

**CENTER FOR
STRATEGIC AND INTERNATIONAL STUDIES (CSIS)**

THE SAFETY OF FOOD AND DRUG IMPORTS

**WELCOME AND MODERATOR:
J. STEPHEN MORRISON,
SENIOR VICE PRESIDENT AND DIRECTOR,
GLOBAL HEALTH POLICY CENTER, CSIS**

**KEYNOTE:
MARGARET HAMBURG, M.D.,
COMMISSIONER OF FOOD AND DRUGS,
U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES**

**SPEAKERS:
REUBEN JEFFERY, III,
SENIOR ADVISER, PRESIDENT'S OFFICE, CSIS**

**THOMAS BOLLYKY,
VISITING FELLOW,
CENTER FOR GLOBAL DEVELOPMENT**

**HENRY CHIN, M.D.,
THE COCA-COLA COMPANY**

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J. STEPHEN MORRISON: Good morning and welcome to CSIS. I'm Steve Morrison; I direct the Center for Global Health Policy here at CSIS. And we're delighted and honored to host here today Dr. Margaret Hamburg, FDA commissioner. We're also thrilled that David and Betty Hamburg, her parents, are here today: Welcome, special welcome to them for being with us today. David is a legendary figure here in Washington, for those who work on conflict issues and the prevention of conflict, so it's really delightful to see you both here today

Also want to thank some of the people who helped us put this event together, particularly from the FDA side, from Molly Muldoon, Art Allen and George Strait, who have put a lot of effort into making this happen. On our side, Emily Poster and Daniel Porter and Karen Meacham put a lot of time in in coordinating and mapping this out.

We're here really to hear from Dr. Hamburg about a rising dimension of global health, one that has really been underappreciated, but with – through her leadership, and that of others, is now getting a much more careful consideration.

And that's the international food and drug safety challenges that are before us, and the U.S. role that that implies, in terms of protecting American consumers, bringing inspection closer to the point of origin, building partnerships with other governments and with industry, including inspection capacity – building inspection capacity with partner governments, and using our diplomatic tools and our relations with key multilateral and intergovernmental institutions to get better results.

It's a very – as we'll hear from Dr. Hamburg, this is a daunting, complex and quick-evolving set of issues and challenges, and it's a, it's really a major moment in which these are coming forward and we're beginning to see them. It's a frightening moment, but it's a hopeful moment, in terms of what we can do as we set a course. And it's one where U.S. leadership remains essential, but is just one component.

Let me digress for just one short moment here, to say something that's relevant, which is that back in April, here at CSIS, we started a commission on smart global health policy, and it's co-chaired by Helene Gayle and Adm. Fallon. And it's 25 very diverse, very prominent American opinion leaders, who agreed to take on this job of, over the following 10 months, considering, what is at stake for the U.S. national interest in terms of global health? And what might a long-term strategic approach look like?

And we'll be rolling that report out next week, February 10th, beginning at 9:30 a.m. at the Mayflower Hotel, and I invite all of you to come. If you can't come, it will be webcast live on the smartglobalhealth.org site. But other than advertising that event, and the many different people from Congress, from business, from government, from media and philanthropies who are part of that group of 25 opinion-leaders, we also put a special focus in that report – didn't go into

considerable detail, but we did flag that this is, the international food and drug safety issue, is now, there's no question, a very vital dimension of global health.

And we did get our four members of Congress and our 21 other members to sign a consensus document calling upon Congress to really strengthen the mandate, the authorities, the resources and skills that FDA will require to move forward with this agenda, looking out. And I'm very proud that we were able to get a consensus around that position, and I'm very indebted to one of our colleagues who we'll hear from today, Tom Bollyky, who did the analytic work that we published earlier this year – you have that paper; we distributed it today – that provided the background, really, for persuading the commissioners that this really is a vital part of this. Please, I hope, I encourage you all to read Tom's work.

Now, back to what we're going to do this morning. I'm going to introduce Peggy momentarily, and she will speak and deliver her speech, for 15 or 20 minutes, and there's a short video tied to one of the announcements that, contained in her speech, that will come right at the conclusion of that.

And then we will move from that segment of the program to a more interactive roundtable discussion. And that will include Tom Bollyky, from Center for Global Development. That will include Dr. Henry Chin, a food and safety director at Coca Cola, and will include my colleague from CSIS, Reuben Jeffery, former undersecretary of economic, business and agricultural affairs at the Department of State, who is now a senior advisor here at CSIS. And we'll carry on a more interactive conversation for a couple of rounds, and then we'll open the floor to you for comments and questions. Please keep those very brief, and people will be bringing microphones to those of you who put your hand up and wish to have an intervention, and we'll cluster those into two or three at a time, and come back to our panelists.

Now, our keynote speaker, Dr. Margaret Hamburg, is an esteemed medical doctor, a scientist, a public health expert, a public health executive and now the commissioner in charge of the Food and Drug Administration. She's a graduate of the Harvard Medical School. She began her career as a scientist, as a neuroscientist at Rockefeller University, as a researcher on neuropharmacology at NIH, where she became an institute assistant director at NIAD.

She went on to become the, in the early '90s, to become the commissioner of health in New York City, during a period in which the city faced a grave challenge from a tuberculosis outbreak that required quite courageous and determined efforts to bring those under control, under her leadership. Tom Frieden was part of that effort as well, who has now gone on to CDC.

She, several years later, at the request of President Clinton, took on the position of assistant secretary for policy and evaluation in HHS, and after that, became a leading figure in the Nuclear Threat Initiative: became the senior scientist there, and one of the leading figures in standing that very important initiative up. I'm very proud that CSIS was able to play a role in scoping that and organizing that, and building the credibility and legitimacy around that initiative, and I hope that we can continue to play a similar supportive role as FDA attempts to move this very vital agenda around international food and drug safety forward. So please join me in welcoming Dr. Hamburg. (Applause.)

DR. MARGARET HAMBURG: Thank you for that wonderful introduction. I feel that in some ways you've already given all the important points in my speech, but it's always good to have important information reinforced, and I must say I'm delighted to hear about your global health report that's coming out.

I knew about the activities of the group, but I did not expect that you would be putting in a targeted plug to the FDA, and for that I'm immensely grateful, and very pleased to be here this morning to talk about an issue that is so important to FDA and so important to the American people, and in fact so important to the peoples of the world, which is the safety of food and medical products in a global age.

And I think that we'll have an opportunity to have a lot of interesting discussion with the panel that follows, and also drawing on the expertise of this distinguished audience. And I really want to take a moment to compliment Tom Bollyky, wherever he is, for the excellent paper that he put together. It really was, I think, an extraordinary overview of the nature and scope of the problem and what are some of the important solutions we need to pursue.

