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Oral Testimony
U.S.-China Economic and Security Review Commission
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Hearing on the Access to Information in the People's Republic of China

Panel V: The Impact of PRC Information Controls on the United States

HEARING COCHAIR HOUSTON: All the panelists have been very patient in going over time limits, but let's go ahead and get started.

Our last panel is the Impact of the People's Republic of China Information Controls on the U.S., which is really the crux of what we're trying to get at today. This last panel will address the impact that Chinese information controls have on the United States. We will be addressing this issue through the prism of food safety, and we have two outstanding panelists.

The intersection of this is that the lack of access to information in China plays out to a lack of consumer safety here in the United States, and we're very grateful to our two panelists who will be talking about that today.

Mr. Drew Thompson is the Director of China Studies at the Nixon Center in Washington, D.C. Mr. Thompson has worked extensively on issues related to public health in China and prior to joining the Nixon Center worked as the National Director of the China-MSD HIV/AIDS Partnership in Beijing.

He has also served as Assistant Director to the Freeman Chair of China Studies at the Center for Strategic and International Studies and was once the president of a company that manufactured snack foods in China--not steam buns, I hope, with cardboard. Mr. Thompson graduated with a bachelor's degree in Asian Studies from Hobart College and received a master's degree in Government from Johns Hopkins University.

We also have with us Dr. Scott Gottlieb, who is a practicing physician and a Resident Fellow at the American Enterprise Institute. He has served in a variety of capacities at the Food and Drug Administration and served as Senior Policy Advisor at Center for Medicare and Medicaid Services.

On July 18, Dr. Gottlieb testified before the Senate Committee on Commerce, Science and Transportation on the safety of Chinese imports, and he is to be congratulated for his very diligent and hard work trying to protect the American consumer on pharmaceutical safety.

Dr. Gottlieb, if you're ready, go right ahead.

**Statement of Dr. Scott Gottlieb, MD
Resident Fellow, American Enterprise Institute, Washington, D.C.**

DR. GOTTLIEB: Thanks a lot. Ms. Chairman, commissioners, thanks for the opportunity to be here today. In recent weeks in response to mounting concern about the safety and purity of food and medical products imported from China, the government of the People's Republic of China has taken steps to increase their regulatory oversight of the manufacture and export of these products. While these steps are encouraging, I believe taken alone, they are not enough to improve our confidence in these goods. The Chinese approach to regulation remains conditioned on arbitrary enforcement of existing rules and ad hoc disclosure of findings of shortcomings and wrongdoing. Until the approach to regulation works to guarantee more consistent and complete enforcement of their own rules and, in particular, the disclosure of problems associated with these goods, then our ability here in the U.S. to make meaningful steps of our own to better ensure the safety of imported products is hampered.

First and foremost, effective regulation relies on good information about potential safety problems. In China this kind of information is a currency that remains under tight control, eroding confidence in that regulatory system. There are many components to public confidence in government institutions, but principal among them is openness and transparency.

Openness from the perspective of the U.S. and our regulatory bodies is based in large measure on access to information. Transparency means explaining how regulatory agencies act on information they collect, which helps to make sure that regulations are enforced with consistency and predictability. The U.S. FDA helps maintain one of the safest food and drug supplies in the world.

American rule require businesses to disclose information about their performance that consumers can make smarter choices about what they buy, and citizens groups and the press can identify and publicize organizational failures and push for improvements.

Not only does the public need to have access to some of the same definitive information about safety issues possessed by regulatory bodies, but they need to have the ability to understand how regulatory agencies act on these facts.

As I said at the outset, there are encouraging signs of progress in China. The State Food and Drug Administration, the body that regulates drugs inside China, announced on July 12 revised drug registration provisions that on paper will improve supervision of approval standards. Along with these new rules, on April 5, the People's Republic of China State Council also issued the provisions of the People's Republic of China on a Disclosure of Government Information.

This regulation will go into effect May 2008 and is aimed at improving disclosure, for example, requiring administrative agencies to divulge information the government has about issues of, quote, "vital interest to citizens."

It remains to be seen how consistently and completely Chinese officials will follow the new provisions, which themselves use broad and sometimes vague terminology to describe the kinds of information that will be released. In some places, the new regulations refer to the disclosure requirements as voluntary.

With the specter of unhappy consumers both in China and abroad as well as the threat of restrictions on exports of its products, one would hope things inside China could be changing. I recently returned from a trip to Beijing where among drug officials there was a palpable sense that they need to step up their own standards.

The SFDA is promising that the new provisions will strengthen the drug registration requirements and enable the agency to better ensure safety in part by making the registration process itself more open to the public. Among other things, the regulations would require SFDA to take new steps to confirm the clinical information filed in support of a new drug application to inspect manufacturing sites and to improve the collection of drug samples by picking them at the site of manufacturing instead of relying on samples sent by the applicant as is now commonly the case.

China is taking similar steps when it comes to regulation and oversight of food products. Regulators this year shut down more than 180 illegal food producers. In recent weeks, China's quality inspectors promised to improve quarterly reports to European Union about consumer product safety.

The government said it planned to offer large rewards to citizens who report any illegal practices in the food industry and high ranking officials and regulatory vow to tighten controls over chemicals used by large seafood and meat producers and create a system that holds producers more accountable for selling unsafe products.

They have also taken steps to improve the disclosure of food safety problems, but Article 10 of the provision of the People's Republic of China on a Disclosure of Government Information, the regulation I spoke about previously, already requires the general administration of quality, supervision, inspection and quarantine of China at national and

local levels to periodically publish conclusions of spot checks which can be accessed on its official Web site.

The prevailing view is that there is spotty adherence to these provisions at best, meaning information on problems is sporadic and incomplete. Regulatory agencies at the national and local levels are also required to periodically publish lists of facilities that are found in, quote, "serious violations under their Article 72 of the Implementing Rules of Supervision and Administration of Quality and Safety of Food Manufacturers and Process Enterprises," the holding regulation.

Once again, spotty enforcement plagues disclosure requirements and diminishes confidence that genuine problems get disclosed.

Regulators themselves are also susceptible to corruption and local inspectors can easily be persuaded that cracking down on local companies hurts economic development and risks jobs, once again, impinging upon efforts to try to enforce regulations at the level of the manufacturing.

If the enforcement of requirements for disclosure are sporadic, so are the regulatory requirements themselves in many cases, notwithstanding recent steps taken in Beijing to toughen disclosure rules.

For example, significant findings from safety inspections of drug manufacturing facilities are not routinely published. Ask any American company seeking to do business in China with a particular Chinese manufacturing facility how they go about getting information on a facility and any past violations it may have had, the American firm will describe a Byzantine process they undertake of searching newspapers and unreliable government databases.

