Transcript of FDA Press Conference on China Partnerships

FTS-HHS FDA

Moderator: Cathy McDermott
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Coordinator: Welcome and thank you for standing by.

At this time all participants are in a listen only mode.

During the question and answer session, please press star 1 on your touch tone phone.

Today's conference is being recorded. If you have any objections you may disconnect at this time.

Now I will turn the meeting over to your FDA moderator, Miss Julie Zawisza.

Ma'am, you may begin.

Julie Zawisza: Thank you, (Glenny).

Ladies and gentlemen, good morning. I'm Julie Zawisza, the Assistant Commissioner for Public Affairs. And I'd like to welcome you to this briefing.

We're very pleased that you could join us this morning. And today you're going to hear from the FDA Commissioner for Food and Drugs, Andrew von Eschenbach.

He'll be speaking on his meeting with the Chinese Minister of Health, Minister Chen. And you'll also be hearing from Dr. Murray Lumpkin, FDA's Deputy Commissioner for International and Special Programs.

Both of our speakers today are actually in China and have just concluded a series of meetings with the Chinese authorities. And so we'll hear from then and then we'll take your questions during a brief question and answer format.

At this time I'd like to turn it over to Dr. von Eschenbach.

Andrew von Eschenbach: Good evening. Or I should say good morning and hello from Shanghai. I want to thank you all for joining us on this conference call. I know you're all very interested about FDA's efforts to assure the quality and safety of the food and drug and medical devices that we import and regulate.

I wanted to take the opportunity to give you a first hand report on my visit over the past few days here in China. As you all are aware next to Canada and Mexico, China is the largest exporter of goods to the United States. And we have from a very historical perspective recently been concerned about safety of imported products.

One of the lessons I think we learned from the melamine experience is that we could not simply continue to depend on expanding or increasing in numbers our old system of inspections and be able to keep pace with the radical changes that were occurring in the world around us.

And so because of the fact that the world had changed we needed to begin to reassess and rethink our strategy for continuing to ensure the quality and safety of the drugs and medical devices and the food that we were importing.

And then we also realized that we couldn't do that in a vacuum but needed to be strategically thinking about the future in context of our partnerships, both our partnerships within the United States, within the government, with other agencies like USDA and Homeland Security and others as well as relationships with the private sector. And we also needed to be doing that not just domestically but also with regard to our partners abroad.

We've been continuously working on this effort and have developed our food protection plan that is in the process of being finalized for dissemination. And as you're well aware in the context and process of doing that we became involved and have been playing a very major role in the development of the President's Commission for Import Safety.

One of the processes that had resulted from that effort was early on Secretary Levitt and I began to have meetings with the officials of the Chinese government.

Began to look at opportunities and ways in which we could collaborate and cooperate to address the quality and safety of our imports. And a great deal has been done up to this point in time and a deal of work is continuing to be in progress.

Most importantly, very recently teams of people from the US FDA have been here in China, in Beijing, meeting with our respective counterparts in safe food and drug administration and also with their AQSIQ, which is their agency that is responsible for exports.

That is being done and the context of the development of memoranda of agreement that will forge a formal relationship between our two governments

and setting a foundation in place where we will begin to continuously address opportunities to continue improve the safety and the quality of the products that are being imported and exported.

My visit here in Shanghai has a number of facets to it. One of which is I've been engaged in direct interactions with the Minister of Health of China, Minister Chen Zhu, who has just celebrated his first 100 days as the Minister of Health in China.

And I would point out to you that he is a physician and a scientist as well. He's been very deeply immersed in both the development of biomedical research and biotechnologies and the importance of science and technology but doing it from the perspective of how that can applied to public health. And he's deeply engaged in these issues of public health and improving healthcare for the citizens of China and also of the world.

In addition to my interactions with him, we've had direct conversations and conferences with Deputy Commissioner of the State Food and Drug Administration, Commissioner (Chu). And today I met with the Vice Minister of AQSIQ and tomorrow I will be meeting with Commissioner of the Chinese State Food and Administration.

These discussions have been extremely fruitful and rewarding on a number of fronts. One, there has been a clear opportunity for us to establish a dialog and a rapport with our counterparts and really solidify a commitment to collaboration and partnership.

It is clear to us in our conversations, both Deputy Commissioner Lumpkin and myself, that the Chinese government is committed to the same issues that we are.

They recognize, for example in our conversation today, that food safety is one of their top priorities and it is a major focus for them as it relates to public health. And they are as concerned about confidence in the quality and safety of food and drugs as we are in the United States.