I'm also pleased that I can take this occasion to at least semi-formally announce a new FDA program that should bring us a step closer to assuring the safety and quality of imported foods. So let me say a little bit on this topic. Since I assumed FDA leadership a little over eight months ago, every single day has been an opportunity for me to delve more deeply into another aspect of the vast and complex mission of this agency, an agency that touches the lives of all Americans in the most fundamental ways.

One of our nation's greatest champions of public health, the late Sen. Kennedy, once said that the FDA is the most important health agency in America, and I think some people raised their eyebrows a bit at that thought. But every day I spend on the job, I gain a deeper understanding of what Sen. Kennedy meant, and a fuller appreciation of just how right he was.

For one thing, I did not truly appreciate how crucial and unique the FDA is, as a science-based regulatory agency with a mission to protect and promote the health of the public. It does have a very special role in addressing threats to health, and as a gateway for products that people need and use. And virtually all of our responsibilities are ours alone. When we succeed, the gains for health are enormous. And if we fail, there's no one to backstop behind us and do our job.

Our responsibility and reach is enormous. Consider that the FDA regulates products that account for over 20 percent for every dollar of consumer spending in this country: food, drugs, medical devices, vaccines and biologics, cosmetics, dietary supplements, animal drugs and food, tobacco products and certain products that emit radiation. Today, the agency faces a daunting set of tasks, and globalization has surely multiplied the scale of our responsibility and the challenges we face.

Consider that FDA-regulated products are currently imported from more than 150 countries, with more than 130,000 importers of record, and from more than 300,000 foreign

facilities. This year, we expect that nearly 20 million shipments of food, devices, drugs and cosmetics will arrive at U.S. ports of entry. Just a decade ago, that number was closer to 6 million, and a decade before that, only a fraction of that. It's estimated that somewhere around 15 to 20 percent of all foods now consumed in the United States originate outside our borders. In fact, some 75 percent of all seafood and about 35 percent of fresh produce consumed in this country come from outside our borders.

Strikingly, also, those are some of the foodstuffs that are most subject to potential contamination. Up to 40 percent of the drugs Americans take are imported, and about 80 percent of the active pharmaceutical ingredients in those drugs come from foreign sources. So we're definitely talking about real numbers. The imported medical devices are another rapidly growing area.

The rise of imports has brought clear benefits to the American people. We can eat a huge variety of delicious products from around the world, and enjoy all kinds of fruits and vegetables way out of season. We can benefit from medical innovation across the globe, and we can get certain products more cheaply than might otherwise have been possible.

Yet this tremendous shift in the global market for food and medical products also has brought important new challenges. 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. Simultaneously, the supply chain, from manufacturer to consumer, has become more and more complex, involving a web of repackagers and redistributors, and making oversight significantly more difficult.

So this all adds up to an enormous task for FDA, and we know that there are very real concerns. A few examples: In early 2007, melamine-containing protein ingredients manufactured in China made their way into U.S. pet foods and animal feed, causing illness and death among household pets across the country. This incident also had major economic consequences, including the recall of hundreds of brands of pet food, and state quarantine or voluntary holds on livestock that had consumed suspect feed.

Although these melamine-tainted ingredients were only found in animal products in the U.S., it's not difficult to imagine that they might just as easily been used in the U.S. production of human food products. And in fact, melamine did appear in Chinese infant formula, causing an estimated 300,000 illnesses, and at least six deaths in China, and prompting worldwide recalls of mel-containing products.

And unfortunately, melamine contamination appears to be a persistent problem, as only last week Chinese authorities announced that they were pulling more milk products contaminated with the chemical from store shelves. Soon after the melamine incident, the highly poisonous industrial chemical diethylene glycol, or DEG, was found in toothpaste imported from China.

Thankfully, FDA was able to issue import alerts, which led to voluntary recall of the contaminated products before they brought harm to U.S. consumers. However, other countries

have not been so lucky. DEG-contaminated products have led to scores of deaths elsewhere in the last several years.

And the year before last, many of you may recall the tragedy that occurred when contaminated heparin, a blood-thinning drug, came from China and caused deaths and hundreds of allergic reactions here at home. These episodes were particularly disturbing because they represented economically motivated adulteration – truly despicable acts of seeking profit by putting lives at risk.

We see this also in the worldwide marketing of counterfeit medical products. Here in the U.S., federal and state authorities have done a lot to keep counterfeiting of drugs to a minimum, because of our extensive system of laws, regulations and enforcement, but it requires constant vigilance, and the problem is growing. Counterfeit drugs represent a much more vast and greater threat in the developing world, where the system of laws and regulatory oversight do not afford such protection. Numbers are hard to substantiate and estimates vary considerably, but we know the numbers are worrisomely high. Studies of some countries suggest that between 30 and 50 percent of certain available drugs are actually counterfeit. Needless to say, this is devastating to health and safety.

And, in our modern world, profit isn't the only dark motive that we must face. Sadly, we know that we're also vulnerable to potential attacks involving our food and drug supply by terrorists determined to do harm. And while it's easy to focus on the most dramatic scenarios, there have also been many other significant but less intentional episodes associated with contaminated and adulterated products, both food and medical goods. Outbreaks associated with melons, peppers, raspberries and seafood have all been in the headlines in recent years, to name a few.

In addition, every day FDA rejects imports at the border for a range of problems, including illegal drug residues, bacterial contamination, unapproved food additives, pesticides, heavy metals, and just plain filth. Each of these crises and near misses is deeply troubling in and of itself. There are human costs, economic costs, and sometimes an undermining of confidence in government agencies and critical institutions and in the products themselves. Even more troubling is the fact that these events are more than isolated incidents. They are symptoms of significant underlying problems and globalization has fundamentally altered our market landscape.

When the modern FDA was created, back in 1938, imports were a tiny part of the products used in our country. FDA's import inspection system reflected that fact, and unfortunately, it still does. Massive change will be required for FDA to be able to keep up with a globalized economy. It's easy to see that FDA faces a Sisyphean task if its employees are asked to inspect everything that enters our ports. The estimated 20 million shipments of FDA-regulated imported that will come into the country this year will be handled by fewer than 500 inspectors. Though these employees do work tirelessly, they typically are able to examine less than 1 percent of these products before entering into the United States. And I'm going to talk a little bit about some improvements in this area later.

But it is simply not possible to count on interdicting everything harmful at our borders. Similarly, FDA cannot alone conduct a sufficient number of inspections at foreign manufacturing facilities to help ensure product safety. Current estimates are that FDA inspects only about 8 percent of foreign drug manufacturing establishments each year. So at this rate, it would take us more than 13 years to inspect all registered foreign drug facilities, and that's not to even mention those that are not registered.

We're taking important steps to increase the number of inspections as well as follow-up inspections of establishments that previously had violations or deficiencies. But it is simply not possible for FDA to inspect our way to safety. Clearly our nation's traditional approach – relying on FDA inspections to catch problems at the border or in foreign facilities – needs significant overhaul. We need to recognize that addressing the challenge must be a collective and collaborative effort on an international scale, and it will require fundamental and systemic change in the way we, and all our trading partners, think about import safety.