On the food side, things get even more complicated because in the maze of regulatory agencies in China with overlapping jurisdiction that mitigate against responsibility-taking. I'll recount just a few of these. China has a law of hygiene for food. Everyone producing food needs a hygiene license that is administered. Then there are local inspections by local administration for industry, commerce that has grassroots authority to take action on a local basis.

Sanitary inspections are done by local health authorities, sometimes in collaboration with another agency called the AIC. Meanwhile AQSIQ is in charge of import and export and quarantine as well as making quality standards.

Finally, when it comes to information about the safety of drugs and food products, there is also an "x" factor that no regulation, no matter how well crafted or enforced, can take measure of. This "x" factor is a filter that resides somewhere at a senior political level where potentially embarrassing or politically damaging disclosures get assessed and filtered.

A recent food safety episode will illustrate what I mean. News reports in China several weeks ago detailed an undercover investigation that found a popular form of food, dumplings, was being made by one large food maker using paper pulp instead of real meat. These reports made their way all the way to American news stations.

After a few days, another report came out from official Chinese news stations, this time saying that the original news was faked and that the news reporters behind the dispatch had themselves been punished, but many people inside the media said the news was, in fact, true, but the government had become wary of inciting a backlash. Since dumplings are a popular staple food someone inside the political apparatus coerced a second report. The view of food and drug interests doing business in China is that when it comes to information about safety issues, there is a simple abiding faith inside the highest levels of Chinese government. If the government believes information about problems with products or their manufacturing is sensitive, they may suppress it. There is an internal process in the government that ordinary people cannot figure out.

That means that in the final analysis, although regulations may require the disclosure of certain information, it is highly likely that before it is published, there is an internal review between the regulatory departments and government leaders on how to address the issue and when to publish.

Finally, in China, the historically weak regulations for requirements of public disclosure of problems and more importantly the arbitrary and often sporadic implementation in these rules puts U.S. regulators in an awkward if not potentially dangerous position. The sheer volume of imports coming from China into the U.S. means that regulators here need to take new steps to target their oversight to areas of greatest risk.

They need to take a risk-based approach to the kinds of inspections that we do with food products coming in at the border. Here in the U.S., the lack of reliable information about problems in China prevents our own regulatory agencies, principally the FDA, from being able to target its inspections of Chinese imports and take the necessary steps to implement a risk-based approach to regulation.

We don't know who the past violators are. We don't know who the good actors are and we don't know who the local criminals are. And taking the necessary steps to improve our oversight of safety of imported products is what we need to do in this environment when more and more of the products that we are importing are coming from overseas countries that we don't have good collaboration with, we don't have good ties with, and we don't understand the local lay of the land.

Mrs. Chairman, commissioners, thank you for the opportunity to testify here today. I'd be happy to answer any questions.

HEARING COCHAIR HOUSTON: Thank you very much, Dr. Gottlieb. Before we move on to Mr. Thompson, I just wanted to mention that Dr. Oded Shenkar from Ohio

State University was not able to be with us today, but has submitted testimony for the record.

Mr. Thompson.

**Statement of Mr. Drew Thompson
Director of China Studies and Starr Senior Fellow
Nixon Center, Washington, D.C.**

MR. THOMPSON: Thank you. I'd first like to thank the members of the Commission for the opportunity to testify on this very timely and important topic. I was invited to discuss the issue of access to information in the People's Republic of China in food safety, and I will keep these remarks as brief as I can, hopefully within the seven minute limit.

CHAIRMAN BARTHOLOMEW: We've been lenient today. We've had some rather long seven minutes.

MR. THOMPSON: I'll try my best. I'll also focus my remarks on some of the food issues as opposed to looking more at the mechanisms that we've already discussed today. While the Chinese government has made progress to increase transparency over the past decade, there are clearly areas where transparency and improvement is needed. This is particularly vital in sectors where inadequate transparency threatens U.S. national interests such as public health the environment and food safety.

It's also helpful to consider some recent crises and responses as they will help us develop strategies and policies that will contribute to increased transparency and safer consumer products both in China and the U.S.

The outbreak of SARS in 2003 and China's bungled handling of the crisis was a seminal event for the new leadership of China, demonstrating that it's impossible to mount a successful cover-up of a public health crisis in modern day China.

It further taught the bureaucracy that any attempt at a cover-up will likely damage the country's reputation. The SARS crisis was a positive catalyst in several ways. SARS spurred debate, investment and reforms in the health care sector, including the establishment of programs to address other infectious diseases such as HIV/AIDS. SARS also led to increased transparency. The government learned that a lack of openness caused rumors and panic that undermined its own credibility. It also learned about the penetration of new technologies such as cell phones that facilitated independent information exchange between citizens.

Subsequent to the SARS outbreak, laws were revised, a network of government spokespersons was established, and government made a much more concerted effort to release timely information to the public.

More recently, there's been widespread media coverage of dangerous foodstuffs and consumer products in China. The vast Chinese bureaucracy which is often very slow to

react to any crisis responded awkwardly to the initial reports of unsafe toothpaste and adulterated pet foods, and it's very likely that some officials ordered editors not to report on the evolving situation reflecting the still widely held concern that release of some information to the public can cause embarrassment, chaos, and social disruption.

However, as the consumer product safety story grew, Chinese officials from numerous government agencies responsible for food safety increased the frequency of their public statements at press conferences, through the state controlled media and even making informal remarks on the sidelines of public conferences.

However, many officials, particularly at the county and local levels do not embrace this approach. Media engagement is still a very new phenomena. The State Council only made public its list of spokespersons at all of the provincial level governments and the different government ministries in December of 2004.

The government has announced the approvals of several new regulations, some of which Dr. Gottlieb mentioned, which are intended to improve food safety and which will hopefully establish clear standards and contribute to improved transparency.

A better knowledge of laws and the legal framework will enable officials to release information with more confidence. The State Council has also recently established their own equivalent of FOIA, which Dr. Gottlieb also mentioned, which authorizes officials to release important information to the public and that law specifically covers, quote, "information and inspection and monitoring for environmental protection, public health, production safety, food and medicine safety, and product quality," and this very much reflects the concerns that the central government has about provincial and local level officials not releasing information in these critical sectors.

The infectious disease law was also revised in 2004 in the aftermath of SARS which required disclosure and reporting of infectious disease outbreaks. The Ministry of Health in particular has taken many of those regulations to heart and now releases infectious disease data regularly on its Web site.

While there are signs the situation is improving, like much of the reform process in China, it's neither unconditional nor unequivocal progress. The day after its founding director was executed for bribe taking, the Chinese Food and Drug Administration released new rules that required transparency and independent oversight of the previously opaque drug approval process.

The current Deputy Director of the SFDA was quoted by state media as saying, "Transparency is the enemy of corruption. That's why we've introduced this new regulation."

This is an encouraging development for a political system that has very few checks and balances. However, there are contrasting incidents where information that is relevant to the public is tightly controlled. In 2005, local officials attempted to cover up a pig disease

outbreak in Sichuan province and despite punishing four officials for their role in the cover-up, other officials ordered local media to only rely on official press releases.

