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Woodrow Wilson International Center for Scholars
Lee H. Hamilton, President and Director, Woodrow Wilson Center
Margaret A. Hamburg, Commissioner, U.S. Food and Drug Administration

LEE HAMILTON: Good afternoon, thank you very much for coming to the Woodrow Wilson International Center for Scholars for today's Director's Forum with the Food and Drug Administration Commissioner Dr. Margaret A. Hamburg. Margaret Hamburg was confirmed as the 21st Commissioner of the U.S. Food and Drug Administration in May 2009. She is only the second woman to hold that critical position. It is a special pleasure for me today to welcome her to the center because of my very long standing friendship with and affection for her family. And I am just immensely pleased that David Hamburg and his wife Betty Hamburg, both of whom have had enormously successful professional careers, are here this afternoon.

I should tell you there is a bit of bias in my comment here because David Hamburg and I share the same hometown, Evansville, Indiana. They are without a doubt two of the finest people that it's been my pleasure to know. As the top official of the Food and Drug Administration, Dr. Hamburg is committed to strengthening programs and policies that enable the agency to carry out its mission to protect and promote the public health. She earned her MD degree from Harvard Medical School, completed her residency as what is now New York Presbyterian Hospital/Weill Cornell Medical Center. She conducted neuroscience research at Rockefeller University in New York, studied neuropharmacology at the National Institute of Mental Health, and later focused on AIDS research as the Assistant Director of the National Institute of Allergy and Infectious Diseases. In 1991, after just 1 year in the department, she was named commissioner of the New York City Department of Health and Mental Hygiene. During her 6-year tenure she implemented rigorous public health initiatives that tackle the city's most pressing crises head on including improved services for women and children, a needle exchange program to combat HIV transmission and the nation's first public health bioterrorism defense program. The most celebrated achievement during her leadership was her aggressive approach to the city's tuberculosis epidemic which led to an 86 percent decline in drug resistant TB in 5 years' time.

In 1997, three years after being elected, one of the youngest ever members of the Institute of Medicine, President Clinton named her Assistant Secretary for Policy and Evaluation in the U.S. Department of Health and Human Services where she served with distinction until the end of that administration. She then became founding Vice President for Biological Programs at the Nuclear Threat Initiative, a foundation dedicated to reducing the threat to public safety from nuclear, chemical and biological weapons. Upon Dr. Hamburg's confirmation by the United States Senate, HHS Secretary Kathleen Sebelius has praised her as "an inspiring public health leader with broad experience in infectious disease, bioterrorism and health policy." And then she added, "Personally, I have been impressed by the calm and confidence Dr. Hamburg has shown in the face of a wide variety of challenges." So, it's my very great pleasure to introduce to you Dr. Margaret Hamburg. She will deliver her remarks and then take some questions from the audience. Dr. Hamburg, we're very, very pleased to have you.

MARGARET A. HAMBURG: Thank you. Well, thank you so much for that very kind and extensive introduction. You probably know more about me than you need to know but I'm delighted to be here at the Woodrow Wilson Center today and to have a chance to talk about a

subject close to my heart, the Food and Drug Administration. I've been really looking forward to speaking here today. Many of our FDA employees do have in fact working relationships with this center in one key area of activity, the Project on Emerging Nanotechnologies. But I think that this audience is a little bit different that many that I speak to. Your work covers critical topics in and out of science and health and I think that the people in this audience span a broad range of academic disciplines in government agencies and areas of policy focused. So it's kind of an opportunity for me to talk about the FDA and generate a discussion that hopefully will be informative and interesting for you but also I hope that your questions and ideas will really bring a freshness to some of the issues that I struggle with everyday and potentially shed some new light on how to think about some of the problems and their solutions that we really need to bring FDA fully into the 21st century. So, besides my deep respect and abiding admiration for Lee Hamilton and his leadership and vision here at the Woodrow Wilson Center over many years, I also have a very special and personal affinity for the mission of this Center. The bridge between the world of ideas and the world of policy, the bridge that I think really epitomizes so much of the work at the Woodrow Wilson Center in what it produces is one that I've been really endeavoring to trend, traverse since my very early days in medicine.

