do all of these things really in concert and in a coordinated way to get to the end result. That's the real system redesign part. We can't be in the situation that we've been in of having a system that gets the results that it does, and that's why really we've taken this new approach.

So, with that, I want to thank everybody again for their incredible hard work and participation, energy, and dedication and throw this back open to questions.

Male Speaker:

Thank you, and thank you for the presentation. My question is for Commissioner Hamburg, and with regard to the initiative for -- Regulatory Science Initiative, improving the legal and regulatory framework.

My question simply is to what extent the initiative focuses on harmonization of both the process, the regulatory process, and the standards of review among the United States and our principal allies. There's a substantial body of opinion that says that the threats that you alluded to -- well, everybody has alluded to on the panel -- can be manifest not simply in the CONUS and not simply at Americans, but would have dreadful impacts on national security even if they impacted our allies. There's clear indication that among our allies, there are inconsistent procedures and inconsistent standards with regard to licensing of medical countermeasures.

In addition to the security implications, from an entrepreneurial perspective, opening up other markets is a way to incentivize engagement. The United States is not the only market. It is big but it is limited. So, my question is to what extent the new initiative addresses transnational harmonization of both procedures and standards?

Margaret Hamburg:

Well, your question is a very important one, and it addresses critical priorities within FDA in addition to an arena of great importance to the success of this effort. FDA can no longer operate as a domestic agency exclusively, and it is very important that we operate as part of a global community of regulators and that we address that both in terms of harmonization of standards and approaches to the greatest degree possible, and also in terms of the recognition that science is a global enterprise and that the research that underlies our decision making as well as that underlies the products that come before us for review is produced as a result of international scientific efforts.

So, yes, we are very much concerned about working in collaboration on an international basis. We have already seen the value of that in other arenas, including in addressing H1N1 this past year, where, as I'm sure you know, different approaches were, in fact, taken by different regulatory authorities in different nations in terms of some of the

specifics of the vaccines that were developed. But we were working in close coordination, we were sharing information, and we were also, in important ways, sharing opportunities so that if it had been needed, we were going to be able to adjust approaches using information that was emerging from the experiences of other nations.

For example, had we -- we were prepared -- if we needed to, on an emergency use authorization basis -- to move towards the use of adjuvants, and the experience of other regulators in other parts of the world with adjuvants was very informative to our thinking then and certainly going forward to our thinking.

So, yes, a strategy of working as a global partner is very fundamental to our overall approach today in the FDA and to the needs of addressing medical countermeasures.

Kathleen Sebelius:

Go ahead. On the phone?

Operator:

The first question coming from Maggie Fox with Reuters. Your line is open.

Maggie Fox:

Thanks very much. I just want to clarify a little bit more about the money. Exactly how much money is going to be needed over the first year and over the coming five years and where precisely it will come from? Thanks so much.

Nicole Lurie:

Sure. Well, as you heard from the secretary, about \$1.9 billion has now been allocated and identified to get all of these activities off the ground. I think you also heard that one of the things that we've undertaken is really a five-year budget planning process so that we can anticipate -- identify and anticipate budget needs down the road in a much more holistic and comprehensive way so that we're not continually looking at doing things a year at a time.

So, as you heard, the current funding has been identified from current allocations to HHS in large part from allocated and re-purposing flu funds, and we'll be continuing to work with those funds as we move forward.

Chris Revere:

Good morning. I'm Chris Revere with the National Commission on Children and Disasters, and certainly, the Commission appreciates the effort in putting together this report and we want to thank you.

Children represent 25 percent of our population. There are 74 million children under the age of 18 in our country, yet there are few medical countermeasures that have been approved for use in children. There are few medical countermeasures available in stockpiles across this country, and there are little if any viable incentives for manufacturers to create these important medications for children. So, the question is,

with this report, which is very timely and important to the Commission's work, how do you believe the recommendations and the mechanisms and the investments going forward can be applied to the critical needs of children in the country?

Nicole Lurie:

Great, thanks so much for that question. I don't know if others want to jump in here, as well, but I'll start.

And I think you came in after the secretary had just finished saying that one of the important things we heard throughout our review was the set of issues about the need for countermeasures in children. And I think, as you know, we have really begun to look at the processes through which we do that.

To begin with, you know, we need to put in place all the processes through which we get products in general, and, in large part, that's what this is about. But the process of what we call "requirement setting" -- first of all, identifying who the populations are that are going to need the countermeasures, what countermeasures they need, and in what form -- is a critically important thing. Young children don't swallow pills and so you need liquid, just as a starting point. Young children are not just small adults and you can't just cut the dose in half and think it's going to be safe and effective. And so as we look at both the setting of requirements and then what we call those "target product profiles": what it is about this product that you're actually looking for.

The process gets redesigned and hardwired so that every time we do a requirement and every time we do a target product profile, you've got to think about the needs of children. You've got to think about the needs of pregnant women. There are a number of populations that don't act, you know, like the average American, as if there ever were such a thing anymore as an average American. But the needs of children are very clearly up there.

