

Margaret A. Hamburg, M.D., Commissioner of Food and Drugs - Remarks at the Woodrow Wilson International Center for Scholars

Remarks as Delivered of Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs at the Woodrow Wilson International Center for Scholars

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Thank you so much Lee [Hamilton] for that kind introduction and thank you to the Woodrow Wilson Center for inviting me to be here today.

As my staff can attest, I have been looking forward to speaking here. Although many FDA employees do have close working relationships with folks from the Woodrow Wilson Center — specifically, with the Project on Emerging Technologies — this audience is a bit different from those I usually speak to. Your work covers critical topics in and out of science and health, and your members — and those of you here today — have backgrounds that span a broad range of academic disciplines and government agencies.

Which means that our discussion today will not only, I hope, be interesting and informative to you, but it will also be of great service to me. Your questions and your ideas can bring a freshness to the issues that I struggle with every day and even shed new light on the solutions we need to bring the FDA fully into the 21st century.

Plus, besides my deep respect for Lee Hamilton and the leadership and vision he has brought to the Woodrow Wilson Center over the years, I have a special — and personal — affinity for the mission of this Center. The bridge between the world of ideas and the world of policy — the bridge your work continues to fortify every day — is one that I have been traversing since my days in school.

I had originally planned a career in academic medicine, balancing clinical care with research and teaching. But as I progressed in my medical training — and much to the chagrin of the Chairman of the Department of Medicine — I found myself drawn away from a career in academia and toward the world of public affairs, public policy and ... public health. It might have happened anyway, but the precipitating cause was the emergence of HIV/AIDS.

As a first-year medical student, no one knew of the existence of AIDS, but by the time I was doing medical specialty training in New York City, I was taking care of a lot of AIDS patients. By then, we knew the cause of the disease — and it had a name — but there was little we could do for the patients.

They were wasting away before our very eyes, but there were no drugs available ... only supportive care. I knew that we had to make progress and I wanted to be part of that process ... and I wanted to do that through public health. And that's because the public health perspective considers the collective societal impact of programs and policy decisions on disease, risk, and health outcomes.

So I immersed myself in the field and never looked back. And the principles of public health have defined the arc of my career and now guide my leadership at the FDA. This is a new perspective for the leadership of the agency and one I believe can have a major impact on the way we fulfill our mission, which is, after all, to promote and protect the public's health.

That is what the American people demand — and that is what we will deliver.

So this afternoon, I would like to tell you a little 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 some depth about two of my main priorities as Commissioner.

It has been a year since I began this job, and I can tell you now that the learning curve has been steep. But every day has been a chance to explore fascinating — and sometimes perplexing — issues, and an opportunity to learn about another component of this agency's vast and complex mission.

I must admit that before I took this job, I did not fully appreciate how crucial — and how unique — FDA really is. As a science-based, regulatory agency with the mission of promoting and protecting the public health, it commands a special role.

In fact, the late Senator Kennedy — one of our nation's greatest champions of health — said that the FDA is the most important health agency in America. Some might argue, but every day I spend in this job, I gain a deeper understanding of what Senator Kennedy meant ... and of how right he really was.

The FDA regulates products that account for more than 20 percent of every consumer dollar spent in this country — food, drugs, medical devices, vaccines and biologics, cosmetics, dietary supplements, tobacco products, animal drugs and food, certain products that emit radiation ... and now, for the first time in FDA's history, tobacco products, as well.

Our responsibility and reach is enormous. We are responsible for the oversight of products people really need, products they care about, and products that matter in a most fundamental way to their health, safety and well being.

In other words, if FDA does not do its job well, there is no one to backstop behind us. It is critical that we fulfill our role completely and responsibly.

This would be a daunting task under any circumstances ... but we can all agree that I think 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 we do, for better and for worse.

And we live in a time when science and technology are changing life in dramatic ways. We are seeing an explosion of knowledge and capabilities emerging from many domains of research and from around the globe.

It is clear that the job of empowering the FDA to fulfill its mission today is a fundamentally different — and far more complex — proposition than it was even a few years ago. And one 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 let me talk a little more specifically about the tasks before us and the approach that I bring to them.

Obviously it makes a difference that I have spent so many years in public health. As you can imagine, after I became Commissioner many people began asking whether the agency was now leaning pro-industry or pro-consumer. In my opinion, this is the wrong way to think about 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 are trying to protect.

And that's why we've pushed forward with a public health agenda for the agency.

Understandably, people sometimes ask: what does that really mean? The Institute of Medicine has defined the mission of public health as "fulfilling society's interest in assuring the conditions in which people can be healthy."

To be healthy, people need access to a safe and nutritious food supply and to innovative, safe, and effective medical products. And the FDA's job is to support this access and, in doing so, promote health, prevent illness, and prolong life.

But I am not surprised that there is sometimes a little confusion about the public health role. So, since my father is here, I'll embarrass him with a story about his Aunt Winnie — who was sort of a second mother to him and a grandmother to me.

Nearly two decades ago, when I first began my career in public health and accepted the position of New York City Health Commissioner, my great-aunt Winnie was baffled and upset by my decision. She complained to my father that she just couldn't understand why I would give up the opportunity to be a "real doctor."

My father tried to offer some consolation by telling her that I would still be a real doctor, but that instead of having one patient at a time, I would have eight million. Aunt Winnie didn't buy it — but I did.

And now I guess I have more than 300 million patients, which is a responsibility I take very seriously.

That's why I operate from a specific set of principles ... principles that are fundamentally intertwined with my background in public health and that help me to position the FDA as a public health agency.

As a public health agency, we must prevent problems before they occur, focus on outcomes for individuals and populations, balance risks versus benefits, address unmet public health needs — and prioritize partnerships and multidisciplinary approaches to finding meaningful and sustainable solutions to the complex challenges before us.