Their systems are relatively new compared to ours. And yet at the same time they have made an enormous amount of progress as it relates to their development of infrastructure. But they are anxious to work collaboratively with us and to share and exchange knowledge and information.

So we have committed to continuing the effort to finalize the memoranda of agreement both with AQSIQ and with SFDA. Both of those Chinese agencies will have a contingent of people coming to the United States to Washington to meet with members of the Food and Drug Administration later this month to finalize many of the details that are going to be completed on those memoranda.

And we expect that they will be finalized and ready for signatures to occur in December when Secretary Levitt comes to Beijing for the next session of the strategic economic dialog.

We are looking at those memoranda as a foundation, a foundation upon which to build an ongoing relationship around product safety of food and drugs and devices.

We are looking at opportunities to collaborate in helping to build capacity to develop systems for information sharing and to be able to create opportunities to really learn and understand from each other in our approaches to the importance of assuring the quality of these products.

One of the very interesting aspects of this trip for me, in addition to the intensive meetings and discussions, was I had the opportunity this afternoon to visit the Port of Shanghai. Shanghai's port by tonnage is the busiest and most active in the world.

And like I had the opportunity with Secretary Levitt to visit ports in the United States and look at our processes and mechanisms for identification of products, inspections, etcetera. We had the same opportunity to do that here in Shanghai and witness the - their import inspection process.

It happened to be that they were particularly evaluating a shipment of Tyson's chicken legs, which were being imported from the United States into China for consumption here.

And so it's been a very important and very interesting opportunity for us. And I wanted to share that with you because I know you have been concerned and interested in what our progress has been like.

And I recognize that we have a process that's in place and we're looking forward to completing that process as rapidly and as efficiently as possible. Most certainly want to do that in a thoughtful and deliberative way and these kinds of interactions and opportunities I think were an important part of that.

I'm going to turn the conversation over to Deputy Commissioner Lumpkin to add a few specific points. And then we're going to look forward to taking your questions.

Murray Lumpkin: Thank you, Commissioner.

I think the Commissioner has outlined very well today the things that we've been doing the last several days here in Shanghai. And I think as he mentioned, I just to reiterate that our preference is obviously not to have to catch problems in the products for which US FDA's responsible at our borders but rather to prevent them at the source of their manufacturer.

And I think we as all of you there realize that in this new 21st century the reality of the market place is that many if not most of the products that we over see are now international commodities and they're source is often a place outside the United States.

So that's really why we have come here and why so many of our colleagues at HHF and at US FDA have been working so hard over the last several months to figure out how to develop best practices with our counterpart agencies here in China and with many other parts of the world. Because I think what we're trying to figure out is how we can best leverage their knowledge of their own country, of their own manufacturing, of their own transport sources and of their own resources to do inspections and to assure compliance with certain standards.

And they likewise are very interested in how they can work with us, learn from our experience, learn from what we do and our knowledge and how they can leverage our resources.

I think they're very interested, as the Commissioner had said, in knowing for sure that the products that they import, the products that they manufacture are indeed safe, good products for their people.

And I know we as Americans are all interested in knowing for sure that no matter where the products we purchase in the United States actually originated

they indeed are going to do the job they say they're going to do and that they indeed are safe.

And that really is the mission why we've been over here, why our counterparts have been over here and what we hope these memoranda will help us do into the future.

Thanks.

And, Julie, I think we'll turn it back over to you now.

Julie Zawisza: Dr. Lumpkin, thank you and thank you, Mr. Commissioner for those remarks.

Operator, let's go ahead and open the lines.

Ladies and gentlemen, we have a large number of people on the phone today, all or whom or many of whom would like to ask a question. So please limit yourself to one question. And if you must have a follow up it needs to be very quick. Okay?

Thanks a lot. Let's open it up.

Coordinator: Thank you.

At this time if you would like to ask a question, please press star 1.

Please record your first and last name when prompted. To withdraw your request, press star 2.

Once again, to ask a question, please press star 1.

One moment please, for your first question.

Your first question comes from Richardo Alonso-Zaldivar of LA Times.

You may ask your question.

Richardo Alonso-Zaldivar: Good evening and thanks for taking my question.

There was a hearing at - of the House Energy and Commerce Committee yesterday where they looked at Hong Kong and Japan as possible models for the US in dealing with China and particularly Japan.

And I gather that a couple of the elements of their system is that - are that they deal with a fixed list of suppliers in China and also that they inspect a great deal more than we do. Are you looking at those elements going forward for the USA?

Andrew von Eschenbach: Yeah, that's a very important part of what I believe our discussions and our strategic thought processes have to encompass. Where are their own (unintelligible) in place that we can either emulate or there may be parts or pieces of those systems that would be appropriate to adapt.