To assure the safety of imported products and fulfill our public health mission in a global age, the FDA must adopt a new approach, an approach that takes into account the entire supply chain and its complexity, and an approach that will address product safety by preventing problems at every point along the global supply chain, from the raw ingredients, to production and distribution, all the way to our consumers. We must move from an approach based on reacting to problems to one that proactively prevents such problems from ever occurring.

This is a simple yet profound paradigm shift. This idea is embodied in the food safety legislation now moving through Congress, which would, for the first time, allow FDA to establish basic preventive controls throughout the food production process. This modernizing of our basic authorities is critical to our success as a public health agency and a regulatory agency in the 21st century.

And we must apply this basic principle of prevention to all imports. We're starting now to make this shift. So let me share a few elements of our overall strategy. First, we're seeking better controls at the point of production. This is a shared responsibility: among manufacturers, who have the primary responsibility for the quality and safety of their products; national regulatory agencies, which we are supporting through collaboration and with technical assistance; and the global regulatory community, which must come together as never before.

We're moving into a phase in which FDA works with regulators, manufacturers and suppliers wherever they are. We now have permanent FDA offices in Beijing, Shanghai and Guangzhou, China; in New Delhi and Mumbai, India; in San Jose, Costa Rica; Mexico City; Santiago, Chile; and soon, Amman, Jordan. These offices enable us to have a regional presence around the world, and home base from which to undertake a range of important activities. We're working with these countries and others to help assure oversight and regulatory capacity. By helping more countries build their regulatory capacity, we build confidence in the safety and quality of the goods they send us.

But we're doing much more. We're helping them establish the regulatory powers necessary to support safe products for their own domestic use, and a strong, reliable export

market. This will benefit their health and development in very fundamental, long-lasting ways. In addition, there is also much important collaborative work to be done with allies who already have well-developed regulatory systems. In fact, we now have more than 30 agreements with foreign counterparts to share inspection reports and other non-public information that can help us better in the decisions we have to make about the safety of foreign products.

So if a shipment of fish contaminated with a banned fungicide, for example, shows up in a port in Italy, we'll hear about it swiftly and be on the lookout for products from that same shipper. Or if our British counterparts share with us critical information about their inspections of certain factories in China or Egypt or Thailand, we can use that information, and not re-inspect those same facilities behind them, but rather use our resources to inspect elsewhere, to get to places that otherwise none of us would have seen.

For example, FDA and our partners in the European Union and Australia are jointly planning and conducting inspections and facilities in countries that manufacture the starting materials for many of our drugs. And we also now have FDA staff working in the offices of key regulatory agencies overseas to build on these relationships and we have EU representatives working with us here. These programs are promising and all of them make one thing clear: To address import safety, we will not be able to go it alone.

A second key element of our strategy is to hold importing companies responsible for their supply chain. In this day and age, companies must be able to effectively demonstrate that safety, quality and compliance with international and U.S. standards are built into every component of every product at every step of the way.

Some companies already do a terrific job of this, tracking where and how their products are made and the paths by which they reach our shores. Obviously, companies have a vital interest in assuring confidence in the safety and quality of their products and in their brand. These best practices need to become standard practice throughout industry and FDA will work with industry to set standards for technologies and other approaches that can help them strengthen the safety of their supply chains.

On the other hand, companies that sell contaminated products because of loose supply chain oversight need to face serious penalties and cannot excuse themselves by blaming their supplies, blaming the FDA or blaming anyone else. Only when we have a sense of shared responsibility and accountability will we have a truly safe global supply chain.

Third, we, FDA, have a responsibility to deploy our agency's resources as strategically and efficiently as possible. This is more critical than ever as our mandates keep expanding despite these economically challenging times. And in this regard, I want to take this opportunity to announce a new FDA program that will enable us to more effectively and efficiently do import inspections. I've already discussed how, in today's world, we simply can't be guardians at the gate attempting to detect and weed out dangerous and contaminated products at our borders and ports. But as part of a comprehensive program, we still need screening at our borders and we can and must do it in a much more meaningful way.

The system we're now deploying is called PREDICT – the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting. It's a sophisticated information technology system developed for use by our border inspection operations that will allow us to monitor products at the port of entry more reliably and to target shipments for inspection that pose the greatest risk. The system was piloted in the Los Angeles area – they're a very large and active port – and we're currently bringing it online in New York. Hopefully, we'll have it up and running throughout the whole country by some time in the spring.

With PREDICT, investigators will still be checking only a small percentage of all import shipments, but they'll be using better intelligence to decide which shipments to check. PREDICT uses a variety of assessments to rank import shipments according to risk. It considers everything from whether a product is intrinsically risky – raw seafood, for example, falls into that category – to information we've acquired from previous examinations of shippers or producers.

We also can add information on things that might seem surprising, like floods, hot weather or market conditions that suggest whether a particular shipment is at risk of being spoiled or shoddy. These and other factors are added up to give a risk score and the riskiest items are the ones that our investigators will check first.

We expect PREDICT to offer two major benefits to FDA inspectors, to importers and to the public. First, the system will automatically flag potentially risky shipments. Second, the system will give lower risk scores to more innocuous materials which can then be cleared through FDA inspection rapidly. This allows FDA inspectors to spend their time looking at the highest-risk items. It also means that carefully labeled products with good histories will be held for shorter periods and that is better for everyone.

So as mentioned, I have a short video demonstrating the PREDICT system in action, which I think we're going to show at the end of my remarks. It's only about four minutes. But it is something that we're very excited about. This is a major innovation that harnesses advances in information science to enable us to do our job better and to improve our service to the nation. But it's just one step.

More broadly, we're moving from a system that places most of the regulatory burden on the FDA's modest inspection force to one that creates greater oversight at points further back along the production chain. We need to know who is making our food and drugs, where they're located and we need to be sure that these facilities are being inspected and are accountable for what goes into their products, as well as for the products they produce. We need to create a global safety net.

I can assure you that addressing the problem of global supply chain safety and shifting the existing paradigm from reaction to prevention is one of my highest priorities for the FDA. Refining our understanding of the problem and exploring and assessing and implementing possible solutions will be a major focus of our work over this next year and well beyond.

Ironically, 70 years ago, DEG, the same poisonous chemical found just a few years ago in tainted Chinese toothpaste and other products, precipitated another similarly significant shift in the FDA's approach to product safety. In 1937, 105 people in the United States died after injecting elixir sulfanilamide, an antimicrobial medication that included DEG as an ingredient.

In response to this tragedy, Congress passed the 1938 Federal Food, Drug and Cosmetic Act. As a result, FDA moved beyond simply responding to problems and intercepting adulterated drugs on the market. We began to conduct pre-market evaluations to prevent unsafe drugs from entering the market in the first place. The most recent DEG episodes show that we need another fundamental change in the way that we do business, this time on a global scale. This will require new ways of thinking and new partnerships, in addition to new resources and new authorities.