The World Health Organization has also been openly critical of the Ministry of Agriculture, both for its handling of information related to bird flu and to a much more recent and current pig epidemic that's affecting 22 provinces.

Uneven progress can be attributed to several factors, many of which we've already discussed today. Primarily, local officials remain fearful of releasing information that might reflect badly on their performance or affect outside investment in their jurisdictions.

Officials often prefer to selectively release information omitting critical details and statistics, creating what they consider a "correct understanding of the situation." Lastly, the regulations governing state secrets are ambiguous and this provides another circumstance for state and local officials to apply the national interests or social stability arguments in the broad context of state secrets when they refuse to make information public.

I think understanding of the structure of the food industry will help us develop strategies and policies that will have a higher likelihood of success and also encourage increased transparency within the Chinese system, which will ultimately benefit us. I'll highlight several challenges very briefly. First, the food processing industry is dominated by small processors with very little knowledge of quality standards or international standards. There are wide estimates of the size of the industry ranging between one million and 450,000 companies, but the consensus is that the majority of them, up to 70 percent, are small processors with less than ten employees.

One government department estimated that there were 200,000 companies that had improper licenses and 164,000 that had no license at all, and this is in addition to the hundred thousand that had been closed in recent crackdowns.

Second, local governments often lack the capacity or incentive to improve oversight or to implement new regulations and dictates from Beijing. Corruption and collusion allows counterfeits and substandard products into the market and it also discourages safe manufacturing practices amongst legitimate processors.

Third, globalization is changing the social and economic landscape in China. The massive investment in infrastructure has expanded China's expressways from 100 kilometers in 1988 to over 41,000 kilometers in early 2006. A 300 kilometer journey that took me nine hours in 1994 was reduced to three hours in 1997.

And this has created huge changes for farmers and had enabled them to get their produce to urban markets faster, and those Chinese urban markets are now increasingly connected to our international ones.

Finally, the political economic system in China lacks many of the structures that contribute to product safety in other countries, primarily strong consumer protection laws and independent courts that place consumer protection over the local economic and political interests.

In addition, China lacks a robust civil society that can effectively represent the interests of consumers as well as manufacturers. Encouragingly, food security and free trade are common core interests of both the United States and China which allows for active political engagement. China garners no benefit from shipping substandard or dangerous products to the U.S., so we should view their efforts to improve oversight as genuine.

Following the pet food recall incident, food safety was thrust on to the agenda at the Strategic Economic Dialogue this May which set the stage for the U.S. delegation to visit Beijing this week to hold talks toward signing MOUs on pharmaceuticals and food safety.

The key issue facing the negotiators is whether the resulting MOUs have enough substance to make them effective, or whether the negotiators can agree on the metrics and evaluation process to determine if each side is meeting its obligations.

I'll make four very brief recommendations for how we can more effectively engage the Chinese government to improve transparency in the food and consumer product sectors. There are a number of opportunities for both the government and the NGOs in the U.S. to engage Chinese counterparts to build an environment where safe production is the norm. Engagement boosts transparency and it also establishes positive government-to-government relationships which will increase our opportunities to garner more information from the Chinese regulatory system.

The U.S. government has experience establishing company registration as well as product tracking systems, particularly in the aftermath of 9/11 and the initiation of the bioterrorism law in 2002. Engaging central as well as provincial authorities in China to establish lists of qualified exporters would improve traceability in China and increase accountability amongst exporters.

The U.S. currently funds programs supporting the judicial reform process in China which is directly related to public health, food safety and transparency. These programs also reinforce the notion that U.S. intentions towards China are based on common, non-threatening interests that are broadly intended to encourage China to adhere to international standards and norms.

Lastly, I think it's agreed to by many people that the FDA is ill-equipped to address the growing tide of food and drug and device imports. For example, the FDA does not have a permanent presence based in the U.S. embassy or consulates in China. Having a full-time

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presence in these critical exporting countries would help prevent unqualified products from reaching U.S. ports and increase our access to information. That would require significant investment in resources and FDA's capacities.

In conclusion, China has a very traditional notion of state sovereignty. It is increasingly outdated as globalization intensifies and China becomes integrated with world markets. What takes place in the backyard processing plant in a distant province potentially affects consumers around the globe. And this is a notion that challenges China's traditional concepts and puts the responsible stakeholder paradigm in a new perspective for them.

If a future consumer product crisis or SARS or avian influenza epidemic occurs, trust between the two countries, which would be built through close cooperation, will increase the likelihood that Chinese authorities will willingly share information in a crisis situation.

Thank you very much.

HEARING COCHAIR HOUSTON: Thank you very much to both of you for your great testimony and we will start the questioning off with Commissioner Wessel.

Discussion, Questions and Answers

COMMISSIONER WESSEL: Thank you both for being here. Excellent testimony on what clearly is a topic that's on the minds of many Americans, not only pet owners now, but families who are worried about what they're feeding their own kids. We're also seeing this, of course, in product safety, not just food, but as you pointed out pharmaceuticals, and we heard testimony last year as to concerns about car parts, airplane replacement parts and many other things. So we're seeing this all the way up and down the product chain in terms of imports.

And as we all know, while China is currently, of course, the subject du jour in terms of these issues, it's not just a China issue. We face many concerns with regard to imports from other countries as well, but it appears to me that China's stability, which is the driving interest of the party in power, is really dependent on export-led growth. We are seeing, if I recall correctly, roughly one-third of Chinese exports coming to the U.S. market. It appears to me, further to what you talked about in terms of transparency, that we should use the power of our own market to help accelerate and advance their efforts at regulation, oversight and review of their products, and potentially by expanding our country of origin labeling laws here.

Dramatically, we've just seen after a five-year fight that beef products now will finally have some product labeling on them.

But if the American consumer has greater information not only on the end-use product but the ingredients, it seems to me that going back up the food chain, no pun intended, that may yield quicker action in the Chinese market for fear that their stability will be

undermined if people stop buying their products because they're concerned about product safety.

Could each of you give me your views on country of origin labeling to provide consumers really with the right to know where their products come from and how to gauge their own safety?

DR. GOTTLIEB: I'll give you I think what FDA's standpoint would be, not that I speak for the agency, but I think it's relevant here to consider the perspective of the agency. The FDA looks at labeling from a public health standpoint. I think when you speak about country of origin labeling, you're really talking about a consumer issue. So if a product was inappropriately labeled as not having a protein that could be allergenic, for instance, that would create a certain public health issue, and that's the place where the agency would necessarily take action.

But in terms of just creating greater consumer awareness around where the ingredients are coming from, from a regulatory standpoint, I think it's awkward to think about imposing the burden on the agency to require that kind of labeling when it doesn't necessarily translate into a public health issue.