We don't simple want to adapt someone else's system. We want to work collaboratively with our partners and define a system that's going to be appropriate to the United States. And obviously that's going to take in to account a number of variables.

Some of those systems that are in place would be appropriate for us to incorporate, some others may not. But we want to tailor those according to what our strategy is.

We're looking at this across the continuum of prevention, intervention and response. The intervention piece, the inspection piece is just one part of that strategy.

We not only want to increase the number of inspections but we want to also focus those inspections more appropriately by having better tools to predict risk and to target where those inspections should be.

We also want to enhance the technologies that we're using in those inspections. For example, product identification to our (unintelligible) or using technology that will allow us to do analysis, laboratory like analysis onsite rather than have to send specimens back to reference laboratories.

So all of those parts and pieces have to be considered rather than just simply adopting someone else's mechanism like Hong Kong or Japan.

Richardo Alonso-Zaldivar: Thank you.

Julie Zawisza: Next question, please.

Coordinator: Your next question comes from Brian Hartman of ABC News.

You may ask your question.

Brian Hartman: Hi.

Also on the congressional findings over there, they seem to come back - the investigators come from China with, you know, being very troubled, saying that they were alarmed by what they found over there.

And were they looking at the same things that you were and they're just seeing a glass half full and you're seeing it from another perspective? Or did you find things there that were troubling? Are you briefed on the House investigators findings?

Andrew von Eschenbach: We've been briefed on the House investigators finds. I can not specifically say that we visited the same sites or places that they did or spoke to the same people that they did on this particular trip.

As I indicated, however, I want to point out the fact that we had multiple people from the US Food and Drug Administration visiting China, engaging in conversations and discussions.

Just earlier in the week we had members of the US FDA that were here with other government representatives that were actually engaged in onsite activities at the port here in Shanghai.

So we - I've been dealing primarily at the level of Ministers as opposed to going around and doing a lot of the grass roots inspections. So I can't say I looked at the same things they've looked at.

I think what the real point of the conversation is that we recognize that both in the United States and here in China is the fact that the world is radically changing around us, the fact that our systems are different presents a unique and different challenge.

China's trying to address some of those challenges internally as they look at the number of producers that they have in agriculture. And we're looking at the problem as it relates to how we can put better systems in place.

We're working collaboratively with them at the outset. We can make sure that we're building quality in at the outset and preventing some of the kind of problems from occurring rather than just depending on inspections to inspect the problems that we'd rather build quality in.

So I don't know that it's seeing the glass half full or half empty. I think we see both the challenges but also the opportunities and I tend to want to focus on how we can seize upon those opportunities and essentially by doing so we'll eliminate the challenges.

Julie Zawisza: Let's go to the next question.

I just want to remind everyone that this availability is for credential media. We have other folks listening but I would ask that the questions come just from credentialed media. Thank you.

Coordinator: You're next question comes from Jennifer Corbett of Dow Jones.

You may ask your question.

Jennifer Corbett: Yeah, hi.

I just had a question. You mentioned a memorandum of understanding that you hope to finalize.

Andrew von Eschenbach: Memorandum of agreement. I'm sorry, memorandum of agreement. An M...

Jennifer Corbett: And…

Andrew von Eschenbach: …OA.

Jennifer Corbett: And what would that do? Would that give USA the power to inspect China or…

Andrew von Eschenbach: Well, the memorandum of agreement has a number of articles in it in which these bilateral discussions have been ongoing and looking at ways that we could create opportunities and initiatives to work together collaboratively that would enable us to begin to assure and ascertain that we were creating systems that we're going to accomplish what we are intending and expecting, namely the assurance of the quality and the safety of the products that are being imported.

Now I'll let Mac Lumpkin to some of the specifics of how those memoranda of agreements are being developed and what they're focusing on.

Murray Lumpkin: Thank you.

I - in developing these memoranda of agreement I think what we're trying to do here is to come to agreement with our Chinese colleagues both at the State Food and Drug Administration and at AQSIQ on how we can work best together to help assure, from our perspective, that the products that we import in the foods world and feed world and the medical products world are indeed products that reached the standards that we and American people want.

We've tried to this by looking at the information that needs to be shared, how that information can best be shared, how we can help each other build capacity in areas where we think the other has capacity that we could use and would be of assistance to us in assuring the quality of these products.

We're also trying to look from a risk based perspective at those products that we know historically have been most troubling and how we can focus and leverage the resources that exist here and those that exist at our borders to best address some of those problems.

The details are what we are still negotiating at this point in time. As the Commissioner said, one of the outcomes of our meetings over here in the past few days is that we got agreement on when the next series of negotiations that we hope will be the final ones that will dot all of the "i's" and cross all of the "t's". Those will be taking place in Washington.