Now is the time for FDA to fully engage bilaterally, multilaterally and through international and regional organizations to work with countries throughout the world to share scientific and technical expertise, to harmonize international standards for safe food, drugs and medical products, to work with industry to enhance compliance with standards and, very importantly, to help countries with less mature economies and regulatory systems build capacity so that they can produce food and commodities that are safe, wholesome and meet international safety standards – both for their own consumption and for export.

Such an approach represents a shift to a new paradigm for safety, and it will not be easy to accomplish. We will need to marshal the support of our stakeholders, our international partners and Congress. However, the benefits of this new paradigm for global product safety go well beyond our borders and, in fact, they go beyond health. When governments collaborate to invest in the capacity of countries to produce food, drugs, medical devices and cosmetics for export in accordance with strong safety standards, there are multiple and mutual benefits.

Although my duty as FDA commissioner is to protect the health of the American people and, importantly, the safety of our nation's food and drug supply, my experiences throughout my career have shown me, time and again, that public health protection is a global endeavor. All people in the world deserve access to safe food and quality medical care. All nations deserve the opportunity to participate and prosper in the global economy.

We as an agency have difficult work ahead of us, but this is a challenge that we're eager to meet. And I know that if we are to meet it, it must be done in partnership. I welcome the opportunity to hear from the panel and from all of you about strategies that can help us move forward toward a global vision for import safety and how we can do it together. Thank you very much. (Applause.)

Thanks. And I think if you'll indulge me before we go on to the panel, we're just going to show you this brief video clip about PREDICT because this is our formal launch and, as I said, we're very proud of this program. It may slightly repeat some of the framing that already was done in my remarks, but I hope that you'll find it interesting.

(Begin video clip.)

(Cross talk.)

NARRATOR: Despite recent and well-publicized problems, the FDA's record for keeping unsafe food, cosmetics and medical products out of U.S. commerce is extraordinary. But with almost 20 million shipments from hundreds of countries coming into the U.S. last year – a number that is continuing to rise – a basic challenge for the FDA is now how to best ensure that these imported products are safe.

DR. HAMBURG: Globalization has fundamentally altered the markets for food and medical products and FDA needs to change in order to keep up.

NARRATOR: Change because the current safety system has been plagued by too few inspectors operating a system at our ports that has been described as rudimentary, manual and reactive. Dan Solis is in charge of inspections at the port in Los Angeles.

DAN SOLIS: A lot of it was hit-and-miss. Oftentimes, there's information provided to them and it wasn't matching up with what they actually see.

NARRATOR: But by the end of this year, FDA inspectors across the country will begin to use a new Web-based system. It's called PREDICT, a name that mirrors the agency's new approach to food and medical product safety: prevent problems before they occur.

MR. : PREDICT is about taking prevention to a whole nother level. We simply can't look at everything. The volume of entries that we have has been growing exponentially over the past decade and what we really need to do is better target our resources to those entries that present the greatest risk to the consuming public. And PREDICT is a real good tool to help us do that.

NARRATOR: This is the Port of Los Angeles. It's the largest port in the country. More than a thousand ships a day unload their cargo here. Huge warehouses like this one receive shipments from around the world that include everything from frog legs to fettuccine, pacemakers to surgical lasers. Inspectors here have been using PREDICT for about a year and they say the improvement has been remarkable.

MS. : So this system does everything for you automatically. As soon as the information's transmitted, it does it all for you.

MR. : That means you're less likely to miss something.

MS. : Yes, you are.

NARRATOR: PREDICT works this way: Each product, when it's unloaded, is checked for a specific product code. That code is transmitted to FDA headquarters where inspectors operate PREDICT. The computer system is attached to or can access hundreds of databases with all manner of product information, such as the manufacturer, country of origin, has the product

or the processor ever been part of a recall, is the product susceptible to being a security risk?
Tamara Alexander (sp) is inspecting a load of specialty seafood from Asia.

TAMARA ALEXANDER: I'm actually looking for if the manufacturer's on import alert, if the product is on import alert and then, do we have any history for this product?

MR. : It's going to find patterns that may not be obvious to our entry reviewers as they're looking at individual entry.

NARRATOR: In just a few minutes, PREDICT scans all of that information, assesses the risk and gives the inspector a score. If there is a problem, a red flag appears.

MS. : It's had a previous violation from a previous manufacturer so that we have to detain it coming in.

NARRATOR: These products from South Africa were red-flagged. Inspectors stopped their entry and are preparing to have them tested for contamination. Before PREDICT, these inspectors picked shipments at random and decisions were often based on educated guesses.

MS. : You'd have to do a lot of it manually or by –

(Pause video clip.)

DR. HAMBURG: So much for technology, huh? (Laughter.)

(Resume video clip.)

NARRATOR: – from all around the world, so there's no way to remember everything.

MS. : Exactly. Yes. So yeah, it was kind of hit-and-miss before.

NARRATOR: PREDICT allows FDA's limited number of inspectors to take a close look at products for which there is evidence that they are a real threat.

MR. : This is actually Hisbanit (ph). It's a cosmetic product that has a drug claimed (ph) on it.

NARRATOR: This is where products that pose the greatest threat end up – destroyed, before they can become a problem.

(End video clip.)

DR. HAMBURG: Okay, thank you. I think, you know, part of why we wanted to show that is just because the scenes of the port, I think, do give some real sense of the volume and the complexity and the challenge. But we're ready to either go on to the panel or questions, whichever you – okay, great.

MR. MORRISON: First of all, please join me in thanking Peggy Hamburg for that remarkable speech. (Applause.) Thank you so much. We're joined by three remarkable additional folks to our panel who I'll very quickly introduce. You have their bios. To my left, Reuben Jeffery III, who is a senior adviser at CSIS, spent 22 years on Wall Street very successfully, and since then has done a remarkable sequence of things and most recently was undersecretary for economic, energy and agricultural affairs at the Department of State.

Prior to that was a senior director and special assistant to the president in the National Security Council with responsibilities for international economic affairs, played a key role as a representative of the Pentagon at a key moment in the creation of the coalition provincial (sic) authority, played a key role in advising the president after 9/11 in the redevelopment of lower Manhattan. And I could go on and on, but in any case, quite a remarkable array.

Tom Bollyky – you've seen the paper that he's written. Tom trained as a biologist and historian at Columbia, went on to a very distinguished tenure at the Stanford law school, was president of the law review, went from there to the U.S. Trade Representative's office, where he was a senior director there on intellectual property issues and was a very important personality in the negotiations with Korea and China in a very sensitive and complex set of issues around the intellectual property rights and safety issues.