It's hard to argue that consumers don't have a right to know where their product is coming from, and manufacturers should refrain from being deceptive about the origin of their products. When you talk about meat or whole products, it might be something that's even achievable. But we're living in an age when a chocolate chip cookie can come from 20 different countries so I think it makes exceedingly hard to actually implement that kind of legislation.

I know there have been proposals to do it, and I know people have thought through this. I think from a practical standpoint it would be somewhat challenging. From a public health standpoint, I think the current labeling regulations address the public health issue. So this really falls outside the FDA's mandate and into a consumer question.

COMMISSIONER WESSEL: Mr. Thompson.

MR. THOMPSON: I think what is valuable is that our system has many of these mechanisms that the Chinese system does not, and recognize the strengths of our system, provide opportunities for them to take what they can in terms of technology from our system. We discussed earlier today about democracy, and it's pretty clear they're not going to accept Western democracy wholesale, but they'll create some sort of democracy with Chinese characteristics.

I think there are opportunities for us to export our concepts, including industry standards, as opposed to compulsory regulations, and help them better understand the role of a free media, civil society, such as associations, consumer advocates and watchdogs, as well as the manufacturers' associations, which China has, but perform a very different role than the Grocery Manufacturers Association-Food Products Association, which helps food

processors adhere to standards and understand the very complicated and evolving labeling laws.

In the case of allergens, it's very, very complicated. The regulations don't require certain, for instance, statements about allergens. If you go through carefully and read the Code of Federal Regulations, it's not there, but unfortunately for the Chinese it's now an industry standard and it's an area that's quasi-regulated on a voluntary basis, which for them is an oxymoron. It's very hard for them to understand how you can voluntarily comply with something. You're either compelled to or not.

But all of that comes about because we have a very strong legal system that puts the onus on the, in this case, an importer if it's an imported product or the U.S. domestic producer if it is locally made. You have insurance companies and you have retail outlets that require your insurance coverage to cover from the manufacturer to the retailer, which puts a great burden on the importer or the processor to design a safe product.

COMMISSIONER WESSEL: I think there are tremendous gaps in the system. My time has expired and I'll seek another round later, but there are tremendous gaps in that liability. An importer of record is not necessarily the distributor, and you may have that importer of record simply insuring against product breakage or actually receipt and not providing derivative liability down the stream for liability for an unsafe product.

MR. THOMPSON: Food products require a million dollars liability.

COMMISSIONER WESSEL: I'm talking about all products, not just food, and ingredients where other nations have already put some labeling in saying this product may contain ingredients, going back to your cookie example, coming from X, Y, Z. I understand that the chips and the sugar and all the other things.

HEARING COCHAIR HOUSTON: Commissioner Fiedler.

COMMISSIONER FIEDLER: Is there any reason that an American citizen should have any degree of confidence about ingesting Chinese food imported into the United States from China? Not Chinese food in--not cuisine food.

MR. THOMPSON: I think you have to really differentiate between products and recognize that there's a broad range of manufacturing quality from poor to the very high end, very high quality products that do come to the states in a variety of sectors. It has been reported that 80 percent of the global vitamin C, ascorbic acid, production is in China, but actually the companies that produce them include European companies based in China.

So they follow essentially the manufacturing standards that they would use in Europe, and when they export to here, they follow our standards, and I think as long as you're consuming products from established manufacturers with brands, from companies with

access to technology, capital investment, something to lose in this whole game, then you can have a fairly high level of confidence that you're going to get a safe product.

COMMISSIONER FIEDLER: Yes, go ahead.

DR. GOTTLIEB: To follow up on Drew's point, from a marketplace standpoint, the large manufacturers are taking significant steps to police their own supply chain. If you look at what the U.S. pharmaceutical companies have done for a very long time, when they source their active pharmaceutical ingredient in China, they don't just buy it from a Chinese manufacturer, they'll actually go in and either stand up the facility or help upgrade the facility and maintain very tight control over the manufacture of the product, literally sending inspection teams in every week or so to inspect the plant. The food producers historically haven't done that, but they're starting to do that, much more vigilantly now, where they'll actually go in and look more closely at the source of production rather than just buying the product on the market.

From a regulatory standpoint, the fact of the matter is we still have an exceedingly safe food supply in this country and strong regulatory protections in place.

But the reality is FDA was conceived as a domestic regulatory agency, not a regulatory agency equipped to regulate a globalized supply chain. We have increasingly reluctant inspectors who have a difficult time going into a lot of the regions where products are being produced. It was one thing when products were produced in Europe and quite another when they're produced in China and other countries that are difficult to get to. So people are increasingly reluctant to go there.

We don't have enough inspectors to do those kinds of foreign inspections. The reality is, and we also don't understand the local culture, the local language, we don't know who the local criminals are, as I've said, so there are things that we can be doing, I think, in this country from a regulatory standpoint certainly to improve our oversight of these products.

I see no reason, having been at the FDA very recently in a senior role, why American consumers shouldn't be confident in the food supply in this country. But that said, I think there are some significant steps we could be taking to make it even safer.

COMMISSIONER FIEDLER: Let me see if I can restate your answer. If they're European produced and big, we should eat their stuff if it comes from China?

MR. THOMPSON: I said you can be confident that the food is going to be of high quality.

COMMISSIONER FIEDLER: Yes, but here's the problem. I go to the store. I go to Safeway and I go to Giant, and I don't have a list of the big companies with brands in China that are reliable. I don't know whether the packaged frozen peas that came in and were sold to Jolly Green Giant, I have no idea where they're from, and from the

testimony we've received today from you and others, nobody else has any idea where they're coming from either until somebody chews on it, dies, and then we go investigate. How do we have any degree of confidence in what we ingest, with all the problems that you guys have stated and others have stated? I don't understand. I asked a simple question, which was a level of confidence. Now, you're saying FDA has been an agency and blah-blah-blah, that's fine. I didn't attack the FDA. I'm saying how do we know? How do we have any degree of confidence? And I don't think I've got answers from you on that yet. You're avoiding me on it.

DR. GOTTLIEB: Your question is predicated on the assumption that products coming in from China are less safe than products coming in from other countries, and I don't think we have--

COMMISSIONER FIEDLER: No, I didn't address other countries. I'm just addressing China. I just said China. I didn't say Mexico. I might ask the same question about Mexico, but I just asked you the question about China.

DR. GOTTLIEB: But, the question is are you talking about country of origin labeling as a consumer right to know issue or as a safety issue?

COMMISSIONER FIEDLER: No, I'm actually talking about how, after you've said that the system out there is broken, and we don't know what they put in the food, we don't know this, we don't know that, we don't know if the local criminals are sending this stuff into Dole. Then how do we have any degree of confidence in what we put in our mouths? I'm sorry. I'm taking too much time.

DR. GOTTLIEB: I think both of us are saying that there are gaps in the system that right now--

COMMISSIONER FIEDLER: So you're saying that there is no confidence?