NIH right now is investing in a whole series of studies to look at some of the existing countermeasures and their dosing in children. BARDA right now is supporting studies as we speak to look at the palatability of different kinds of countermeasures because children don't swallow pills and we've got a lot of pills in the stockpile. We have to get to another formulation.

And, you know, that's a great example of something that's going to help not only in the countermeasure domain, but I think across many other domains. Actually, if you can make the stuff taste better so that kids won't spit it out it's going to be a lot easier to get all kinds of other medicines in children, just as an example.

And FDA is really looking hard at the set of issues about how to move forward with the kind of evidence that's required to determine, you know, when some of these countermeasures are -- it's going to be likely to be safe and effective. I think that's part of what Commissioner Hamburg was talking about when we talked about kind of looking at all the components of regulation, the science, the legal/regulatory framework that's

there.

So, I see that the issues of children are sort of baked in at every step of the way. I don't know if anybody wants to jump in more with that.

Female Speaker:  
[Inaudible] another --

Nicole Lurie:  
Question on the phone?

Female Speaker:  
Yes.

Nicole Lurie:  
Great. Another person on the phone, please?

Operator:  
The question comes from Maggie Fox of Reuters. Your line is open.

Maggie Fox:  
I'm also intrigued about this hint at the U.S. government actually becoming involved in vaccine manufacturing and development. Can you all broaden the details of that plan, please?

Nicole Lurie:  
So, I think the U.S. government has, for a long time now, and particularly in the area of pandemic, supported vaccine manufacturing, as you know, as a part of our pandemic plan to get ready for H5N1 and then very much used for H1N1. We supported commercial vaccine manufacturers to expand or retrofit their existing facilities. We've partnered with a facility in North Carolina to be able to create surge capacity as necessary to manufacture vaccines in the case of a pandemic or other emergency.

And these -- and I'll turn this over to Robin in a minute -- but these Centers for Advanced Development and Manufacturing are intended both to help the developers of these vaccines or other products, get them to market and, as well, to create additional surge vaccine manufacturing capacity for the United States. But the intent is largely for these to get made as part of a public-private partnership but in the private sector.

Robin, you want to jump in here?

Robin Robinson:  
Yes. Thank you, Dr. Lurie.

As she said, this is a true public-private partnership which we've established. Some examples already have been cited. We will not be producing the vaccines. People that

now have the best know-how -- the pharmaceutical companies and their academic consultants -- will be providing these vaccines and these core services. We will be in a cost-sharing partnership with them; the more core services they provide, the more the government will provide funding. But we will be there to help manage the products as they go through, but they will be making the actual products and the facility will actually be theirs.

Nicole Lurie:

Was there another question on the phone or are we going to over here? Okay.

Female Speaker:

Hi, I have --

Nicole Lurie:

I'm going to get three more questions.

Female Speaker:

Oh, I have a question -- sorry. [laughs] I have a question. This one might be a little more difficult, though.

I know in the report you talk a lot about how you want to communicate more with industry, but, like, when BARDA cancelled its contract last year for the anthrax vaccine and then also when Human Genome Sciences went before, like, the FDA committee, on its Raxibacumab, there were, like, some -- these kind of last-minute issues that came up that they -- in both of these situations -- industries seemed to be caught off-guard, kind of blindsided by both of those situations, where the -- when Human Genome Sciences came to the committee, they couldn't actually vote on whether to approve that product because there were some last-minute issues that came up with the FDA just right before the meeting.

So, what are you all going to do to kind of communicate better to industry so that they are not walking away in instances like that, where they feel like, "Well, what's the incentive for us now when we get in situations where we've got to --" you know, so far in development and then either the contract gets cancelled...And that one, with the BARDA one, it was because they said that they didn't think they could meet the eight-year BioShield.

But what can they do maybe to communicate more early on or something like that so the industry doesn't lose that incentive that they have to develop the products?

Nicole Lurie:

You know, I think you're asking a really great question. And, you know, as part of this review, we actually went back and looked at our experience with every single product, and we looked at the things that worked really well and tried to figure out what made them work well and do more of those, and we looked at some of the things that didn't work very well and tried to figure out what went wrong and where we had some

successes. And we really looked at -- smallpox vaccine as a great example.

What we found is that you had CDC, NIH, FDA scientists working together with the developers from the beginning and meeting on a regular basis so that you could say where is the science taking us, what new science is needed, and bring scientific expertise to bear, where are we going to move forward on regulation, what are the regulatory pathways, anticipate some of these problems before they arrive -- arise, and have early, frequent communication.

You know, where things have not gone so well, there hasn't been a process of early, disciplined, frequent communication, and so, what you have at the back end -- and not only communication, but really, active problem solving. Now, sometimes, the science just isn't going to be there, and we have to face that. And as Commissioner Hamburg -- and, really, everybody in drug development -- says, another task is to figure out things that aren't going to make the cut, how to identify those early on in the process so that people don't spend time and energy and money and put those resources to things that are more likely to success. But I think we have all recognized and dedicated ourselves to a very different way of working together going forward.