Henry Chin is the senior safety and regulatory officer at the Coca-Cola Company, the sort of gold standard for these safety issues. He served for 30 years at the National Food Processors Association. He's a chemist by training, completed his Ph.D. at USC – prior to that was an undergraduate at Berkeley, where he returned as a post-grad. So long loyalties to those two great universities.

So let me try to kick off the first round of our discussion and ask a very broad question and ask Tom to, sort of, perhaps kick off the answer. And the question is, we've heard Dr. Hamburg's discussion around the agenda that we face, which is a very complex, daunting agenda, and that the U.S. is seeking to be more engaged along these multiple levels.

Tell us a bit, as you look out, what the major challenges are going to be in achieving success, both – in terms of U.S. policy – the kind of past efforts that we've had and what those experiences might tell us and looking 5 years out or 10 years out, what might success look like for us? Maybe you could just offer some quick comments and we'll invite Henry and Reuben to weigh in and then we'll come back to Peggy for her thoughts.

THOMAS BOLLYKY: Sure, I'd be happy to. First, let me start by thanking Steve and CSIS for the invitation to participate in this great panel, as well as for their support in publishing my paper on food and drug import safety. I also want to say what an honor it is to share the stage with Commissioner Hamburg and Reuben Jeffery and Dr. Chin in this discussion.

Let me begin by saying that I very much agree with Commissioner Hamburg's characterization of the food and drug import safety problem, as well as the need for a paradigm shift in the U.S. government's approach to the issue. Unsafe food and drug products at this point

are no longer just simply issues of domestic public health threats that can be addressed with stronger border control or port inspection. They really have become – food and drug import safety has really become a global health problem.

The heavy health burden of food-borne disease and contaminated and adulterated foods and drugs is really experienced internationally, in importing and exporting countries alike. And for all the reasons that the commissioner has cited – the exponential growth in the food and drug trade, the proliferation of sources of these products, particularly in developing countries, with less regulatory capacity, as well as the complexity of the products and the supply chains – all these mean that no one national regulatory authority, not even one as good as the FDA, can alone ensure the safety of the food and drugs that we import.

So you need a new strategy. And I think the overarching strategy that FDA has put forward is a good one. And it's consistent with strategies that have been successfully employed to address other types of global health threats that cross borders, like infectious diseases, that cross borders with trade and travel.

First, they have called for measures to improve control and monitoring at the point of production of these products and talked about traceability, accountability for local manufacturers, as well as cooperation and information sharing with regulators. Next, the commissioner has talked about the need to invest in indigenous regulatory capacity in developing countries so that they may themselves ensure the safety and quality of the food and drugs produced in that jurisdiction.

Third, she talked about the case for the buy-in for exporting countries in this initiative around food and drug import safety, specifically talking about the benefits that accrue to the consumers in those countries themselves who really are consuming the same products, the same foods and drugs that we are consuming and are exposed to the same threats. And also talked about how improving the safety of these products improves the brand of those exporting countries.

And last, she talked about the need to coordinate with regional and international authorities on this issue. So in a sense, this is a very classic public health strategy in dealing with transnational threats and I think it's the right one. I think the challenge to get to your question about the success of this effort and its feasibility will be in the details in the implementation.

Just to throw out a few issues and then open it up for discussion – around traceability, a lot of the question will ultimately be around the scope and compliance with those requirements. The 2002 Bioterrorism Act, for instance, provides for traceability of some foods but doesn't extend to foreign producers and compliance with it has been lousy. A recent OIG report has determined that you have roughly 40 percent compliance with that requirement.

To the issue of regulatory capacity building, there's a bottomless need in developing countries for regulatory capacity building. And I think the question will be, from the FDA's standpoint, what sort of political mandate will the FDA have from Congress? What sort of

resources will it have in order to start to address those needs but also whether or not those resources will be deployed in a risk-based sustainable manner.

Historically, as I discuss in the paper, this has not been the case. You haven't seen FDA really have the ability to engage in this type of regulatory capacity building and the resources have gone to countries, typically, like Egypt or Colombia, which are not necessarily the producers of high-volume, high-risk products.

The third issue would be whether or not the move towards this strategy can be done in a way that's consistent with international trade commitments. And I'd love to hear Reuben Jeffery's thoughts on this as well. I certainly agree with the commissioner that the idea behind food and drug safety is reaffirming of trade. The question is, in this economic environment and the domestic political environment around trade policy, whether or not the bills that emerge from Congress will be supportive of that goal.

The last issue, I would say, is I think the commissioner is quite right in emphasizing the need for corporate support and accountability as being a foundation for moving forward with these efforts. I think the big question is going to be how and what blend of – what will be the characteristics and the mix of carrots and sticks employ in order to foster that support and capability. And I really think moving forward on those types of four examples will be determine where we are in 5 years on this problem. It really does, as the commissioner outlined, require a paradigm shift.

MR. MORRISON: Thank you. Reuben, would you like to add –

REUBEN JEFFERY III: Yeah. Steve, thank you. And I want to add my thanks, Dr. Hamburg, to you for being here today and for your service to our country and, importantly, for really the extraordinary record of the FDA over time in keeping food and medical products and medicine safe in America. We're the exemplar in the world of, kind of, best practices in this regard and we can all have confidence under your leadership that will continue to be the case. So thank you.

Just a couple things to add to Tom's commentary and stress the magnitude of the implementational challenge here when it comes to import safety across the suite of products, from food to medical products. It requires success over time – it's going to put a premium on communication, collaboration and coordination across a variety of fronts, starting in our own government.

Not that the interagency process doesn't always work seamlessly, but there's certainly a lot of equities at stake in any one of these issue sets. And you know, there are departments at agencies; there's FDA, there's Agriculture; there's State; there's USTR that gets into the – and the trade aspects. And it's very important that we as a government continue to be lined up in terms of definition of priorities, sense of desired outcomes and then negotiating an implementation strategy.

Secondly, at the international level, we've got a variety of fora through which we can achieve the objectives of food and medical product safety; first at the bilateral level. And the issue sets are very different depending upon the particular trading partner.

Take China as one of your 150 sources of imports. There the issues are one of scale and economics. Just the pure size of China is overwhelming – they have 200 million – 200 million – farms, however defined. You can't inspect them all. So it's absolutely imperative that we have the right understandings at the right levels, as we've begun to do.

We've made significant progress with the Chinese. They and we both recognize that we have a long way to go and prioritizing pursuant to those agreements – and Tom, you were involved in putting these together – there are now third-party certifications of certain export facilities. We have inspectors there; they have some people here. And it's the beginnings of a process which will hopefully lead to greater confidence on both our parts of product integrity going in both directions.

Africa – you alluded to this as well, Tom – challenge completely different. It's one of development and developmental capacity. I mean, agricultural – not to generalize in Africa; every country is different, of course – is clearly important for the basic food supply, the help and welfare of the people; and also in certain countries as a source of export earnings.