DR. GOTTLIEB: There's a difference between saying there is no confidence and saying that we could take steps to make sure that we are more confident about the oversight of the products coming in from China.

As I've said, we are much better equipped to regulate domestic producers than we are to regulate international producers, not just in China, but all over the world. China happens to be a little bit more difficult for us because we haven't had the bilateral relationships historically that give us access to good information so that we can target out inspectional resources.

You're saying no confidence. I think that's a difficult statement.

COMMISSIONER FIEDLER: If you said to me that I think their apples are better than their lemons, that would be a reasonable answer, but I asked you a general statement, and I don't see--

DR. GOTTLIEB: I think their apples are better than their seafood. How's that?

COMMISSIONER FIEDLER: That's progress. That's progress.

MR. THOMPSON: I think that's a critical point. If you consider that you have varying risks of safety with any food, whether it comes from one country or the other, and if you're consuming raw shellfish or raw seafood, you're at a higher level of risk than you would be consuming, say, frozen peas with a Birds Eye label on the bag bought at a Safeway.

What you can be certain of is if you get a bag of frozen peas that may come from China or Chile or Mexico, wherever, if it says "Birds Eye" on it, and it's bought in a Safeway, and you get sick from it--

COMMISSIONER FIEDLER: I can sue them, yes.

MR. THOMPSON: You can sue their pants off, and as a former food processor, I had little fear of the FDA. I was afraid of getting my pants sued off. I could lose my house.

COMMISSIONER FIEDLER: That doesn't satisfy me if I'm sick.

MR. THOMPSON: Our legal system is very, very effective at weeding out the companies that cut corners, and if Birds Eye cuts corners and has a problem, we have recourse to enforce that.

The problem is Chinese consumers don't have that, and having lived in Beijing for the last year and a half, they have significant problems. Now, that said, the Chinese also have learned to adapt.

I had a cook who would go out and shop in the market, and I gave her very strict instructions everyday. I want you to buy the soy sauce not from the guy with the pump and the 55 gallon drum, but buy it in the bottle and make sure it goes [click sound] when you open it.

Now, the problem is when you've got the very poor rural people that don't know any better and say, oh, yes, but this only costs five mao and that costs eight mao, I'm going to buy the five mao. Well, the five mao is made with ink instead of good soybeans.

Regarding our discussion about the fake buns, I think Colonel Wortzel lived in Beijing, and I think he knows, especially in the late '80s and early '90s, it was something of an urban legend, the Sweeney-Todd syndrome--God knows what was in your dumplings, and everyone said don't eat there, and don't eat there and there, who knows what meat is in their dumplings.

I also watched that CCTV, or the Beijing TV undercover report. It seemed dodgy to me. It looked like some very, very fine spy cam work that just didn't have that real authentic

feel. The pictures were too well framed and it was like someone just took a Handycam and put a black frame around it so that it looked like it was a spy cam, but it didn't look genuine to me when I watched it.

That said, you've got plenty of back alley dumpling makers that probably are cutting corners. If you buy something in a bag that's not well marked, that's not labeled, you don't trust the brand, you're probably going to have a problem, and the Chinese inspectors deal with it the same way.

If they have an uptick in the number of people getting sick in a particular restaurant, they have a risk-based system, they go after that restaurant. If you've got a restaurant with good turnover and good volume and a lot of people, your probability of getting sick there is much lower.

DR. GOTTLIEB: Your question gets to the issue of what we did in the bioterrorism regulations in response to 9/11, which was develop a system inside the FDA or Department of Homeland Security to target inspections and quarantines based on the perception of risk of a product. So whole produce from Canada doesn't get stopped, but loose spices from the Middle East do.

I don't know what the top secret algorithm is, but there's an algorithm for assessing risk. We don't have that, something nearly as good, when it comes to just regular food coming in from countries that falls outside of the bioterrorism framework because we don't have the information to target inspections based on risk.

HEARING COCHAIR HOUSTON: Thank you very much. Commissioner Wortzel, do you have any other questions that are going to make us never want to eat again?

COMMISSIONER WORTZEL: Actually I think Commissioner D'Amato may have the food safety question.

You both have mentioned market-based forces in one form or another. And it's in your written testimony, Dr. Gottlieb. But let me go back again to the same question. And I do this with a lot of witnesses. If I said take off every piece of clothes on you made in China, how much would you have on? It's not just a rhetorical. I ask this of a lot of witnesses, in other words I have nothing on made in China. There is nothing on my body made in China for a couple of reasons. I can't stand the god-damn government there.

HEARING COCHAIR HOUSTON: Can you prove that to us, Larry?

COMMISSIONER WORTZEL: And that's not always the case, but I go out of my way as a consumer to buy it from Mexico or Cambodia or Indonesia or Czechoslovakia. I go out of my way for a variety of reasons.

So I'm going back to the same thing. If I can look at a shirt, as a consumer, and I can look at a machine tool as a consumer and make an informed decision. I have Haier refrigerators all over my house. I think they make a good refrigerator.

CHAIRMAN BARTHOLOMEW: And that costs a whole lot more than the clothes.

COMMISSIONER WORTZEL: And I can make an informed decision about what I want to buy, I don't care about protecting Chinese citizens from the Chinese government. I don't care. They can kill each other all they want. I don't care how many food inspectors they have to execute before guys stop polluting their food if it gets here, as long as I know where it comes from.

So, leaving aside regulation, what legislation could be crafted that would allow Americans to know what they're feeding their children, their dogs, their wives, their cats? Now that's a very different question.

COMMISSIONER WESSEL: In that order.

COMMISSIONER WORTZEL: In any order.

COMMISSIONER D'AMATO: In that order?

COMMISSIONER WORTZEL: Why should I worry that the vitamin I take happens to have the same Chinese wheat gluten in it that killed a thousand dogs? How can I know that? Not regulation. Legislation.

DR. GOTTLIEB: Legislation translates into regulation, but--

COMMISSIONER WORTZEL: Right. Properly written.

DR. GOTTLIEB: I don't know about Drew. I'm by no means an expert on the country of origin legislation. I read it a long time ago. I do think it's important to separate out what is a public health issue and what is a consumer right to know issue. If you're advocating country of origin legislation labeling as--

COMMISSIONER WORTZEL: I'd label it as consumer right to know.

DR. GOTTLIEB: Okay. So then that's outside my area of involvement and expertise. It gets into what I would like to know as an individual. I think from a public health standpoint, though, if you're advocating the labeling, country of origin labeling as a public health tool, that needs to be conditioned on the belief that we have definitive information that products from China are more risky than products from other countries. I think perhaps outside of a small subset of food where we've found voluminous violations, seafood being one of them, that's hard to say right now, given the information we have.

MR. THOMPSON: I have little to add on the labeling regulations. I think it's certainly applicable to raw materials, meat and seafood, though I'm not sure the average consumer ambushed by Jay Leno would know the difference between shrimp from Thailand or shrimp from China. I think something like 90 percent of our imported shrimp comes from Thailand, not China.

