

faced with the reality of not being able to put the manufacturer's code in?

MR. : What can the FDA do?

MS. : The answer back has to be in rewriting the rule or confirming that the rule is the way we want it now.

[Simultaneous discussion off microphone.]

MS. : Right. So we've told you what happens in three weeks. But we have also told you that there is enforcement discretion for a period of time, right, and that does -- one thing that enforcement discretion period gives you is also a way of proposing in comments an actual change that's workable within the auspices now of not just one rule, but both rules.

MR. : But you're going to reject it if it doesn't have the code in it.

MS. : Right.

MR. : We're never going to get the entry through if you don't have the 11-digit code, and if it's not in there because you don't have it, then we can't even file a prior notice

properly. So you're not even going to respond to it.

MR. : And I'm sure there's lots of cargo under those conditions coming in right now on the way into the United States. So that's going to create chaos. Even if you put the supplier's facility registration -- let's say it's coming from Panama, for example, if you register their facility, if you use their registration, you still couldn't get it through without the manufacturer's identification, registration number?

MS. : They haven't manufactured the product, have they?

MR. : No.

MS. : No, so the one thing we do want to make clear is that we don't want you to give us somebody as a manufacturer who isn't the manufacturer.

MR. : No, no, that's not what I'm suggesting. I'm suggesting -- you're saying that we need to declare the registration of the manufacturer, and the facility that's shipping it,

because they're holding those goods over there. They've probably held them for months. Now they shipping it, so don't they have to be registered, too?

MS. : The shipper, yes.

MR. : Yes. So even if we use their registration, which we will know, we can get it through without a manufacturer's registration; is that what you're saying?

MS. : No. You have to give us both the manufacturer and the shipper. The actual manufacturer and the registration number, the actual shipper and their registration number if they have held the food.

What we have tried to explain through the process of enforcement discretion is that there will be a period of time where we may not refuse because of that. Okay? And that is also going to coincide with the time you get to make comments.

I'm just -- we can't comment on comments, for one thing. You know, you give us your comments and we deal with them. But you should go back and

not only look at the preamble to the proposed rule, but also look at the comments that came in on the proposed rule, and see how we dealt with those comments about disclosure of the registration number. Okay?

MR. : Okay. My last question is that is there any training being offered by the FDA right now and how do we access to that?

MS. : Training?

MR. : Training about these new regulations.

MS. : This would be at --  
you're at it.

MR. : This would be it?

[Laughter.]

MS. : Yes.

MR. : You're certified.

[Laughter.]

MS. : I don't know if there will be additional -- I mean we're doing a series and we're finished tomorrow with a series of regional outreach about prior notice and

registration. I don't know about Customs and FDA about some of the operational issues or the system issues.

MR. : There will be help desks.

MS. : And then we'll -- there will be help desks. I think we are doing like some trade associations, and we plan -- you know, part of the educational period that we're doing in that four months is we plan additional outreach. I just don't know if it will be a series of meetings like that, or the district personnel will take over and do it. If they come to these, they won't, right? You're going to say no, I'm not doing this.

MR. : Even through the Internet, sending e-mails about questions?

MS. : Right. That last e-mail address that I put up, that's where you can send questions, not comments about the rule, but questions for clarification. And that's going to be up for quite a while.

And now the guy behind you is going to knock you over. Well, no, he isn't.

MR. : Hi. My name is Ray and I work for a software provider, Editrade (phon.). I got just two pretty simple quick questions.

First one might be directed maybe better to an ABI rep. Just let me know. The case that they have mentioned a lot here is if it comes in to say Miami and gets in-bonded to Atlanta, Chicago, whatever, in Miami when you submit the prior notice, you would submit all the FDA information, the FDA product codes, et cetera. Will it be possible through ABI for say the broker in Atlanta to not have to do the FDA product codes, just merely put in the FDA confirmation number and that's it? Because FDA wouldn't really care anymore once it's cleared in Miami, right?