So supporting these countries through our own bilateral efforts and through the development community writ large in improving their own domestic quality for their own benefit and then also translating into that to the requisite protections where exports for exports coming into our market and other markets is an absolutely critical dimension to addressing the problem longer term. And it clearly goes beyond the purview of the FDA; the FDA can't begin to take in all these responsibilities. But it speaks back to the importance of making sure we as a government have a whole approach to this suite of problems.

And then finally, there are all these various multilateral forum. Every region has a regional grouping of which we are a part – I don't need to name them all. You've got the G-8, which historically – or the G-7 – has taken on food security and health issues. Query whether or not some of these challenges will now get taken up by the G-20. Personally, I think that these are challenges, given the stakes, that are well worth the while of an institutionalized G-20 process in the fullness of time.

But how these organizations and groupings take on these challenges in a way that is supportive of solving the problem – i.e. assuring food safety – while at the same time does not interfere with the normal flow of appropriate, trade, commerce and investment activity – if you didn't have enough to do – (chuckles) – that's just another layer of international considerations.

MR. MORRISON: Henry, would you like to add a few comments?

DR. HENRY CHIN: Well, first, thank you for inviting me to be part of this distinguished group. I feel a little bit out of place here but I wanted to emphasize a little bit of the remarks that

were made by Reuben and also parts by Dr. Hamburg applauding FDA on what's on the initiative going forward.

The food industry has always felt that a strong FDA is vital to safety but not only to safety – but consumer confidence improves safety because that's obviously very important. But the initiatives that Dr. Hamburg has talked about in terms of building local capacity, getting troops on the ground in the countries that – (chuckles) – (inaudible, off mike).

MR. MORRISON: We can hear you just fine up here. (Laughter.)

DR. CHIN: Sorry about that. Hopefully, you heard my initial comments saying that the food industry is very supportive of FDA. We've been supportive of a strong FDA. We believe a strong FDA is vital to having consumer confidence in the safety of the food supply.

And the initiatives that Dr. Hamburg has outlined in terms of having additional capacities on the ground, building of relationships in those countries, moving responsibility further down into the supply – further up into the supply chain. Those are all kinds of things that food companies do when they go into those markets.

And so in many ways, what FDA is doing is mirroring what the most responsible companies are doing in those developing markets already, but having the clout of the FDA and FDA bringing resources in, certainly going to be a great improvement and certainly it will – and the FDA's intention to be collaborative – and I think the food industry would really want to share some of our best practices in terms of how we do audits of suppliers; how we qualify suppliers; how we trace our ingredients. We really would like to be able to share some of those best practices with FDA.

MR. MORRISON: Peggy, should we come back to you for some reactions?

DR. HAMBURG: Well, you know, number one, I'm enormously encouraged by the level of support for what we're trying to do and the recognition of the complexity of the challenge, the time-urgency of the challenge, but the fact that we simply must make this a priority and that if we're really going to address this problem over the longer term, we cannot lose time going forward now.

It is just a very, very difficult undertaking on every level. You know, I tried to lay out something about the nature and scope of the challenge in terms of the expanding global market. But when you think about what are sort of the modalities in which an agency like FDA needs to implement, it's also very, very complex.

You know, internally, it requires working with partners in government that historically we may not have always worked as directly with – many of which we have. But aligning the trade and commerce issues, the diplomacy in international relations issues, the issues with the Department of Agriculture and other components of government and finding a way to strike the balance between what are the compelling public health needs and what are the other priorities of

government because clearly, we want those interests to all align. The truth is they don't always align.

And so obviously as FDA commissioner, part of my responsibility is to always make sure that the public issues and concerns get fully on the table and addressed and that they get the primacy that they need and deserve. But framing those in the broader context of all of the tools and the infrastructure for actually implementing solutions in an international context.

The second great challenge of the sort of logistics of this, I think is the global governance issues. We have developed and will continue to develop bilateral and multilateral arrangements. That gets us moving forward but it still is a fragmented piecemeal approach and I think what we really want to strive for is increasing harmonization of standards and broader sharing of both information and technical expertise, as well as just plain old resources.

But there isn't really a clear governance structure for this issue. The World Health Organization obviously plays an important and vital role. There are FAO – the international food organization – plays an important, vital role.

There are other dominant players, like the European Union in the drug arena, their EMEA, which is the FDA equivalent, and there are other very strong regulatory authorities out there that sort of provide some informal governance. But you know, I think we do need to think about if we want to really institutionalize some of these approaches and really have a strong foundation on which to build going forward, do we need some innovation in that regard?

And it's made even more complex by the fact that these issues – we're talking here about both food and drugs and devices. Not every regulatory authority is structured in the same way. In fact, we are the exception to the rule, doing drugs, devices and medical products, as well as, now, tobacco product and a few other important consumer goods. So that is a major challenge.

What is really exciting to me, despite all of the bumps in the road before us, is that there is, I think, this strong appreciation of just how important these issues are. And the fact that CSIS is both hosting this forum, but has taken this major advance that you mentioned at the beginning of your remarks to really include this issue as part of the overall global health strategy, and the fact that people in very different roles than health – people that work on economic development issues, people that work on trade issues, people that work on diplomacy issues – are also starting to see that this is an issue that they need to fully engage on and they need to work with us.

You know, it gives me hope that, moving forward, we can accomplish a lot. And finally, industry is such a critical partner, and as you said, we can learn a lot from industries such as Coca-Cola that have a long history and a strong track record in assuring the safety of the supply chain. And I think that when we think about how we're going to extend our global reach and work with key partners, industry is an essential partner in that effort.

MR. MORRISON: Thank you. Reuben, can you comment a little more about what kind of diplomatic strategy in this situation is going to make sense? We're in a period of pretty rapid and very ambiguous transition, where the G-8 – we're not sure where the G-8 will migrate, and

what will it look like in 2 years, when we're the host, if it still exists? And we've got a G-20 that's rapidly taking shape, and that's just one piece of the puzzle. Do you want to add –

MR. JEFFERY: Yeah, first, just I want to make an obvious point, but related to the attention of not just Americans, but the world community on this issue set, and that is simply that a consumer in China or an African country, no less one in the United States, in this world of rapid communications, they know a problem when they see it and they don't like it and they hold their governments accountable.

And I think that's a good thing on maintaining momentum on international process or a series of processes. I think, Steve, your question's a tough one because there are not an easy answer here, because there's a lot of in-place mechanisms and there's institutional structures. You mentioned the U.N. ones; there are all these various regional ones. Different countries were organized in different ways, in terms of how they regulate. I think what we've got to do is sort of simultaneously move on the existing fronts, and through those, one identifies the really big issues, whether it's a particular product of concern or a particular region of concern.