So the question is, would it have a major impact? It would help you make a more informed decision, and I think there are many people that would like it to happen. Again, from drawing on my personal experience, my previous company worked with Alaskan salmon processors, and we purchased Alaskan salmon, which I have a personal preference for. It tastes better than farm salmon. It's a better product; it's organic, even though it's not allowed to be labeled as organic, or free range, but it is wild salmon as opposed to farmed.

We shipped it to China where there was a huge building full of 800 young migrant workers from Sichuan who sat there and cut it up in pieces by hand and packaged it, and then shipped it back from China. And at the bottom, we had a long, long debate with the National Food Processors Association and the FDA about whether we could label it as "Alaskan salmon" or "made in China," and ultimately it ended up being "made in China," but it was really "made in China" Alaskan salmon.

COMMISSIONER FIEDLER: Which was accurate.

HEARING COCHAIR HOUSTON: Thank you very much. Chairman Bartholomew.

CHAIRMAN BARTHOLOMEW: Thank you and thank you, gentlemen, for certainly interesting and lively testimony. Larry claims he's asked that of other witnesses before, but I have to say I don't recall.

COMMISSIONER WORTZEL: Nobody challenged me.

CHAIRMAN BARTHOLOMEW: And for those of you who didn't know the reference to Commissioner D'Amato, he got quite ill eating something.

COMMISSIONER WORTZEL: Seafood.

COMMISSIONER D'AMATO: We don't know what.

CHAIRMAN BARTHOLOMEW: Eating seafood when we were in China. A couple points, and then I'd like to try to tie this back into the conversations that were happening earlier today about access to information.

Drew, I also wanted to acknowledge all of your leadership on addressing the global AIDS crisis, particularly the AIDS issue in China, and I think that that gives you a particular perspective on some of the challenges of issues that the government might not want to be

facing, the role of the NGO community, all of those things. So thank you for your work on that.

I do want to just say, though, you sort of point to established brands, and I think one of the reasons that the pet food situation was so alarming to people was those were established brands that people were buying. It was the first time that American consumers started having to think about the composite ingredients that go into what they buy. So it wasn't just generic pet food that they were buying. Those were established brands, and I think, much as I am a pet lover and would be absolutely upset if something happened to my pets, that in some ways it was an important wake-up call for us to deal with a crisis that happened first in pet food before it happens on a large scale on food. You make reference to the dumplings. It's very interesting to me that I walk away from this quite confused about whether those dumplings were or were not filled with cardboard, and it gets right to the question of access to information, too. We cannot trust that an official statement that comes out from the Chinese government saying, no, that it's not true that those were made of cardboard is true, and there is no way to verify that. So it's the kind of issue that just because a statement is put out saying there's not a problem here, we can't believe that there's not a problem. That's one point.

Another point is we talk about more MOUs or any of these agreements that take place, but we know that there have been nine agreements on intellectual property rights, and the problem is not so much the fact that there aren't agreements. The problem is enforcement, and that's going to be, I think, a very big challenge that we have.

But I want to go right to the question of access to information. Do U.S. investigators going into China to try to investigate cases of these things when they finally happen have access to information? Did the FDA get the kind of access to the factories where that gluten was being made so that they could determine what was going on?

DR. GOTTLIEB: I don't know what's publicly known with respect to the difficulty the FDA had on the gluten case. It is, I think, a matter of public record that the FDA did have problems getting in immediately after that, getting access to some of the manufacturing facilities, and it took some high level help to get our inspectors over there.

I think routinely the fact is that inspectors have difficulty accessing these countries. We don't, at least from an FDA standpoint, there's not a lot of inspectors capable of going into these countries who know the culture and can speak the local language, and when they do get into these countries, they have difficulty getting access to both the facilities and the information needed to conduct their own inspections.

It's not just true of China. It's true of other countries as well that have equally underdeveloped regulatory systems.

CHAIRMAN BARTHOLOMEW: Drew, anything?

MR. THOMPSON: I only know what Senator Durbin released from his office about making initial contact with the Chinese government and then having approvals from

received about 19 days later. I don't know what the normal processing time for a U.S. government official to make an application to the Chinese government, to then have the background checks, and then have a visit approved.

I know the FDA did make public statements that once the Chinese government had decided to allow three inspectors to come in, that, for instance, the embassy here in Washington issued visas for some part of the delegation on the same day and other parts within one hour, depending upon when they received the passports. However, the entire process took 19 days.

So what I think the main challenge is, as you said, is enforcement and the challenge that Beijing has working with its localities, and one of the issues is that Beijing, because that was where the application would come from, has to go and apply to Jiangsu Province to get permission for not only the FDA officials, but also the Beijing-based officials, the central government officials, to visit the province.

I've personally been involved in joint inspection teams with the Ministry of Health who have attempted to go and conduct measurement and evaluation, (M&E) investigations on Chinese government-funded programs on HIV/AIDS in a number of provinces. And this was an interesting and positive development in itself, that they wanted to bring in foreign experts to help them evaluate their own programs.

Two out of the seven provinces actually rejected the Ministry of Health's request to visit. Now, they didn't reject it. They postponed the visit. The provinces came up with reasons, but by the time this happened, who knows what happened to those programs? Who knows what happened to the accounting? Who knows how many patients were shifted from here to there?

CHAIRMAN BARTHOLOMEW: Right.

MR. THOMPSON: So in some ways I think it's important to recognize these are their internal challenges as much as they are challenges that we confront. So seeking opportunities to collaborate with them in a way that increases trust. For instance, I mentioned placing FDA officials on the ground in Beijing on a regular basis to help do more of the liaison work, but I think also what's important is we need to take a look at how other countries manage the problem.

Hong Kong is a good example. Hong Kong deals directly with Guangdong provincial authorities because, as Scott mentioned, they know where the bad guys are. Beijing cannot maintain a current list of manufacturers in each province, but the provinces do. So having provincial-to-U.S. regulator level relations and contacts will help us react more quickly.

Now, that's easy to say. There are 31 provinces. You could maybe focus on the top 18, but combine that issue, recognizing the organizational challenges that they face internally, and then adapting to it, will help us get better access to information, and that

includes things like registration lists so that we can essentially develop cartels. How do you make sure that you've got branded products coming out of China? And that includes ingredient suppliers, so you're not just buying on the open market; you need to have qualified suppliers.

Then you have a supplier in China with something to lose. Then the supplier has a business to protect and a brand, and privileged access to the U.S. market, and that's an incentive for them to not cut corners, to not adulterate their product, to keep up with the standards, and that will improve our food supply.

CHAIRMAN BARTHOLOMEW: Right. But it's an important point that you make about the central government not even being able to get access to the information. I read somewhere that by the time the FDA got to at least one of the facilities, it had actually been bulldozed down. So somebody was obviously behind all of that.