MS. : You're talking about after we've received prior notice?

MR. : Yeah, because part of the prior notice would be the normal stuff that you'd get, anyway. So basically through ABI the person in Atlanta just would put in the confirmation number and that's it, wouldn't have to put in their

product codes and --

MR. : Right. That way the system knows that it isn't looking for another prior notice.

MR. : Okay. Okay. Good.

And then one last question. Are there any exceptions to things that are required by FDA that you wouldn't need prior notice, you might need to submit to FDA, but you wouldn't need prior notice, or is everything that requires FDA --

MS. : Food, foods for humans and other animals, except for dinner -- you know, food contact substances like packaging and dinnerware and pesticides.

MR. : Oh, those would be the ones that --

MS. : Those are the exceptions to foods for humans or other animals, and then just things that are included in the -- that are excluded because they don't fall within the scope of prior notice, or the fruit, you know, Antilles fruitcake, if you carry something on. But there

are many, many things that are covered by prior notice that you may not traditionally think of.

MR. : Okay. But something like silverware, you would still need to submit FDA information?

MS. : Very good, yes.

MR. : But not prior notice?

MS. : It's still a food under the Food, Drug & Cosmetic Act, it's still subject to admissibility decisions. But you don't have to tell us about it ahead of time.

MR. : Okay. Okay.

MR. : You don't have to register; correct?

MS. : Right. You don't have to -- if you are --

MR. : If you stored silverware, you would not have to register?

MS. : No.

MR. : Because it doesn't come under the act?

MS. : Right.

MR. : That was it. Thanks.

MR. : It's me again.

MS. : Oh, you.

[Laughter.]

MR. : One, I think you guys are doing a great job. And I want to say thank you.

Two, is it possible to get a copy of your executive summary, because it would make my job --

MS. : Slides?

MR. : Yes, slides. Showing it to my boss, it would save me having to rewrite all this, and I could just use my notes.

MS. : Oh, no, you don't want to do that. Go into the Web site, [cfsan.fda.gov](http://cfsan.fda.gov).

MR. : Okay.

MS. : Go into Bioterrorism Act. Go look at the October 28th satellite downlink and it has two subsections. One is registration --

MR. : I went to that and I have that.

MS. : Then do you have the slides?

MR. : I have the slides because  
I went to the --

MS. : Right. Those are the  
only slides that we can hand out.

MR. : Okay.

MS. : Lawyers like their own  
slides.

MR. : I understand.

You were going to talk about samples. Is  
there anything special on samples?

MS. : I was hoping no one would  
ask after we went the U.S. goods returned.

MR. : No. Well, I just want to  
ask about samples.

MS. : Yeah, they're covered.

MR. : They're covered?

MS. : Yeah. Samples -- there  
are samples that are covered, are covered by prior  
notice. Samples of foods for humans or other  
animals. But the preamble discusses that there are  
samples and there are samples. So if it's a sample  
that is meant for analytical testing and in its

downlink, you can see it in the privacy of your own room. Why you would want to do it, I don't know, but --

[Laughter.]

MS. : But it's there, and then the fact sheets are there, and then these brochures that should be coming out are all there. And I think those have been translated into Spanish.

MR. : Good afternoon.

MS. : Hello.

MR. : My name is Larry Reid.  
I'm from Howard Reader.

MS. : And you're still here.

MR. : And I'm a custom broker.

MS. : I know.

MR. : I thought I was the guy you were looking for, the last one in line, but I see somebody else.

MS. : No, somebody came behind you.

MR. : It's nice to have you back here, Mary.

form it could not be eaten, then, you know, it would be like a sliver of celery or something that was coming in for a pesticide analysis, things like that, then, no, it's outside of the scope. But -- because it's not a food.

But if it's a sample like sales samples or any of that kind of stuff, it is covered by prior notice.

MR. : Now could you just give that Web site again?