I had originally planned a career in academic medicine balancing clinical care with research and teaching but as I progressed through my medical training and to the chagrin of the chairman of the department of medicine where I was training, I found myself drawn away from a career in academia and toward the world of public affairs, public policy and public health. And it might have happened anyway but the precipitating cause was the emergence of HIV/AIDS. As a first-year medical student at Harvard, no one knew about the existence of AIDS. In fact, I've been thought by some esteemed professors that the era of infectious diseases was basically over with the advent of antibiotics and vaccines. But then we watched the first few cases of this strange and disturbing immune deficiency syndrome emerge. And by the time I was doing my medical specialty training in New York City, I was taking care of a lot of AIDS patients. By then we knew the cause, by then the disease had a name but there was little that we could do for these patients. They were wasting away before our eyes but there were no drugs available to treat them. We could only offer supportive care and I knew we had to make progress and I knew that I wanted to be part of that process and that I wanted to do it through public health. I wanted to work at the intersection of medicine with broader social, legal, economic, ethical issues and the public health perspective considers the collective societal impact to programs in policy decisions on disease, risks, and health outcomes. So, I immersed myself in the field and really I've never looked back. And the principles of public heath have defined the arc of my career and now guide my leadership at the FDA. And this is a shift in perspective for the agency from past years, but one that really goes to the heart of the agency and its history and I think really is essential for fulfilling what is the core mission of the Food and Drug Administration, which is to promote and protect the health of the American people. And I think this is what the American people expect and this is what we will deliver. So, this afternoon, I'd like to tell you a little bit more about my vision for the FDA and our role in meeting the vital and increasingly global challenges of the 21st century and speak in a bit more detail about two of my main priorities as commissioner.

It's been just a little over a year since I began this job and I can tell you that the learning curve has been extremely steep. Everyday has been a chance to learn more about the fascinating and sometimes perplexing issues and an opportunity to really learn everyday about another aspect of

these agency's vast and complex mission and I have to really admit that before I took the job, I didn't really appreciate how crucial and unique the FDA really is. As a science-based regulatory agency with a mission to promote and protect the public health, it really commands a very special role.

In fact, the late Senator Kennedy, one of the great champions of health in this country said once that the FDA was America's most important health agency and at the time it raised some eyebrows and I think some would still argue but I have to say that everyday that I've been on this job I have a deeper understanding of what Senator Kennedy meant and how right he really was. The FDA regulates products that account for more than 20 percent of every consumer dollars spent in this country. Food, drugs, medical devices, vaccines and biologics, cosmetics, dietary supplements, animal drugs and food, certain products that emit radiation, and now for the first time in FDA's history, we also have the authority to regulate tobacco products. Our responsibility and reach is enormous. We're responsible for the oversight of products that people really need, products they care about, and products that matter in the most fundamental way to their health, safety and wellbeing. And so at the end of the day, if the FDA does not do its job and hopefully, do it well, there is no one to backstop behind us. It's critical that we fulfill our role completely and responsibly. So, this would be a daunting task under any circumstances but I think that this is a particularly challenging time. At this juncture, our agency faces a broad range of critical public health tasks.

In addition, there are powerful forces shaping our world to which we must adapt. For one thing, we live in a globalized world, a fact that affects everything that we do for better and for worse. And we live in a time when science and technology are changing life in dramatic ways. We're seeing an explosion of knowledge and capabilities emerging from many domains of research and from around the globe. It's clear that the job of empowering FDA to fulfill its mission today is a fundamentally different and more complex proposition than it was even a few years ago. And one of my chief priorities as commissioner must be to accelerate the transformation of the FDA into a regulatory agency fully capable of promoting and protecting the health of the American public in the 21st century. So, I really want to take my time this afternoon to talk a little bit more specifically about the tasks before us and the approach that I bring to them.

Obviously, it makes a difference that I've spent so many years in public health. I was surprised after I became commissioner by how many people began asking whether the agency was leaning pro-industry or pro-consumer. In fact, there was one blog that during my confirmation hearing actually went through and added up how many times I said the word innovation and how many times I used the words safety and that was viewed as a measure of whether I was pro-industry or pro-consumer. I was really surprised both that people listened to that carefully and also that that was the frame through which our agency was viewed because in my opinion that's the wrong way to think about the FDA's role. Both consumers and industry groups have a tremendous stake in a strong FDA that takes science-based action on behalf of public health. Actions that are transparent and can inspire trust in the public whose health we're trying to protect and that's why we pushed forward with the public health agenda for the agency.

Understandably, people sometimes ask well, what does that really mean? Well, the Institute of Medicine has defined the mission of public health as, "fulfilling society's interests in assuring the

condition in which people can be healthy. To be healthy, people need safe and nutritious food supplies and they need access to innovative, safe and effective medical products and the FDA's job is clearly to support this access and in doing so, to promote health, prevent illness and prolong life." But I'm not surprised that there are sometimes a little confusion about the public health role and since my father is here, I'll embarrass him with a brief story about his Aunt Winnie who is sort of a second mother to him and a grandmother to me. Nearly two decades ago when I was first named New York City's Health Commissioner, really that marked the beginning of my career in public health. My Aunt Winnie was baffled and truly upset by my decision to become health commissioner. She complained to my father that she just couldn't understand why, especially after all that training I would give up the opportunity to be a real doctor and my father, you know, I think was initially sort of surprised because he thought it was kind of a big deal that I was the health commissioner. But he tried to give her some consolation and he explained to her that I would still be a real doctor but she had to think of it that instead of having one patient at a time, now I would have 8 million patients. And she didn't really buy it, she was never convinced but I did and now I think that I have about 300 million patients and it's a responsibility that I take very seriously. And so that's why I operate from a set of principles, principles that are fundamentally intertwined with my background in public health and it helped me to position the FDA as a public health agency. And as a public health agency we must endeavor to prevent problems before they occur, focus on outcomes for individuals and for populations, balance risks versus benefits, seek to address unmet public health needs and importantly, appreciate and prioritize partnerships in multidisciplinary approaches to find meaningful and sustainable solutions to the complex challenges before us.