And as to those issues, as a country and as a matter of diplomacy, we need to think long and hard whether or not it's better to elevate them to some wider group, whether it's the U.N. mechanism or the G-20 or something else. But there has to be some kind of structure since any one organization can't deal with all of the issues because they're so broad, they're so diverse, they're so numerous, whereby we, in our own minds, prioritize what those issues are and bring them to the fore in these broader, globally representative groupings, again, be it the U.N. or the G-20, so that there's some real, concerted, organized action on a common basis to address the particular issue.

MR. MORRISON: Tom, do you have anything to add on that?

MR. BOLLYKY: Sure. I think the comments have been really great. I agree with both Reuben and Commissioner Hamburg's discussion of efforts, particularly the commissioner's discussion of the need for new diplomatic approaches. I think the last administration had a fairly mixed record in pursuing bilateral agreements around trying to improve food and drug safety. I think we achieved a memorandum of agreement of somewhat varying quality with China and the efforts to negotiate those agreements with India didn't get off the ground.

I think some of the issue we'll be moving towards – and I think the commissioner's comments in identifying this as a more global issue will help, in the sense of no longer targeting countries as particularly bad actors, maybe moving from more of a bilateral model of these contentious negotiations more to an international model I think will help. I think more attention needs to be paid to what is in it for these countries – the buy-ins. I think having resources to actually provide regulatory capacity-building is certainly one of those carrots.

There's a great FDA pilot program right now about the Secure Supply Chain initiative looking at preferential access to drug manufacturers that meet verified quality standards. That's a good approach as well. But I do you think you need a more integrated, interagency approach involving USTR, Commerce and others, in terms of moving forward with this approach. That's

both because of tapping other sources of expertise, but also other sources of linkage – other things that you can provide to move this debate forward.

But I also think better use needs to be made of international fora, and I'm a fan of pursuing initiatives in Codex around these issues, moving towards more commodity-specific production standards for high-risk products would be a better way to go, in my view, than trying to pursue these on a bilateral basis.

MR. MORRISON: Henry, do you agree with that?

DR. CHIN: Yes, you know, I was just going to mention that Codex – in the food area, obviously, Codex is a forum for talking about harmonization of international standards on foods. So there is that forum. Probably one of the things that, unfortunately, Codex does have a reputation of not moving very swiftly. So one of the things that we could all benefit from is some way of moving Codex along a little bit more swiftly.

You know, it was interesting, as we're talking about harmonization of international standards, I just came from a meeting, I guess a week ago, where they were talking about regulators in different countries were talking about their efforts at harmonizing their regulations. And we had a presentation from China talking about they're trying to harmonize regulations between China, Hong Kong and Taiwan. And you know, they have some challenges.

We had a presentation from governments in Southeast Asia trying to harmonize regulations between Singapore and Taiwan and the Philippines and all that. So there's a lot of effort, a lot of attention going on, in terms of harmonizing regulations. Unfortunately, you know, in some ways, we got to where we are, in terms of the different standards, over a period of many decades. It will take maybe a little bit of time to unravel and harmonize, but I think we all agree that harmonized standards are the way to go.

And this is where FDA comes in, because FDA is really powerful in the sense that they are a science-based organization. And so the things that Commissioner Hamburg was talking about, about risk-based inspections, you were talking about traceability. And having that risk-based, I think, goes a long way. I mean, you don't want to waste the resources on things that are low risk, but on the other hand, you want to focus on those things that are high risk.

And also, in the area of talking about harmonization, it's interesting that while we're gathered here, there's another conference elsewhere in the city – of course, I guess, that's not too unusual for Washington – but there is a conference that's going on called the Global Food Safety Initiative Conference, where a large number of multinational companies and other food companies are gathered together talking about harmonizing or developing a procedure to harmonize audit standards and those kinds of things.

MR. MORRISON: Thank you. Why don't we turn to our audience for some comments and questions? Just stand up or put your – yes, here and here on this side. Let's start – we'll gather together three. Yes, please. Just identify yourself. And there's a microphone. Seth Gannon (sp), who's been very instrumental in helping us put this together, will bring that over.

Q: Hi, I'm Jared Frivoli (sp) from Dow Jones. This question is for Mr. Chin. I'm trying to figure out, does Coca-Cola support the proposed food inspection user fees?

MR. MORRISON: Okay, hold on that for one second. Back here?

Q: Hi, Bill Pote (sp) with Booz Allen Hamilton. Have you taken a look at – you talked a little bit about some of the penalties you're putting on foreign importers – have you looked at, from their perspective, what the tradeoff is between the risk of getting those penalties and the costs to their business of improving food inspection, because that's what will drive their business.

MR. MORRISON: Right down here in front.

Q: Thank you very much. Raghbir Goyal from India Globe and Asia Today. My question is for the commissioner – excellent talk, of course – one, what sort of agreement do you have with India, as far as the food safety and imports of medicine or drugs are concerned? At the same time – (inaudible) – are talk of the town in America and around the globe today – if you have considered or if you have gotten any request from any Indian facilities?

And finally, as far as terrorists are concerned, they try to hurt people in many ways, and now they may be looking through some food and medicines and so on. So what sort of safety are you considering for the terrorist attacks?

MR. MORRISON: Okay, just one more. Jim Harrington, here, and then we'll come back to our panelists for responses.

Q: Thank you. Jim Harrington from the National Institutes of Health, Fogerty International Center. Excellent talk, Commissioner, thanks so much. My question is on the bigger picture. What about a framework convention on food and drug safety, not unlike the framework convention on tobacco control? Would that be something that would help harmonize and bring to bear the countries that actually would sign on that and ratify it?

MR. MORRISON: So Henry, we had one specific question for you. Maybe you'd like to do – and then we'll turn to Dr. Hamburg on the broader ones.

DR. CHIN: Well, actually, I don't think that I'm – I'm not actually the right person to address that. That's something that our government affairs people are, you know, better equipped to address. I'm the science and regulatory guy; I'm not the user fee guy. (Laughter.)

DR. HAMBURG: Well, maybe I can use that to give – (laughter) – an answer on the other, because I think in a way, what the gentleman from Booz Allen Hamilton was discussing was the issue about relative incentives and disincentives to participate in the marketplace. And you know, it is true that there are importers of various sizes and certain demands and expectations.

And penalties on smaller importers, you know, does create a potential concern for them. I guess I would say that, whether you're large or small, the products that you bring into this country needs to be safe and the importer does have a clear responsibility and needs to be held accountable for being able to ensure the safety of those products. I think we need to be willing to work with those importers to help them better understand how to fulfill their responsibility in terms of the safety and security of the supply chain.

As we touched on earlier, industry has a lot of interest and experience in this arena as well, because in the final analysis, if the products aren't safe, and particularly if they cause serious problems in people in this country or anywhere else in the world, that's going to be even worse for the business of those employers. So I think we view it as a partnership. We want to work together. We want to create the support and incentives to ensure compliance rather than enforcement and penalties, but you need to have the enforcement and penalties that you can bring to bear when necessary.

