

**Remarks as Delivered of Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
Partnership for Safe Medicines Interchange 2010
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Good Afternoon, and thank you, Mr. [Scott] LaGanga for that kind introduction. I'm delighted to be here today to thank you for your efforts—and your critical support—in promoting the safety of our drug supply and the health of the American people.

The work of the Partnership for Safe Medicines, particularly your work reaching out to consumers, goes a long way in our collective fight to eliminate harmful and unsafe medicines and promote the quality and efficacy of every product consumed by our friends, families, and neighbors. Which is why I am happy that today, we can strengthen the partnership between the FDA and your organization. On the topic that we are here to discuss today, we are pleased that the Partnership for Safe Medicines is a partner in FDA's Counterfeit Alert Network.

After all, we have a common mission: to ensure the safety and efficacy of drugs and medical products and to secure the increasingly complex global supply chain that so many of our drugs navigate before they arrive in our pharmacies and hospitals. So it's encouraging to me to see so many of you here today discussing an issue that is so important to the future of public health...particularly in our increasingly globalized world.

I know that Special Agent Nancy Kennedy from our Office of Criminal Investigations has already spoken to you about some of our ongoing activities at FDA, but I welcome the opportunity to offer some perspective of my own.

As you can imagine, when the modern FDA was created by Franklin Delano Roosevelt in 1938, the world was a very different place. And although the fundamental mission of our agency has not wavered, the issues we address on a daily basis look very different than they did to my predecessors decades ago.

This is a particularly challenging time. We are seeing tremendous breakthroughs in science and technology...an explosion of knowledge and capabilities from many fields of research, innovation and industry—and coming from around the globe. For better or for worse, globalization has affected everything we do.

Which means that to address the range of critical public health tasks before us—including the one being discussed here today—we must adapt to the powerful forces shaping our modern world. We must equip our agency to fulfill its mission in a fundamentally different, and far more complex, environment.

So one my chief priorities as Commissioner, since I took this job 18 months ago, has been 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. Of course, doing that effectively requires a clear set of principles—a guiding force, if you will. For me, that guiding force is public health.

Ever since I began my career in public health at the New York City Health Department 20 years ago, I have operated 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.

Understandably, people sometimes ask: what does that really mean? Well, 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." And to be healthy, people need access to a safe and nutritious food supply and to innovative, safe, and effective medical products. The FDA's job is to support this access and, in doing so, promote health, prevent illness, and prolong life.

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. 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.

This is the spirit in which I lead the FDA. And it is the spirit I bring to the issue of counterfeit drugs and drug safety.

Now that you know a bit about my approach to my job as Commissioner, let us turn more specifically to the issue at hand.

As you know, the issue of counterfeit drugs is one of both domestic and international concern. It is shocking to realize that, in some parts of the world, somewhere between 30 and 50 percent of drugs to treat serious diseases are actually counterfeit. And even still, it's hard to really know the full extent of the problem.

Estimates, in fact, vary a lot and we do need better surveillance and data to truly define the magnitude and the scope of the problem. But what we do know is that it is growing everyday.

Drug counterfeiting, diversion, cargo theft and economically motivated adulteration are crimes of opportunity, and the opportunity is flourishing because of the dramatic way our world has changed in a relatively short period of time.

In the past decade or so, the pharmaceutical industry has shifted a large part of its manufacturing operations and supply sourcing overseas. Today, nearly 40 percent of the drugs Americans take are imported and nearly 80 percent of the active ingredients in the drugs on the American market come from overseas sources. So, in addition to the growth in volume of imports, there has been a dramatic increase in the variety and complexity of imported products.

As a result, the supply chain—from raw material to finished product—has become more complex and mysterious involving a web of repackagers and distributors in a variety of

locations. Like any chain, the drug supply chain is only as strong as its weakest link, and the proliferation of additional handlers, suppliers and middlemen creates new entry points through which contaminated, adulterated and counterfeit products can infiltrate the drug supply.

And this, in my view, is simply unacceptable.

When our agency approves drugs based on scientific evidence and federal legal standards, the American people have every right to expect that the medicine they rely on for treatment is exactly what the package and label says it is—a medicine that has been carefully evaluated by the FDA in terms of safety, efficacy, quality and purity.

Drug counterfeiting involves larceny and fraud on several levels. Certainly, it involves theft against the drug manufacturer, but perhaps even more importantly, it robs the American people of the faith and confidence they deserve to have in drug products they believe are FDA approved.

Passing off a fake medical product or stealing it for re-distribution on a gray market is a direct and indirect threat to public health. Fake medical products may contain too much, too little or the wrong active ingredient, and could contain toxic ingredients. They can also increase the likelihood of drug resistance and they may prevent patients from getting the real medical products that they need to alleviate suffering and save lives.

Counterfeits, diversions and cargo theft are all part of a growing criminal enterprise, which also includes the deliberate adulteration of drugs and consumer products to maximize profits and unknown threats that have yet to surface.

We have seen that the threat from economically motivated adulteration, counterfeiting, and cargo theft is real. And, unfortunately, we know that the results can be tragic.

In Haiti, Panama and Nigeria, many children died due to cough syrup and teething medication poisoned with diethylene glycol.

In 2008, as I'm sure you know, adulterated heparin caused injury and some deaths in patients throughout the world.

Earlier this year, patients received counterfeit over-the-counter diet pills that had an ingredient that is found in a prescription diet pill. Patients who have certain cardiac conditions were at great risk if they took the pill that they received as directed on the label because they would ingest a dangerous dose of the prescription version.

And last summer, FDA found adverse events reports in our MedWatch system from patients reporting that their insulin was not controlling their blood sugar levels. Upon investigation, it was found that the patients were using insulin from the same lot numbers that were stolen months before. It is thought that the insulin was not stored or handled properly by the thieves and lost its potency.