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.

Let me begin with regulatory science. First, what is it? Regulatory science is the science we need to translate breakthrough discoveries into safe and effective products and life-saving cures for 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. We need to close that gap ... and 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's safety, efficacy, quality and performance — in other words, the field of regulatory science — is underappreciated and underdeveloped.

Billions of dollars have been invested in biomedical research — an effort that is indispensable for medical progress — but this research will not translate into real-life therapies for those who need them unless we make an appropriate investment in regulatory science.

We can no longer rely on the techniques and approaches of the 20th century 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 it can work. But regulatory scientists must help develop the knowledge and tools to translate discovery and innovation, into those products that hold 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 targeted subpopulations, and the list 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, 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.

It is also important to recognize that a robust field of regulatory science must include a wide range of disciplines and approaches, and must involve basic and clinical research, as well as epidemiologic, statistical, imaging and bioinformatics tools and systems.

So let me give you some concrete examples of the kind of needs and opportunities before us in regulatory science:

I know that some of you here today are from the Center's Project on Emerging Nanotechnologies and that you have worked with our agency to explore the future of this cutting-edge field of science. So let me begin with this one:

As many of you know, the size of engineered nanomaterials makes many novel and innovative products — medical or otherwise — for people. The obstacle that remains is safety. For example, nanomaterials can increase uptake into and between cells, which could facilitate targeted delivery of molecules to specific cells. But it may also contribute to tissue inflammation and 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.

We at 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.

Here's another example. Promising research is underway using stem cells to restore brain function lost in patients with Parkinson's disease, and to treat various other medical conditions, as well. 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 cannot be realized.

In another somewhat different example, the NIH, industry, and foundations are working together on an artificial pancreas for juvenile diabetes—which would continuously monitor a patient's blood sugar and automatically inject the right amount of insulin. But for patients to benefit, we must develop a scientifically solid testing path that ensures that the devices control blood sugar levels without risking 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 combinations of therapies. But for these markers to be routinely applied in clinical practice, ushering in the much 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 and use of new diagnostic tests in that context.

The opportunities are extensive. It may not be as sexy as discovery science, but regulatory science is a dynamic and essential part of our scientific enterprise and an important driver of both health and prosperity, in our nation and in our world.

It is a field of endeavor, I believe, that must be fully embraced by academia, industry and government especially as science becomes an increasingly global enterprise. If we work closely with regulators from around the world work together, we can develop strategies to evaluate complex new areas of science and technologies.

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 our regulatory pathways and procedures.

But this is much bigger than the FDA. A robust field of regulatory science will help get products to people, but it is also critical if we are 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 competitiveness. This has big implications.

At the same time, the world in which the products we regulate are discovered, developed, and marketed is effectively getting smaller. When FDR 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, global commodities.

Every day the percentage of imported products we consume continues to increase, and the distinction between domestic and foreign products becomes increasingly blurred. This is a challenge we share with many other countries . . . and it’s urgent that we address it.

About 70 percent of seafood and 40 percent of fresh fruit and produce on the U.S. market comes from other countries and some 80 percent of active pharmaceutical ingredients in drugs consumed in the U.S. come from outside our borders. So we’re definitely talking about real numbers here.

In addition to the sheer volume of imports and foreign facilities, there has been an increase in the variety and complexity of imported products . . . and a large expansion in the number of countries involved in producing these products . . . including many with less sophisticated regulatory systems than our own.

This all adds up to an enormous task for the FDA — especially because we’ve already seen the warning signs.

The recent problems with contaminated heparin, the melamine-tainted milk products, the international problems with diethylene glycol adulterated products and the growing prevalence of counterfeit drugs make clear that we must bring our oversight in line with the reality of the global economy.

This means that we must extend our reach. Certainly, this means finding 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 numbers of products coming in through hundreds of points of entry around the country

We can conduct more inspections at foreign facilities that and we can establish strategic foreign in China, India, Latin America and other places. But this will barely scratch the surface considering 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 from overseas.

Yes, we need new approaches. But more importantly — we cannot accomplish this task alone.

The new global reality requires new global partnerships. And this is a challenge that we all share.

So we will work closely with our sister regulatory authorities, with international and national organizations, and with industry. We will find new ways to share information. And we will learn, step by step, to leverage international resources to accomplish FDA's domestic mission.

Today we are involved in a wide range of international activities — including efforts to harmonize scientifically rigorous standards; share scientific and technical expertise; provide training in applicable regulatory disciplines; strengthen detection, surveillance and assessment systems; and design innovative new information systems ... and we are working hard to strengthen and extend these efforts.

And the benefits of this new paradigm for global product safety will go well beyond our borders — in fact, they will go well beyond public health.

When governments collaborate to 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 and economic development through productive industry and a strong, reliable export market. All countries gain access to safer, higher quality products. A win-win situation for all involved.

So even though my duty as FDA commissioner is to protect the health of the American people by ensuring the safety of our nation's supply of food and medical products, there is one thing my career has taught me beyond a reasonable doubt.

And that is: public health is a global endeavor. It has to be.

No one understood the global nature of public affairs better than the man memorialized by the important work you all do, 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 PHS could better recruit and retain officers. And this meant more physicians were available on the ground during both the war and the pandemic.

President Wilson looked forward when making decisions. He was forced to. And, even though times have changed so dramatically — as you all know — 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 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. You believe in that too. Your mission and your work make that clear.

So did President Wilson. He was also the man who said “nothing is worthwhile that is not hard” and the man who challenged his nation 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 his challenge. And we must think anew about the challenges we face now — and the solutions that will lead us into the 21st century.

Thank you.