So, this afternoon I want to focus specifically on two of these challenges, strengthening the field of regulatory science and responding to globalization, especially the urgent issue of import safety. And let me begin with regulatory science and you know, I would expect that some of you may be asking well, what does she mean by that? Regulatory science is the scientific understanding and tools we need to translate breakthrough discoveries into safe and effective products and potentially life-saving cures of the American people.

We know that the continuing developments in science and technology in fields as diverse as genomics, synthetic biology, stem cell research, and nanotechnology hold the promise of major therapeutic advances but a gap has formed between biomedical research and the development of these potential new medical products and we need to close that gap and I believe that we can. But right now, one critical component of doing so is lacking. The science and tools we need to assess and evaluate a product safety, efficacy, quality and performance. In other words, the field of regulatory science which for far too long has been underappreciated, underdeveloped and under-resourced. Billions of dollars have been invested in biomedical research, an effort that's indispensable for medical progress but the potential that that research really hold will not translate into real world products and programs that really matter in people's lives unless we make an appropriate investments in regulatory science. I'm not talking billions but I'm talking enough to support a companion effort to biomedical research for we can no longer rely on the techniques and approaches of 20th century science for the prompt review and approval of the prevention treatment and cures of the 21st century. Just as biomedical research has evolved over the past few decades, regulatory science must also evolve in important and powerful ways. Regulatory science is after all the critical bridge between biomedical research and new medical

products for people who need them. A bench scientist may develop a new approach to a disease. A clinician may be able to show that it can work, but regulatory scientists must help develop the knowledge and tools to translate discovery and innovation into those products that holds so much promise. A strong field of regulatory science can make the difference in speeding the evaluation of new products, tracking safety, recognizing potential problems in products earlier on to avoid wasted time and money. Honing in on the value of certain drugs that may work or have bad side effects for certain subpopulations and the list of opportunities goes on. We must support and extend such critical opportunities as the identification of novel biomarkers of disease, innovative trial designs, valid safety assays and other regulatory advances. We can even use regulatory science to ensure good manufacturing practices for a broad range of products. And unlike work performed by specific sponsors or companies, regulatory science is important for multiple products and stakeholders. The knowledge generated from such studies informs a whole body of innovation, rather than a single product.

So it's really important to recognize that a robust field of regulatory science is critical to our advance and it must include a wide range of disciplines and approaches and must involve basic and clinical research as well as epidemiologic, statistical, imaging and bioinfomatics tools and system. And I think it might be helpful for me to give you a few concrete examples of some of the kinds of needs and opportunities in regulatory science for us and why I see this at the high priority. I suspect that some of you in the room today are from the center's Project on Emerging Nanotechnologies and that you have in fact worked with our agency to explore the future of this cutting edge field of science. So let me begin with an example for nanotechnology. As many of you know, the size of engineered nanomaterial makes many novel and innovative products possible. The obstacle that remains is safety. For example, nanomaterials can increase uptake into and between cells which could facilitate the targeted delivery of molecules to specific cells for treatment of disease. But it may also contribute to tissue inflammation and tissue damage. And this means that we need to develop systems to test how these novel properties impact the potential performance of nanomaterials as well as their safety in humans. And we have to better understand the impact of persistence of such materials in human tissue over time.

We at the FDA have a number of ongoing projects to develop this area of regulatory science including one to characterize sunscreen and assess its penetration through the skin and another to develop screening methods for the detection of nanoscale silver in FDA regulated products. And we're working in partnership with academic institutions to expand our understanding about both the opportunities and safety issues related to nanotechnology. Another important example, promising research is underway using stem cells to restore brain function lost in patients with Parkinson's disease as well as to treat other medical conditions. But before these treatments can reach patients we must develop scientifically valid standards and manufacturing processes for stem cell therapies so they can be produced reliably and safely. Without these, the technology's promise can not be realized.