MS. : Yeah, it's cfsan -- that's Center for Food Safety and Applied Nutrition, .fda.gov.

MR. : And then where do you go from there?

MS. : You look for Bioterrorism Act. It should be like in the center column. And then when you are in Bioterrorism Act, it's pretty self-explanatory. You look for the satellite downlink of October 28th, and they'll have the slides and I don't know if it's up yet, but we also plan to have a video stream. So if you miss the

downlink, you can see it in the privacy of your own room. Why you would want to do it, I don't know, but --

[Laughter.]

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MS. : No, somebody came behind you.

MR. : It's nice to have you back here, Mary.

MS. : Thank you.

MR. : You add a lot of sparkle to a kind of a controversial subject.

MS. : Yeah, it's not dull, is it?

MR. : No.

MS. : No, not anymore.

MR. : Three simple questions.

The first one is when the Food & Drug designates a shipment for inspection because of the Bioterrorism Act, is that also going to be coordinated with Customs' homeland security effort, or are we -- is it possible that we're going to end up with an FDA inspection for bioterrorism, an x-ray inspection for that inspection, and then we have -- for homeland security, and then we have the SET team, drug enforcement team wanting to take a look at a shipment?

MR. : Part of our -- the FDA targeting is going to be in conjunction with our national targeting center, so if there's something that -- they're going to coordinate these things.

So that if it's a hit for bioterrorism, it would be a hit for our security purposes as well. So that the targeting centers would coordinate the activity to make sure we're not duplicating effort.

MR. : So then we should have one inspection for all three?

MR. : Yeah.

MR. : Okay. That doesn't happen now. We can end up with a --

MR. : That's part of our more closer working relationship that we're building right now towards.

MS. : You still may have a separate exam for admissibility determinations if it then hits --

MR. : Well, I understand that sampling and that sort of thing after the fact could be, but I'm just talking about the freight sitting at the dock and you don't have any idea what's going on, because basically we are in the dark when those processes are happening.

MS. : Right.

MR. : We just have to wait and see.

MS. : And you'll stay there.

MR. : So the answer really is, is that the likelihood is it probably could happen, because we have x-ray and drug enforcement inspections separate from each other now.

MS. : Right. Provided they are all coming out in the national targeting center, that's where we plan to be.

MR. : We can hope for one joint

--

MS. : Right.

MR. : Okay.

MR. : That's the intention.

MR. : I think this question may have been answered, but I would just like to clarify it. There are many possible registration facilities, or there are many facilities that need to be registered in a particular shipment, but they don't necessarily all have to be listed in the prior notice; is that right?

MS. : That's right, just the manufacturer and the shipper, if the shipper has a facility and if the food is destined for consumption here.

MR. : Okay. So we are talking two --

MS. : Two different things, right.

MR. : Okay. If we -- the last question. If we have an air shipment, for example, that we know about two days ahead of time that's coming in from Europe, and it's -- and we transmit it to Customs, will we receive back a prior notice number, prior to response from Customs? We know that Customs will not respond to us on the -- until the day of arrival or when wheels are up.

MR. : Right.

MR. : Are we going to be able to transmit prior to the arrival of this prior notice in the ABI system?

MR. : No, we're going to hold it until the appropriate window opens up, and then

we will -- I think the idea then is to send the information to FDA. So we're going to store it.

MR. : So actually we're not, on an air shipment, getting five prior days to send the information other than having it in the system?

MR. : No.

MS. : You can transmit it --

MR. : You can transmit it, but we won't act on it until that -- until the appropriate four-hour window opens up, or the wheels-up message.

MR. : So all our responses are going -- so we would get a response back for prior notice and for entry?

MR. : Right.

MR. : Two?

MR. : Uh-huh.

MR. : At the same time. Okay.

Thank you.

MR. : Uh-huh.