With respect to the question about U.S.-India, very, very important relationship, both with respect to drugs and food imports. We have a lot of working relationships with India and we have two new offices, in terms of an actual on-the-ground presence – I'd have to get back to you with respect to what, you know, specific signed agreements we have. I'm not certain of that. But there's been an explosion of activity in India in terms of medical products – generic drugs, of course, being very well recognized, but also, now, you know, more innovative products as well.

And that relationship and our ability to work with those companies and have on-the-ground presence is very, very key. And India, as you well know is a leader in certain food products, particularly spices, which are highly vulnerable to contamination. And again, really working with India to make sure that the products are produced in ways that are in compliance with international and U.S. safety standards is absolutely key and in the interests of both of our countries. And I expect that we'll be working more and more with India over the time to come.

The framework convention – you know, it's an interesting idea. Interestingly, there have been very, very few international conventions around health, with the tobacco framework convention being one and the biological weapons convention being another. I kind of think this issue is not one that's cut out for a convention, per se. I think that you would end up actually potentially causing more harm, because the sort of specific things you lay out would actually box you in, rather than enable the kind of broader engagement and commitment that you need.

But I think the strategy of really trying to convene in a more international and support different kinds of fora for addressing questions of harmonization and coordination is very, very key. And we need to do more about that. And as we do that – I mean, I liked your notion of moving forward with the sort of structure and institutions that are already in place, but thinking about how we might reformulate as we better understand our needs, as we also experiment and learn about what works and what doesn't, I think we need more global fora for talking about these issues and acting on these issues. And I think we need a sort of a multiplicity of different strategies, though.

MR. BOLLYKY: Sure. Just to respond to a couple of those points, on the liability and penalty side, it's an important issue. I will say that it's true that, from a regulator's perspective, the costs of regulating important products and their production are a lot higher. And there is a justification for having penalties to encourage better production – safer, high-quality production of those products in light of those higher costs imposed on U.S. regulators to try to ensure the safety of these products.

I will say, that being said, there is an important issue around least-developed countries, for which agriculture is a sole area, often of comparative advantage. And the question of how these countries – small producers in these countries – can meet rising standards is a real one, and I do think there needs to be an attempt made to try to facilitate. One of the things I talk about in the paper is the possibility of collectives as a way of trying to pool resources to allow them to meet these standards. But it's a real issue.

On the framework conventions, I think I concur with the commissioner that international approaches are important but you do have both the SPS and the TBT agreement already with extensive provisions on harmonization around safety and safety for food and drugs, so I think you would have a hard time moving forward with the convention on that same subject when you already had those agreements.

We also, in the U.S., have had a difficult relationship with these public health framework conventions to begin with, tobacco being the obvious example. So I'm not sure that model would really be the best, although the international approach, I think, is the right one.

MR. JEFFERY: Yeah, listening to these various responses, it sort of underscores the need for leveraging the resources that exist. There's the FDA; there's the broader regulatory committee in the U.S. There are all these multilateral fora. And the private sector really does play a key role. I won't comment on user fees. I'll leave that to the government affairs people or whatever.

But the resource of the private sector to monitor supply chain management, assure best practices, consistent quality through the supply chain, to train people, professionals, young people from around the world in their companies and in the ways of doing safe and effective business and production is absolutely critical. So that partnership with government and governmental bodies is one that needs to continue – it's already strong – but needs to be strengthened and reinforced.

MR. MORRISON: We're getting to the end here, so I'd like to – there's a woman right here in the middle, here.

Q: Hi, Kaitlyn Christensen (sp) with the Global Health Technologies Coalition. It's evident that the health of non-U.S. populations is a major priority of this administration. And enhancing national regulatory authorities in the developing world would be a significant step to improving global health. Another issue is the role that the FDA plays in the review of products – that the FDA can and does play in the review of products that are intended for disease found in the developing world, or diseases not primarily found in the U.S.

The European medicines agency, or the European equivalent of the FDA, has recently implemented a new process by which it reviews products intended for non-European populations in partnership with the WHO, called the Article 58. I'm curious whether you see a potential role or similar process that the FDA might consider in that regard to help with the review of products for the developing world.

MR. MORRISON: Thank you. Let's take one more question/comment, please.

Q: Commissioner, I'm Rob Cortell, former U.S. federal maritime commissioner and father of the container security paradigm. I'm also chairman and CEO of Intelix, which built PREDICT. And when I walked in today, I didn't realize you were going to announce it – (laughter) – so as soon as I walk out, I've got to link to your Web site from my Web site.

But, A, we're honored to be involved with FDA and, B, it took a great deal of courage to actually push through these kinds of technologies because they really are advanced beyond what people are typically used to. This is a conference – so my question is, however – this is a conference about food imports, but I would be curious about what you're thinking of regulation of domestic products that you regulate as well, because many of the same technologies can be applied in this space as well.

MR. MORRISON: Thank you. I want to come back to the commissioner.

DR. HAMBURG: Okay. Well, I'll start with the last question first. You know, I think we need to think about many of these strategies not as international or domestic, but as common problems in a dramatically fluid and interconnected world, and the same kinds of strategies that we need to apply internationally, we need to apply at home – the shift from a reactive mode to a preventive mode, the focus on really assuring the safety and security of the supply chain, the notion of working in critical partnership with both industry and, domestically, with state and local health authorities.

You know, I think that we're talking about import safety in a sort of targeted way in part because it's been underappreciated and under-addressed and because of the growing number of imports of all kinds of consumer goods into this country, there really is an urgent need to step up to the plate and really begin to do things differently and to acknowledge and respond to what is a very serious vulnerability and threat to health. That doesn't mean that domestically, we don't have a job to do and we don't require some of that same paradigm shift.

And I think the overall message that I hope to convey is that FDA is a critical player, domestically and internationally, in promoting and protecting the health of the public, and that in order to do so, we need to be adequately supported, we need the appropriate authorities, we need to be in a position to truly leverage science and technology and we need to work in full partnership.

The other question was about our role in helping to support access to medical products in other countries. And of course, we do have to operate within a very well-defined and scrutinized

legal and regulatory framework, and you know, that approach being taken by Europe isn't one that we can just adopt here at home. But we do have a commitment to trying to make medical products more available around the world. I

In the PEPFAR program, we were able to go forward with an innovative approach – what's called the tentative approval process, but it's more than tentative – and more than 100 products have been made available for use through the PEPFAR program in the developing world. So we will continue to work on those efforts. It is a priority. And I think that another aspect of what we're trying to do through this import safety and the broader framing that we're applying to import safety is to support the capacity of other countries to be able to make innovative medical products and safe foods more available for their own communities.

MR. MORRISON: I think we're at the end of our time here, so please join me in thanking Commissioner Hamburg and our other panelists. (Applause.) Thank you so much.

DR. HAMBURG: Sure, it was a lot of fun.

MR. MORRISON: It was fun.

(END)