In another somewhat different example, the National Institutes of Health, industry, and foundations are working together on an artificial pancreas for juvenile diabetes. And this would continuously monitor a patient's blood sugar and automatically inject the right amount of insulin. It would dramatically change the lives of children, youth, and adults with juvenile diabetes. But for patients to benefit, we must develop a scientifically sound and solid testing path that ensures

that the devices control blood sugar levels without risking life-threatening hypoglycemia. And basic research studies are identifying potential tumor markers that can indicate whether a patient's cancer will respond to a specific therapy or combination of therapies. But for these markers to be routinely applied in clinical practice ushering in the match sought after era of personalized medicine, we must use new science to guide the assessment of subpopulations of responders and non-responders and the evaluation in use of new diagnostic test in that context.

So the opportunities are extensive. It may not be as sexy as discovery science but regulatory science is a dynamic and a central part of our scientific enterprise and an important driver of both health and prosperity in our nation and around the world. It's a field of endeavor that I believe must be fully embraced by academia, industry and government working together and especially as science becomes increasingly a global enterprise, we need to work collaboratively on an international basis as well to develop strategies, to evaluate complex new areas of science and technology. Obviously, this is crucial to FDA's work. After all, we want FDA to serve as a gateway not a barrier for the products that people need and count on everyday. And a strong robust field of regulatory science will open up that gateway. It will help us to modernize, clarify, and hopefully streamline the regulatory pathways and procedures. But this is much bigger than FDA. A robust field of regulatory science will help get products to people but it's also critical if we're to keep the engines of innovation running. Frankly, this matters hugely for health but it also matters for the health of our economy and for our nation's global economic competitiveness. So this has really big implications.

At the same time, the world in which the products we regulate are discovered, developed, and marketed is effectively getting smaller. When Franklin Delano Roosevelt first created the modern FDA back in 1938, imports were just a tiny part of the products used in our country. But in 2010 it's a different story altogether. What we as Americans consider our products are in reality today global commodities. Every day, the percentage of the imported products we consume continues to increase and the distinction between domestic and foreign products becomes increasingly blurred. This is a challenge that we share with many other countries and it's urgent that we address it. Here, in this country, about 70 percent of seafood and about 40 percent of fresh fruit that we consume and that's available on the U.S. market in fact comes from other countries. Some 80 percent of the active pharmaceutical ingredients in drugs consumed in the United States actually come from outside our borders and 75 percent of the aspirin that we take comes from China. So, we're definitely talking about real numbers here and in addition to the sheer volume of imports and foreign facilities, there has been an increase in the variety and the complexity of imported products and a large expansion in the number of countries involved in producing these products including many that have far less sophisticated regulatory systems than our own. So, this all adds up to an enormous task for the FDA and we know that there are real concerns to worry about.

You probably all remember the recent problems with contaminated heparin from China, a blood-thinning drug whose use resulted in many deaths and many serious allergic reactions, the melamine-tainted dairy products and pet food, the international problems with diethylene glycol-adulterated toothpaste and other products and the growing problem of counterfeit drugs, all of these things make it clear that we must bring our oversight in line with the reality of the global economy and this means that we must extend our reach. This means employing more

sophisticated strategies for intercepting problems at the border but even under the best of circumstances that approach is limited especially when you think about the vast number of products coming in to hundreds of points of entry around the country. Undertaking more inspections at foreign facilities that are importing products into this country and the establishment of foreign offices in strategic places including China, India and Latin America have also given us more of a presence around the world but it's still the tip of the iceberg in terms of the magnitude of the challenge before us. FDA simply does not have and will never have the resources to inspect every foreign manufacturer or every shipment of products coming in from overseas. The truth is that we need new approaches but more importantly, we need to recognize that we can not accomplish this task alone. The new global reality requires new global partnership and this is a challenge that virtually all nations share. This means working closely with our sister regulatory authorities around the world, with other international and national organizations and with industry. We must find new ways to harmonize standards and approaches as well as to share information and there's little doubt that international engagement and cooperation as well as efficient leveraging of international resources is key to FDA's success in accomplishing its domestic mission. Today, we're involved in a wide range of international activities including efforts to harmonize scientifically rigorous standards, share scientific and technical expertise, provide training in regulatory disciplines, strengthen detection surveillance and assessment systems, and design innovative new information systems.

So, we're working hard on these efforts, we're working to strengthen those that already exist to extend them and to put in place new collaborative efforts and the benefits of this new paradigm for global product safety will go well beyond our borders and in fact will go well beyond public health. When governments collaborate and invest to help strengthen the capacity of developing countries to produce food, drugs and other medical products in accordance with strong safety standards, those countries gain multiple benefits: a domestic source of safe quality products, an economic development through productive industry, and a strong, reliable export market. All countries gain access to safer, higher quality products. So, it's a win-win situation for all involved. So even though my duties as FDA commissioner specifically are mandated to protect the health of the American people by ensuring the safety and quality of our nation's supply of food and medical products, there's one thing that my career has taught me and that I strongly believe in and that is that public health must be a global endeavor and that as we work to address our own public health issues, we can do a better, more effective, more sustainable job by taking a global approach.