But if the problem is also communication between the central government and the provincial governments or even somebody more local than that, it really does call into question whether anything is accomplished by the FDA coming back and saying, guess what, we signed this agreement. You have to question the nature of the agreement and what is it that the agreement gets us.

It is simply not going to be enough to come back and say we've got an agreement because if the agreement is with the central government, and the central government then takes two weeks in order to be able to get into it, it's not giving us the kind of information that we really are going to need in order to be able to deal with these issues.

One more point and then I'm going to stop. I've been really struck, as I often am, but really struck in a lot of these discussions about it's not just food but consumer product safety examples that have come up, how people in the U.S. government have been dancing around the fact that the source of most of these problems lately has been China. I think that it is important to acknowledge that we have troubles with products coming in from other countries, but I think given the vast magnitude of products that are coming into this country from China, we do our consumers a disservice by pretending that addressing these problems with China would not be a significant step towards stopping those problems and creating standards that we expect everywhere else.

So it's just a caveat there, which is let's not pretend. If the source of most of our concern is China on these products, let's just admit it and deal with the problem.

HEARING COCHAIR HOUSTON: Thank you. Commissioner D'Amato.

COMMISSIONER D'AMATO: Thank you, Madam Chairman. I'm not going to ask the food question because I know the answer. It's bring your own peanut butter sandwiches. But there was a news program either last night or I think the night before on drugs.

CHAIRMAN BARTHOLOMEW: Dateline.

COMMISSIONER D'AMATO: Dateline. Which was a horrific expose of the uncontrolled nature of criminal access, widespread access by gangs of counterfeit drugs

into our system. And it struck me that what you have is an unpoliced series of intermediation in our system that makes it impossible to know whether if you go to a CVS and buy a drug, whether it's counterfeit or not, at least if the news program was in any way accurate.

My question is where do we start with this on both sides of the Pacific? How do you get to a level of confidence that the drugs that are being, Lipitor or whatever it is, being purchased in the local drug store don't have a chance of being fake, not only fake, but dangerous?

I understand that there were some recommendations made a couple of years ago, according to the program, but they've never been implemented by the FDA. But barring the question of consumers going out and finding a laboratory to test the drugs that they're buying, whether they're good, how do you get to a level of confidence here on drugs if the level of criminal activity is anywhere near what was portrayed, a highly lucrative, highly lucrative, and easy to duplicate if you have the technology, the looks of the drugs, the looks of the product labeling, the containers and so on?

Have you given much thought to a recommendation? What would you recommend where we start here to start putting some more confidence in our system of drug intermediation?

DR. GOTTLIEB: When I was at the agency with Dr. McClellan, we put out a very large report from a counterfeit task force that we had convened to look specifically at this issue with a number of recommendations in it. I think the agency from a policy standpoint has found itself caught in a very awkward cross-current of competing political forces on this issue.

On the one hand, we benefit when it comes to drug regulation from a closed pharmaceutical supply chain in this country that was created with legislation called the Prescription Drug Marketing Act, passed probably 15 years ago in response to an episode of counterfeit ciprofloxacin had made its way into the pharmaceutical supply chain. Some women used it for urinary tract infections, didn't get treated appropriately with it because it was sub-therapeutic, and it created a predictable outcry, and the legislation was in part the result of that episode.

We do have laws in place that effectively closed the pharmaceutical supply chain. Now, that's not to say it's impervious to counterfeits, but we have far more regulation in place than we do say on the food side. But at the same time, over the last two or three years, the agency has been engaged--probably longer than that--five years--the agency has been engaged in a debate over drug reimportation and various proposals that would effectively gut PDMA.

And so, on the one hand, we were trying to advance policies to try to increase the oversight, further close the pharmaceutical supply chain. On the other hand, we're facing legislation that would have undone a lot of the existing regulations. So I think it's been a very awkward debate and hopefully that has shifted in favor of more consumer safety

now. I don't hear people talking as much about reimportation. That might be because the dollar is weak against the Canadian currency. I'm not sure.

But with respect to taking steps to try to create more safeguards over the drug products and clamp down on counterfeits, I'd encourage you to take a look at that report. And principal among the recommendations was a proposal to implement an electronic track and trace, a pedigree, to track the chain of custody of drugs.

Right now we've finally implemented that rule probably about eight months ago at FDA. Our FDA finally implemented that rule. But it's still an electronic pedigree. It's still a paper pedigree, not a fully electronic pedigree. I think that the real protections are going to come when we start to have things like tags in the drugs themselves or on the bottles. You know special dye, special inks, other technology that is available. It's somewhat expensive, but it would enable better tracking and monitoring of drugs put in the supply chain.

MR. THOMPSON: I think the issue of illicit substances presents a challenge to any government. I spent the last two years working in very poor area in southern Sichuan Province, which was on the heroin smuggling trail from Burma running up to Chengdu and then into other markets, such as Xinjiang or Shenzhen and then abroad. It's very difficult for any government, to address underground activities, and that's one of the reasons that HIV/AIDS presented such a challenge to the government.

You're dealing with people who are outside the formal economy. It's very hard to get voluntary compliance from a sex worker, a drug abuser or a smuggler, and I think the issue of counterfeits fits very much into that context in China. We discussed counterfeits earlier today and giggle about, "oh, I got the Harry Potter DVD," but it's not so funny when it's something you ingest.

We need to recognize that as consumers, we have a responsibility to purchase from reliable vendors and suppliers and hold them accountable. I don't want to repeat my previous recommendations, but it really comes down to having the ability to track and trace products in the supply chain.

It's an area where we have much more experience than the Chinese government. After September 11, the U.S. food defense system essentially was established where every single food manufacturer and distributor is now at least registered. So you can get into a computer and find out who they are and what kind of products they ship and where they're based, and I assume there is a fair amount more information available to regulators in the system.

We threw out some statistics before. The FDA estimated that there were 210,000 companies that had to register, and correct me if I'm wrong, to comply with the Bioterror Act.

But in China, the estimates are between one million and 450,000 processors of which 100,000 had just been closed, 100,000 aren't even registered, and 164,000 are registered but as something else. I think that's part of what you also see in the difficulty regulatory environment in China where you've got somebody who's making industrial chemicals that are being sold and then being used as a food additive, which is not in compliance with the manufacturers license or with the product's intended "generally recognized as safe" use. Intentional abuse of the regulatory system is always going to be a challenge, particularly for the FDA which is heavily reliant on voluntary compliance.

COMMISSIONER D'AMATO: Obviously, we do have the technology available, as you say, to do a much better job of whatever tracking, tagging, and unless we do it, I don't think it's going to happen in China.

DR. GOTTLIEB: We looked at estimates of when it would become cost effective for our manufacturers to voluntarily start implementing that kind of track and trace on their own, and the costs start to come down when you look at the technology curve of some of the new things that are coming along.