It is sad to realize that we live in a world in which some criminals are willing to maximize profits by placing poisons in products like infant formula, toothpaste and medically necessary drugs. But it is a reality we must face. And, more importantly, it is a reality that we must become more proactive in dealing with.

Which is why FDA has taken a number of significant steps since the heparin contamination crisis to safeguard the U.S. supply of this medically necessary drug—and prevent similar situations from unfolding in the future.

We worked hard to help identify and characterize the nature of the adulterant and the appropriate testing methodologies to determine its presence in the heparin product.

Importantly, also now calls for testing to detect whether the contaminant that sickened patients in 2008, oversulfated chondroitin sulfate, is present in heparin.

And of course, we have invested considerable resources in inspecting heparin manufacturing and testing facilities related to the supply of heparin in the United States to determine if the heparin was manufactured in accordance with current good manufacturing practices requirements.

Overall, FDA's inspectional approach has focused on traceability, testing, verification of controls, and supplier qualification related to crude heparin, so that contamination from crude heparin would be prevented, detected, and addressed.

And our efforts have not stopped there. We are committed to putting preventive measures in place that will protect American consumers from economically motivated adulteration of all imported drugs.

The lessons FDA learned as a result of the heparin adulteration emergency have been more broadly applied toward a strategy capable of identifying and safeguarding other drugs, which may become targets for adulteration. In order to further this, FDA is developing risk models to help us identify drug and ingredients at risk of economically motivated adulteration so we can target our efforts.

We combine risk-based approaches with sound scientific evidence to protect the public from adulterated drugs and take a number of factors into account in determining whether a particular drug ingredient may be at risk for adulteration.

For example, when a drug ingredient depends on raw materials that are particularly expensive, criminals may have extra incentive to find a cheaper alternative to the expensive ingredient. If the cheaper alternative can mimic the chemical activity of the active ingredient, as was the case in heparin and in the use of melamine as an adulterant, the risk of adulteration is of course higher.

To date, the FDA has systematically ranked more than 1,000 active pharmaceutical ingredients in order of their respective risk of economically-motivated adulteration, based on a multi-factorial risk-based model we developed. A subset of these high-risk ingredients is targeted for

additional sampling and testing at the border. In addition, FDA is working to reduce the risk that counterfeit or adulterated drug products reach consumers in the U.S. market by developing standards for track and trace systems that enable the identification of these products and facilitate efforts to recall them.

I also want to underscore that threats to compromise drug integrity and supply chain security is a global problem and FDA cannot work in a vacuum to curtail these threats. To a large extent, our success or failure in this effort will depend on the relationships we establish and maintain with our foreign partners.

That is why we are working closely with our sister regulatory authorities around the world on a bilateral and multilateral basis, with international and national organizations, such as the World Health Organization and the Permanent Forum on International Pharmaceutical Crime, and with industry to leverage international resources to combat counterfeits.

We also share scientific and technical expertise with our fellow regulators, provide training around the world in crucial regulatory disciplines, strengthen detection, surveillance and assessment systems, and design innovative new information systems.

To foster these efforts, FDA has established overseas posts in China, India, Europe, and Latin America, and is doing so in the Middle East. When governments collaborate to strengthen safety and security standards, the result supports safe, quality products and economic development through productive industry and a strong, reliable export market. The arrangement is mutually beneficial.

In addition, FDA is working to reduce the risk that counterfeit or other adulterated drug products pose to consumers in the U.S. by developing standards for track and trace and authentication systems that, when implemented, will provide greater transparency and accountability of our nation's drug supply and facilitate efforts to recall these substandard drugs. Earlier this year, FDA established a standard for unique identifiers for packages of drugs. This standard creates a "license plate" for individual packages of drug products as they travel through the supply chain. This is an important first step in developing a track and trace and authentication system in the US.

The FDA is firmly committed to doing all that we can to further strengthen our nation's drug supply and ensure the quality and safety of all drugs and medical products on the U.S. market. To achieve this, the agency is organizing these efforts into a new Drug Integrity and Security Program based in the Office of Compliance in FDA's Center for Drug Evaluation and Research, which will specifically focus on issues such as counterfeiting, economically motivated adulteration, diversion, cargo theft and other supply chain threats.

This program will take a life-cycle approach by indentifying vulnerabilities for products and the supply chain starting with the raw ingredients, continuing through the when the finished drug reaches the patient and, working with stakeholders, to put measures in place to mitigate these threats. The program is just getting off the ground, but we expect that as it grows and can focus

greater and additional efforts on drug integrity and security, we can advance the ball the domestically and internationally to protect our nation's drug supply.

FDA is also reconstituting its internal Counterfeit Working Group, which will help coordinate our anti-counterfeiting efforts across the agency.

It is also clear that the agency needs new regulatory tools that provide the authority we need to meet the challenges we face in today's increasing globalized marketplace. And we look forward to working with Congress on legislation that will give FDA the ability to protect Americans from harmful drugs and medical products—and fulfill our fundamental public health mission.

I'd like to close this afternoon with a quote I often recall as I grapple with the issue the FDA must deal with every day. It's by the other President Roosevelt—Teddy Roosevelt—who signed the Pure Food and Drug Act in 1906, planting the seeds for what would become our agency a few decades later. He said: “In a moment of decision, the best thing you can do is the right thing. The worst thing you can do is nothing.”

We all play an important role in addressing these challenges, and if we keep this idea in mind—that we must use all the tools at our disposal to do the right thing—I am confident that we can, and we will, succeed in protecting the health and safety of the American people...and people all around the world.

So thank you very much for your time—and for all the work you do.