No one understood the global nature of public affairs better than the man memorialized by this important center, President Woodrow Wilson. It was Wilson who in 1917, just a year before the influenza pandemic of 1918 and in the midst of the Great War, signed an executive order to make the public health service an arm of the military. As a result, the public health service could better recruit and retain officers and this meant that more physicians were available on the ground during both the war and the pandemic flu. President Wilson looked forward when making decisions. He was forced to and even though times have changed so dramatically, as all of us in this room know so well, we can learn a lot from his leadership. If we try to understand the world we live in today while preparing for the world we will live in tomorrow, we can take full advantage of the vast and incredible discoveries, the vast and incredible ideas that are certain to come and we can harness them for the good of the American people and for the good of the

world. That's why I believe in the promise of public health but more importantly, why I believe in the importance of ideas. I think that we all believe in that, the mission of the Woodrow Wilson Center and the work of the Woodrow Wilson Center certainly makes that clear. So, of course did President Wilson. He was the man who said nothing is worthwhile that is not hard and the man who challenged his nation to make the right decisions even when times were tough. You cannot forget your duty for a moment, he said because there might come a time when that weak spot in you should affect you and then the whole history of the world might be changed by what you did not do. So today, we must act. We must rise to this challenge and we must think anew about the challenges we face now and the solutions that will lead us successfully through the 21st century. That is how I'm trying to position the work of the FDA. I thank you for your time and attention and I welcome any questions you might have.

QUESTION: Hi Dr. Hamburg, thank you for your appearance here today. I work with the Wilson Center. I have a question for you about the thing that came up in your hearing is this notion of whether your favored industry or whether you favor individuals and public health. What are the lessons of the gulf that people takeaway is the too pushy relationship between regulators and the regulated industry but then, I guess the counter argument is you need people who understand those industries intimately to be involved in the process? Could you give us your perspective on how you see the FDA's work in this regard?

HAMBURG: Well, I have to confess, I've been watching the situation at the gulf both in terms of course the devastating impact of what's going on there but also in terms of this question of the relationship between regulators and regulated industry. You know, the FDA I think sits in a somewhat different position than perhaps what we've seen unfolding in the gulf. There are very, very clear firewalls between FDA employees and regulated industry. We are certainly, you know, not allowed to engage in some of the activities that are reported to have occurred between the regulator and the regulated industry in that instance. We adhere very, very strictly to the principle that we are a science-based agency and our decision making has to be science driven and evidence based. We need to understand the industry that we regulate of course. More importantly, we have to understand the science that underlies the products that we oversee and regulate because that is the basis on which we make our decisions and we're responsible for the oversight of products throughout their entire life cycle from the time that they're being developed and brought—applications are brought before the FDA through the time that they're actually approved and in the marketplace and take actions as indicated based on emerging safety concerns even once drugs and medical products are in the marketplace of course. It's also I think a situation where at the end of the day, industry, FDA and consumers really do have a shared goal which is trust and confidence in the products that are regulated. So at the end of the day, I think that while industry doesn't always like our interventions and doesn't always like our decisions, they understand the importance of having a strong, fully functional FDA because it does support the public trust and confidence in their products and their brand and overtime that really matters.

QUESTION: Hi, I'm Todd Kuiken from the Project on Emerging Nanotechnologies here. I was encouraged to hear that nano and regulatory science is becoming a top priority at the FDA. We're currently looking at drug resistance and given the threat of antibiotic resistance and sort of the inability or unwillingness of pharma and biotech to offer novel therapies in the near term. Can

FDA work effectively enough with NIH and industry to make potential research breakthroughs available within the next 5 to 7 rather than 10 to 14 years?

HAMBURG: Well, I think there are a number of components to your question and to the answer. I think that, you know number 1, there are important ways to incentivize industry to invest and develop products in critical areas of unmet public heath needs and I certainly have tried to make that a focus in terms of some of our activities and to learn from programs that already exist that have helped move the dial a bit in terms of products entering the pipeline and moving through such as the Orphan Drug Act and the development of drugs and medical products for orphan diseases which are diseases where there's a very limited population of individuals in the country that suffer from those diseases where the market incentives for companies to come in and make products may not be there and so, working with congress incentives were put into place to help address those gaps and it has mattered. And since the introduction of the orphan drug act and our implementation of it, we've seen the number of products really sky rocket in those areas. The Orphan Drug Act also taught us I think that we need to be more creative in how we apply science to the study of new products and that brings me to regulatory science which is very, very important in changing the timelines and the procedures for how we review drugs and other medical products and that's why I think it's so important that we live in a moment and time when advances in science and technology I think really offer new tools and strategies for assessing products.