All the previous discussions have taken place here for the most part in China. There have been some negotiations in Washington but most of them have been here.

And the next round will indeed be in Washington. And hopefully as we're coming in to early December the Secretary will have the final document to announce when he is here in, well, here in China, but in Beijing in the early part of December.

But those are the basic areas that we're focusing on. Information sharing, capacity building, technical assistance and focusing on leveraging the information and resources that we have on a risk based approach to the products that have given us the most problems in the past.

Julie Zawisza: Thank you.

Let's go to the next question.

Coordinator: Your next question comes from Luis Sanchez of Associated Press.

You may ask your question.

Sir, your line is open at this time. Please check your mute button.

Julie Zawisza: Let's go to the next caller.

Coordinator: Your next question comes from (Frank Boteta) of Washington Post.

You may ask your question.

Rick Weiss: Hello. Can you hear me?

Julie Zawisza: Yes we can hear you now. Thank you.

Rick Weiss: Oh, okay. You've got it wrong. This is Rick Weiss at the Washington Post.

Julie Zawisza: Sorry about that, Rick.

Rick Weiss: Okay.

Julie Zawisza: Extensively.

Rick Weiss: I was wondering who (Frank) was.

Two thin- I mean one I have to say that I still have basically no idea what is going to be in these memoranda. They tell us things like they're trying to create opportunities and initiatives to work together collaboratively, to entertain systems to accomplish what we are expecting doesn't really have anything in it that I can tell my readers about what's going to happen here. So I'd love to get more details from you.

But perhaps as a separate question, I'm wondering how, if at all, you're working with USDA because to the extent that we're talking about meat - am I right - imports of meat that could come from China; am I right that that would be USDA's jurisdiction? Because I'm wondering specifically whether these talks have dealt at all with China's ongoing interest in exporting chicken to us?

Andrew von Eschenbach: No, they have not dealt with that. And you're correct, Rick, that that would be a USDA issue.

Let me come back to your first point. I respect the fact that you're anxious to know the details and we're anxious to share those details with you. What we want to share with you right now and make you aware is that we have been working actively, aggressively and intensively to define those details, to work through an understanding and agreement with our counterparts here in China to create a system where we believe we can reach beyond our borders and work actively and proactively to be able to assure the quality of those products before they even come to our borders.

And we expect this progress in defining the details is going to continue over the next few weeks. And then when that memorandum of agreement is finalized and signed then the specific details I'm going to very anxious to share with you.

But in the mean time all I hope to share with you is so that you don't think we're not actively addressing this issue, is to share with you the things we are doing to try to really address the issue directly.

Julie Zawisza: Thank you, Mr. Commissioner.

Next question.

Coordinator: Your last question comes from Justin Blum of Bloomberg News.

You may ask your question.

Julie Zawisza: I guess you are our last caller, Justin.

Justin, are you still there?

Coordinator: Justin, please check your mute button. Thank you.

Julie Zawisza: Do we have anyone else that's waiting in the queue?

Okay. Then at this time I'd like to ask the Commissioner if he would like to make some closing remarks before we close this up?

Andrew von Eschenbach: Well, just that I think I'd to pick on Rick Weiss' important question.

There are many important details that we are in the process of defining. And I think it's important to realize that we're engaged in a process. And this is a process that we're intending to be very deliberative, very thoughtful, very

strategic, but also very aggressive with regard to our effort and to our time table.

We respect and appreciate the urgency of this issue. But I'm enough of a surgeon to recognize that it's important to do surgery efficiently and rapidly but it's even more important that you do it correctly. We're working very aggressively to do this both rapidly, efficiently and correctly.

And I want to continue to keep you all aware of the effort and the progress that we're engaged in and I really appreciate you taking the time and trouble to get on the phone and listen to a little bit about what we've been doing here in China. And I want thank you for that.

Julie Zawisza: I'd like to thank Dr. von Eschenbach and Dr. Lumpkin for joining us from China. I know it's late there.

And I'd like to thank all you.

Ladies and gentlemen this concludes our media availability this morning or this evening depending on where you are.

And if you would like to listen to the replay, we'll have that available for this call in about an hour. And we should've sent out a press release by now and we haven't it will be going momentarily.

We also will be havin- will have a transcript of the call available in about 48 hours so you can download that and also some nice photos of the Commissioner's trip are on our Web site. Last thing is we have an audio file. You also should be able download that for your use.

And if you have any follow up questions please call the press office at 301-827-6242.

That's it for today. And I'd like to wish you all a very pleasant day.

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