I don't know if anyone wants to add to that.

Male Speaker:

I just want to expand on what Dr. Lurie said, is the approach going forward from lessons learned is a case-management approach that includes all of the agencies represented here to assist the developers as they go forward in a frequent and robust conversation, as a real -- as true partners and I think we can avoid some of the issues that would come in before.

Margaret Hamburg:

And I guess, you know, partly, it's just a reiteration of what's already been said, but I think that the approach outlined in this new initiative really seeks to exactly the question you asked, in a sense of the important need to really add clarity and reliability to the regulatory pathway, and that involves both strengthening the underlying science and really harnessing all of the best available science and technology to make that regulatory pathway as defined as possible and as effective and efficient as possible, and also, this early engagement and more interactive engagement from the very beginning to enable the issues to be surfaced early and addressed in a clear and well-understood way moving forward.

Matt Korade:

Hi. Matt Korade with Congressional Quarterly. I have three questions.

[laughter]

One is I'm wondering what the difference is between the strategic investor that you've described and what Congress intended BARDA to be when it created the agency a few years ago. Also, I'm wondering if you can provide more detail on the breakdown in

funding for each of the five points that you've mentioned. And I'm also wondering then if you think that the \$2 billion -- roughly two billion -- that you're going to apply to the program will be enough to incentivize big pharma to get involved with the program.

Nicole Lurie:

You want to start, Tony?

Anthony Fauci:

The first question, good question about what the difference between what BARDA does and what the proposed strategic investment program would do. BARDA is involved with a specific product, not necessarily with the viability of the company and the ability of the company to sustain itself to get through the process. It is involved only with getting a particular product through the developmental stage into the point of having a product that we can ultimately put into this Strategic National Stockpile or purchased through BioShield. What the strategic investment is really more enhancing and assuring the viability of the company because the company may have a product and the investment in the product is making the product go, but the company itself is going to ultimately fail because they don't have the resources or the investment to do that. So, it really is more viability of company versus a very specific product that we're trying to make.

Nicole Lurie:

Good. So, I think the other two questions had to do about with the breakdown of the funds and was two billion enough. So, I'll get to the breakdown of the funds for a minute, but let me just comment on the, "Is two billion enough?" Because this -- it's not simply a cash infusion to industries; it's going to bring people to the table and to get this done. But again, it's sort of really eliminating other barriers and risks that they face along the way.

And so, for example, the issues that you've just heard about, about the regulatory pathway, I think where the most common things that we really heard in terms of why is industry often so reluctant to come to the table because they've perceived it as too risky or the pathway isn't clear, et cetera. So, a huge path of the effort here is aimed at sort of "de-risking", you know, part of that process, reducing the opportunity costs that companies face to get into this or stay in this business, et cetera, and then really, this partnership between federal government and industry along the way. We certainly saw it very dramatically in a lot of our flu effort, and I'm actually very encouraged from all of our conversations within industry that we're very much on the right track here.

No, I don't have a crystal ball and, you know, we don't know, and it may be that some of this going to have to be an iterative process as we move forward. But we've worked very hard to listen to what people had to say to really critically analyze the situation and to look at the ways in which we reduce roadblocks along the way. And if down the road, fine tuning is necessary then we'll do some fine tuning. I don't see any of this as completely cast in stone from that perspective.

Now, in terms of some of the funds and breakdown of funds right now, you know, I think



as things stand now, we would anticipate about 170 million to the regulatory science initiatives at FDA, 678 million right now for the advanced development of flexible manufacturing and core services facilities, the acceleration process at NAID [spelled phonetically] had \$33 million. The whole set of issues related to flu and addressing the advanced development needs in flu in a variety of areas, 822 million, and the strategic investment ideas, about 200 million. I hope that helps.

Last question: Is that on the phone or in the room here? Or if there's not a last question, all right. Well, good. Well, thanks -- oh.

Jill Wexler:

Hi. Jill Wexler, Pharmaceutical Executive Magazine.

At the end of this last pandemic season, with the disease not being as severe as anticipated and the time lag, there was an excess amount of vaccine held by many manufacturers and I'm wondering if that experience might influence the interest of industry in further participating in all these initiatives.

Nicole Lurie:

You know, I think that that's a question that we would need to post to industry, but I also think as you heard Dr. Frieden say, and others, I think it's why really being serious about the early detection and surveillance, getting a jump start on this so that you can start making vaccine faster, and getting it to people much more quickly in a pandemic, and then having faster methods of, you know, manufacturing and getting the vaccine out to people are all the really important things. You know, if you get that right, you're not going to be left with the kind of change in public attitude, I think, that sort of transpired with the pandemic.

So, I think again, all of these initiatives and enhancements will help us do the job better and faster, I hope, for everybody.

Thanks, everyone, for coming and thanks for all your support. I look forward to more.

[applause]

[end of transcript]