Companies are going to be much more likely to invest in developing new antibiotics which is so critically important. If they feel that there's a predictable regulatory pathway towards approval and if they feel that that pathway is going to be streamlined enough that they will see the realization of their investments in a timely way and so, using surrogate markers to more rapidly assess effectiveness, using new clinical trial analytics that enable you to use smaller numbers of patients over a shorter period of time, using new insights into the biology of disease and its manifestations, using new markers for safety and toxicity that will enable us to identify problems at an early stage so that companies can stop investing time and money in products that ultimately are going to fail because based on certain understandings about their chemical makeup, they're going to have kidney or liver toxicities, for example. All those things will make it more efficient in terms of both time and resources to develop products and I think that's going to be important. So, it is really essential that we work with industry, that we understand what are the barriers for their entry into certain markets. Some of them are financial in terms of their perceived ultimate market earnings on the product. Some of it is concerned about the barrier frankly that FDA and the regulatory process has come to represent and so, I think we need a multifaceted strategy but we need to recognize that when it comes to antibiotics, there are very, very significant gaps and we have an urgent need to address them.

QUESTION: Yup, Woodrow Wilson Center. Mr. Hamilton alluded, Dr. Hamburg, to your work in bioterrorism before taking this position. Some aspects of homeland security like locking down nuclear material got a lot of attention. You bring to this position kind of experienced working on bioterrorism issue from the institutional position you're in now and in terms of the Obama administration's overall approach to homeland insecurity. Could you talk a bit about sort of these other dimensions of homeland security like the security of the food chain and bioterrorism and

sort of your perspective on kind of what are the major threats out there and are there areas that we as a society and a government need to be working on in particular.

HAMBURG: I think biological threats remain a very important and time-urgent concern and I think there's a continuum of threats we need to think about and an important set of strategies and I think that there's considerable overlap between deliberately caused biological threats, biological terrorism, biological weapons and actually occurring biological threats and I think we've seen in a number of ways that mother nature can be a pretty effective biological terrorist although I think ultimately she went easy on us with the H1N1 pandemic flu. It certainly could have been much worse but I think that as we need to think about strategies to address them, you know, we need to think about as much as possible building systems that will enable us to address both the deliberate and the naturally occurring and we need to think about prevention and that applies, you know, very specifically obviously to the threat of biological terrorism but it also applies to naturally occurring disease in the sense of vaccines and public health strategies that can prevent infectious diseases from emerging and then we need to think about early recognition and response, so strengthening disease surveillance to recognize problems as they emerge and then being sure we have the systems in place to rapidly respond and then of course, we need to think about you know, recovery when events occur and there's a complex set of demands that need to be addressed in all of those domains with respect to prevention.

You know, we have to think very carefully. I've been talking a lot this afternoon about advances in science and technology and the promise they hold for improving health. Many of those advances in science and technology can also be misused as we've seen other advances in science and technology misused, you know, over centuries, sadly, can be misused and redirected into the development of biological agents to deliberately cause harm. So as we expand our biological research activities, we need to think about biological security and how to make sure that the scientific community understands the implications of some of what they're doing and that we have safeguards in place in terms of the safety and security of those agents in the laboratories and the work being done with those agents. And then, you know, we need to invest in public health so that we have the systems for early recognition and response and we need to make sure that we have a healthcare system that is equipped to respond when problems emerge that we have systems that can be quickly surged up strategies so that we can handle mass casualties in ways, you know, that frankly are at odds with how our medical system is currently run in the sense of everything is sort of just in time and limited hospital beds to contain cost. So, we have a significant dilemma in terms of the management of the healthcare system but I think healthcare reform can help us in that regard in that we will be able to respond more effectively and efficiently when we have a broader safety net, when we have systems that will help people get in to care and strategies to reimburse that care and I think that, you know, we have certainly learned that preparedness matters, that thinking about and planning and doing exercises brings together the critical players across government, levels of government and agencies of government and also with the private sector and the healthcare community.

So, there's a lot to be done. The Obama administration has made this a high priority and actually President Obama in the state of the union address committed himself to a new strategy to develop medical countermeasures which is the other piece of the puzzle and an important aspect that I'm involved in at making sure relating to the question about antibiotics that we have, the

drugs, the vaccines, the diagnostics that we need to respond quickly to emerging and often unexpected threats and of course, the vulnerability of the food supply is also an area of direct responsibility for me in my role as FDA commissioner and again, I need to think about that everyday in relation to naturally occurring threats as well as the potential for a catastrophic intentional threat and that means building transparent systems that engage industry and government to have in place systems to prevent problems from happening in the first place and to recognize them and then respond swiftly when they do.