For certain products, they're already implementing these--products that are more apt to counterfeiting, some of the controlled substances, basically Pfizer's top five drugs. That company alone has the single-greatest incentive to implement these technologies because they face the most counterfeiting over in China. So you've seen some companies take steps to actually implement these technologies.

HEARING COCHAIR HOUSTON: I'm going to call on myself to ask the last couple of questions, and I hope they're fairly simple. I think they're kind of quantitative. Dr. Gottlieb, Beau Dietl Associates, Giuliani Partners, GlobalOptions, Neil Livingstone, all of them have studied counterfeit drugs that come over what appear to be Canadian Web site, which are not Canadian Web sites. These drugs are coming from all over the place--Namibia, Beirut, Dominican Republic, and people think they're from Canada. I think it was Mr. Thompson mentioned that awhile ago, how do we know how much of the dangerous stuff is coming in from China? I know the Asian Triads at one point were trafficking pseudoephedrine over the Canadian border to make methamphetamines. There's clearly a relationship there between the Asian Triad gangs and what's going on in China.

Do you have any idea at all or any sense of how much of those counterfeit or pirated drugs that come in from allegedly Canadian Web sites or allegedly American Web sites come from China?

DR. GOTTLIEB: The FDA has a good sense of how many of the drugs that are coming in from uncertified Web sites are actually counterfeit products. I don't think the agency would know how many of them were coming from China, but that percentage has been reported off of estimates from blitzes that the agency has done, and it's fairly high. I think the broader question, which is how many counterfeit products are making their way into the pharmaceutical supply chain, is a much more difficult question, where the

agency has historically said that they don't necessarily believe that there's an increased number of drugs, counterfeit drugs, coming into the U.S. supply chain, but there's really no way to know for sure.

Certainly all the anecdotal information about the greater sophistication and desire of people to penetrate the market with counterfeit products would suggest that we probably have more of a problem here than we are aware of.

HEARING COCHAIR HOUSTON: Thank you very much. And Mr. Thompson, you gave me heartburn when you said that there's no--Dr. Gottlieb, you could help me with that--that there's no FDA representative at the embassy. We visited all the embassies and all the consulates and there's practically a dogcatcher, a U.S. dogcatcher there. How is that we don't have an FDA representative there?

Is it because the Chinese do not want us to have one there or is it a lack of will or smarts on our side to bring one over there, and do you think that will change because of all the problems that have occurred over the last little while that Chairman Bartholomew referred to?

MR. THOMPSON: There is a health attaché, and there are representatives from the U.S. CDC, and of course the State Department would put the FDA issues under the Science and Technology portfolio in the embassy, so the S&T officers would be responsible for doing liaison and follow-up on these issues.

But that said, the health attaché in Beijing has spent a lot of time in the region and very dedicated and knowledgeable, and I think he's an asset to our country. But he's not an expert on food and drug safety. He doesn't have an extensive or direct network of contacts within the FDA.

So, in some ways, there is representation there, but I don't think it's adequate. I can't speak authoritatively for why the FDA doesn't have somebody there. I would doubt that the Chinese government is rejecting the placement of an FDA representative in the embassy or consulate. I think I would look carefully at also resource constraints within the FDA as the possible reason..

HEARING COCHAIR HOUSTON: Right. It would certainly send a better signal, though, that those concerns are very strong over here.

My other question has to do with sort of the same thing. I know the Department of Energy has people coming over from China all the time, government-to-government. Do we have anyone coming over here from China, any delegations that go to the Consumer Product Safety Commission, that go to FDA, that are learning our system or at least learning our controls and our dissemination of information?

Because the minute the train has the lead paint on it, the Consumer Product Safety Commission is putting out a blurb to alert people. We have recalls here. Clearly, that's very limited in China.

MR. THOMPSON: In 2003, a number of friends from the Ministry of Health came to Washington and I was invited to have a private dinner with them to discuss their visit. And I knew most of the folks there, and there was one particular gentleman that I had never met before, who didn't speak any English, and I asked, well, what is your responsibility within the Ministry?

And he says, "I'm responsible for food safety." And I asked, what he was doing on this visit? The rest of the officials are infectious disease experts--these are all bird flu and AIDS guys, which is where the real bilateral engagement has been traditionally. And he said, well, "I'm here to look at your FDA and find out how we can make ours better." I suggested don't only go to the FDA. Go to the National Food Processors Association (NFPA). And he says, yes, but we don't have any way to really apply what they're doing. We have no good way to engage with them and the answer is no, they're not on our agenda. And I think if you look at the Chinese government approach, they really don't have a non-governmental strategy in anything that they're doing.

We can talk about China in Africa, we can talk about regulatory issues in other sectors, such as environment, and we see the emergence of the concept of civil society, but it's not terribly developed and it's not an area the government particularly wants to expand. They have an association system, but the associations don't really represent the manufacturers or the consumers, they're more of a conduit for information between the party and the association's constituency, and that's true for all of the mass line organizations and GONGOS.

So it's an area where I think they have a pretty steep learning curve and it's one I think they really started learning fairly recently. As I mentioned in my written and oral statements, they suddenly are starting to understand, hey, you know, our system doesn't have checks and balances, and that's a problem because without those checks and balances, we have regulators run amuck, and we executed one to show you that we now get it.

Now, the trick is, how do you translate recent Chinese resolve to improve governance and quality into a more consistent effort and push it down the political chain to the local level. I'd also point out that there is resistance to accepting these systems of checks and balances, such as free media and civil society wholesale. The challenge will remain until they develop some sort of politically acceptable substitute within their system that can perform the role that they do in our system. Until they find a suitable and effective mechanism, they're going to face this challenge indefinitely.

HEARING COCHAIR HOUSTON: Dr. Gottlieb.

DR. GOTTLIEB: I can't speak to the bilateral relationship beyond just with the FDA and there's been contact between the FDA and Chinese regulators. A lot of it, though, has been focused around the desire of the Chinese regulators to try to learn more about our regulatory system to help try to promote some of the drug development in China.

Particularly, there were some discussions around Chinese traditional medicine, where there is lack of clarity around the regulatory process and how they would bring those drugs to the market here in the U.S., which is probably an unrealistic expectation. I just want to add one follow-up. As far as having an attaché in a foreign country, I'm pretty certain that FDA doesn't have a single person in any country. I don't think that we permanently post people in any country, nor do we have any offices or anything of that sort. To try to expand the scope of the agency to do that would require dramatically more resources.

We have very few resources for those kinds of bilateral types of relationships as it stands. So I'm not quite sure that that's something that could easily be accomplished given the agency's current structure.

HEARING COCHAIR HOUSTON: Thank you very much. I appreciate both of you being here with us. Thanks so very much.

Before we go, I would like to thank our trusty staff, particularly Erik Lundh for putting this great hearing together. Thanks very much, Erik.