QUESTION: Eleonore Pauwels from the Project on Emerging Nanotechnologies. Dear commissioner, you mentioned in your speech the importance of transparency which is important for the U.S. public but also on the globalized scene and you also mentioned the importance of new technologies like nanotech or synthetic biology. In the project with—with the work at Wilson Center, we have done a lot of public perception studies and we've got two findings. One is that the level of public confidence in federal agencies is really low and secondly, the U.S. public wants to know more about advances in new technologies like synthetic biology, for example. So my question is how do you envision to implement more transparency in your endeavor in this of the FDA and maybe link transparency to anticipation, do you have new insight to implement this dimension?

HAMBURG: Yeah. Well, it's a very, very important question and I think it speaks to a broader set of issues and concerns, you know, for the nation and the world. You know, I think we have a fundamental problem about scientific literacy and I think that you know, these are complex technologies and superficial understanding of them can either unnecessarily frighten or reassure but the real discussion and the real need to talk about risks and benefits that we often have, you know, requires a bit more in depth understanding of both science and risk and I don't think that we do a very good job educating the public and talking about some of these issues. So at the same time that we're moving forward working in specific areas trying to communicate to the public in specific domains of activity, I think there's a broader national agenda to strengthen, you know, science education and science literacy to help the public, you know, really have the tools to understand and grapple with, you know, some of the issues before us. But I think that we have to really be thoughtful about this set of issues and the public really does want to know more and we see it in areas of emerging technology like nanotechnology. We also see it in areas like nutrition and health. You know, the public I think, you know, over the last decade, I would say has sort of really engaged around these issues in new and important ways and we do feel that part of our obligation is to provide fundamental information so that consumers can make informed choices and, you know. So, we welcome the opportunity to work with you in an ongoing way on some of these areas because some of the expertise that is needed falls outside of our domains of expertise. But if we're going to effectively move forward and we're going to take advantage of opportunities in science and technology, and if we're going to offer people better choices for health, then we need to do it in the context of this broader public and policy maker engagement.

QUESTION: Thank you. Ronald Johnson, AIDS Action Council, good to see you.

HAMBURG: An old friend and colleague. I have to confess I saw you sitting in the audience and I didn't realize it was you.

QUESTION: I was in disguise. Appreciate, certainly appreciate your vision and noting the core mission of the FDA in terms of promoting and protecting the health and I was wondering if you could share your views on the FDA's role in terms of addressing some of the health disparities facing the American people certainly using HIV/AIDS as an example and also tobacco cessation and the regulatory role of the FDA given how advertising has very disparate impacts on communities of color so, your vision of the FDA's role in addressing health disparities.

HAMBURG: Okay. Well, it takes on, you know, several different dimensions and it's a very important question. You know, one important aspect of our role I think is to get new important products that matter to the people who need them and actually HIV/AIDS I think is a good example of how industry, FDA and the research community actually all work together from the beginning to develop, to recognize of course, you know, critical needs and clear gaps in availability of products that mattered for care and treatment but to develop the research studies and the regulatory pathway together so that things could move quickly through the system and also recognizing that, especially in the early days, not everybody qualified for clinical trial but access to whatever drugs were available really mattered for people who had no options. So at that time, the parallel track as it was called was developed so that you could have the more rigorous clinical trials research ongoing so you'd get definitive answers that really would matter for the long term but that people who had no other options and had a lethal devastating disease could still get access to products even if they were still as yet unproved. So, I think there are interesting models from the AIDS experience that we need to, you know, look at and draw from as we move forward. Another important role of the FDA in terms of producing disparities is not just to make sure that new important drugs for critical medical and public health problems get developed and approved but to make sure that they're accessible in terms of cost and the work we do to support generic drugs is very, very important in that regard. I think in—as we get more sophisticated about science and our understandings about differential response to drugs, we also need to look at that in the context of disparities and it's complicated science, it's complicated, sometimes controversial research but I think it is important and we do know that there are some differences. They're not absolute, they're not cut and dried but in proclivities towards certain diseases and response to certain treatments and I think that historically, the way we've done clinical trials hasn't always been adequate. In fact, it's been far from adequate in terms of including sufficient numbers of minority populations and women and you know we need to address that going forward. I would also just mention that as part of the healthcare reform bill, FDA and other agencies within the Department of Health and Human Services have been asked to create offices of minority health and frankly, I'm sort of surprised we don't have one already but we will be standing up that office of minority health in the very near future.

QUESTION: Dr. Hamburg, thank you very much. That was a very, very interesting talk that you gave. I hope we can find it somewhere on the internet. My name is Clare Thorp. I am the Irish Agricultural and Food Attache based in Washington D.C.. I've been here nearly five years now. I think at this stage, I'm the longest-serving European Union Food and Agricultural attache here and over the course of my time here, one of the things that I've enjoyed and also had some frustrations with other dealings that we have between ourselves, the EU and the FDA. We have a wonderful commonality in terms of our fundamental beliefs on food safety and human health and yet we also have a remarkable ability sometimes to disagree with each other. I welcome your comments about working with other governments. I think this is critical. I want to give a

particular example and ask if there's any formal way we might be able to look at how we can overcome some of the ways in which we implement our scientific regulation which actually result in becoming barriers to trade. If you take for example, grade A dairy hygiene, that's one of the differences that we have between the U.S. and the European Union and yet at the same time, we are still striving to achieve the same objectives and to a large extent, we achieve exactly the same objectives despite the fact that we have slightly different approaches. We do tend to debate sometimes different standards and we both come from the perspective of believing in science and yet, sometimes our sciences seem to differ in terms of our opinion and then we get bugged down in the technicalities and the details and so things like equivalency and harmonization become dirty words and yet despite all of these, we are still trying to and in reality achieve exactly the same outputs. So, I was hoping if there was any way we could move forward on this so that after the five years I've been here where we have achieved very, very little, we can actually see some movement forward and that is because of your comments regarding the need to work with other governments and other countries that we're hoping that we can have a new area. One unfortunately which I'm going to miss because I have to leave but which would be wonderful to see and the second comment I have is a much smaller one.

HAMILTON:

QUESTION: Yeah, the first one is about intergovernment cooperation, the second one is that it takes 30 days for security notification to enter into the Center for Food Safety and Animal Nutrition. It takes 10 days advanced notice for any other part of the FDA and makes it very difficult to have government to government contracts—contacts if you have to have a 30-day approval period. Thank you.

HAMBURG: You can't appreciate but the issues that she was mentioning consumes hundreds of hours of people's time in terms of some of these issues that are at the interface of public heath and trade and I think they do speak to some of the challenge that we face in terms of if we're really going to try to harmonize in new ways.

Harmonize doesn't necessarily have to mean that we do everything exactly the same or else it's not good enough but we have to look at outcomes and we have to be able to say that the system that you're using meets our standards and expectations for a safe, high-quality product and therefore, you know, we're okay with it even though you don't necessarily do it exactly the same way that we do and other countries have to be able to look at what we do and say the same thing and there are a number of areas where we've really gotten bugged down and you know, I think often, you know, frankly, it's really a trade issue. It's not a public health issue and public health is being brought in as a fig leaf and I'd just assume not to see that happen but I think that we are starting to step up to these issues. You know, I certainly have been spending a lot of time working with sister regulatory authorities including my Irish counterpart. I think you have a system where the drug and the food is separated. I know the drug guy better than the—but I'm off to the European Union next week to address some of these issues of, you know, regulatory harmonization and so, you know, I think it's—I'm sure it's frustrating on the ground but certainly during my 10 years as FDA commissioner, I want to do everything I can to move the ball forward and to make, you know, science-based public health decisions.

QUESTION: Dr. Hamburg, before we let you go, could you comment on the article on the New York Times this morning. Number of foreign clinical trial—

HAMBURG: I haven't had the chance to read.

QUESTION: Ten medicines approved in 2008 were tested entirely abroad with not a single test patient at the United States, 80 percent of the drugs approved for sale in 2008 had trials in foreign countries, 78 percent of all subjects who participated in clinical trades were enrolled at foreign sites. Now, I don't know much about your business but this is rather astounding. All these drugs being tested abroad, can you comment on what's happening here?

HAMBURG: It's another important piece of the globalization challenge and since I was already addressing, you know, my talk was already probably too long. I didn't talk specifically about that set of issues but it's part of—I mean it is the case. I think it's an important advance that FDA does now accept data that's generated from clinical trials done in other places. There was a period when that was much more limited and it meant that companies had to generate multiple sets of data in order to meet requirements in different countries. So the fact that we're sharing data I think is very, very important in the efficiency of the system but it again speaks to this necessity to be able to provide some oversight and some assurance that the work is being done in the context of both the technical scientific expectations and the ethical expectations that we apply to clinical research—

QUESTION: And you have that oversight—

HAMBURG: In this country and we do have that oversight and we do try very much to make available our own scientific expertise and experience in the area of good clinical practice to sister regulatory authorities and areas that are experiencing an explosion of clinical research where they haven't had some of the oversight and safeguard mechanisms that we expect and require. I just got back a few weeks ago from Moscow where we signed a statement of intent with the regulatory authority there and the main focus of that—there are many issues where we'll work together and share information but the main focus was on good clinical practice. That's an area, Russia and Eastern Europe in general is an area where there's a vast expansion of clinical studies going on. Much of that data is used as primary data to support applications for drugs that come before the FDA and they acknowledge they don't have the systems in place and the expertise they need and so we're going to be doing a series of technical workshops with them to help upgrade their systems and capacity that is very, very important.

HAMILTON: Let's express our appreciation to Commissioner Hamburg for this and we certainly wish you well. You earned a lot of points with us when you quoted Woodrow Wilson several times, Commissioner Hamburg. Thank you very much, we're adjourned.