MS. : Okay, we've got about, I think, five minutes before -- Max has already

missed his plane. So before we have to get finished up. So --

MR. : Mike Sayres, LOC Brokers (phon.). We had been told that the submitter is liable to FDA for the accuracy of the information on the prior notice, but not the transmitter; is that correct?

MS. : Uh-huh.

MR. : And what is the violation if the information is not found to be correct, what is the course of the violation and the submitter?

MS. : Now we're looking at two different things. If the information is not correct, then the food is not covered by an adequate prior notice. Therefore, the food will be held or sent to secured storage until that is taken care of. Okay, so that's the consequences for the food.

Consequences for failure to provide adequate prior notice or failure to provide prior notice are prohibited acts covered by the statute, and that is a variety of civil or criminal actions

by the agency. That would be injunction, prosecution, primarily; or a new prohibited -- a new sanction, I guess, provided by the Bioterrorism Act, which is debarment.

MR. : Is that against the submitter?

MS. : Against the person who was responsible for submitting the information. So according to the registration, the submitter is any person who has the information. The transmitter is only the person who transmits that information on their behalf. And that -- if it's a broker, that gets back into Customs broker registrations and enforcement.

MR. : Okay. There was a few times you talked about the importer, owner, and ultimate consignee, as if they were one person. But how do you define, for example, the ultimate consignee?

MS. : I don't necessarily think they are one person. In the preamble to the statute, when we discuss importer, we refer to

Customs definition of importer of record. When we talk about ultimate consignee, that's ultimate consignee in the U.S., and again we refer to Customs -- if it's not a registration, it's a description of what the ultimate consignee is.

And the owner was provided to us by Congress in the statute. It's also in the Food, Drug & Cosmetic Act 801(a) section, and it always refers to owner, and no one has ever defined owner, so we decided not to, either.

So the owner could be the importer, they could be the consignee. If not, then you're supposed to tell us who the owner is. And by owner, we describe it in the preamble as a person who owns the product at the time you give us the prior notice.

MR. : So you don't need to know who the importer is selling to?

MS. : We need to know the importer, the owner, or the ultimate consignee. So if there are third -- you know, if there are fourth, fifth and sixth parties in there, for the

purpose of prior notice, no. I don't know about for the purpose for Customs. But Customs usually asks for the ultimate consignee as well.

MR. : Yes.

MS. : I don't know how many more firms there are, but there is a lot of them.

MR. : So if the importer resells it to five different people, you don't need to know who those five firms are?

MR. : Not once it clears after prior notice.

MS. : Yeah, not if that's -- that happens after prior notice.

MR. : Oh, okay. Good.

MR. : 801(a), cargo admissibility, it's the importer of record. Two different things.

MS. : Yes. And the ultimate consignee.

MR. : [Inaudible, speaking off microphone.]

MR. : Yes, it is.

MR. : Okay. So like in our industry, for our importers, because the order has to come through us? MR. : Right.

MR. : [Speaking off microphone.]

MS. : It is in the preamble.

MS. : [Speaking off microphone.] The importer of record has nothing to do with that transaction except they have sold their license. They don't own it, they don't touch it.

MS. : They don't have the bond that covers the duty?

MS. : Yes, they do.

MS. : Well, that would be the definition of importer of record that Customs has, pretty much.

MS. : The owner is actually ABC Company, and they are the ones that are responsible for the integrity of the shipment and the FDA registrations. So --

MS. : No, the importer of

record is pretty much the Customs description, that bond holder.

MS. : [Speaking off microphone.]

MS. : All three. The importer, the owner, and the ultimate consignee are all -- could all be the same firm, but if they are different firms, it's not either/or, it's and.

Are you still standing there?

MR. : Yeah, I sure am.

MS. : Okay. One more. Oh, you have one, too? Well, boot him.

MS. : Does the entry need to be in the Customs computer to be valid? Does it need to be transmitted to be used in the prior notice?

MR. : If it originates through our system, then it would come in with the entry transaction, then we would create the entry. But if you are using it through the prior notice system, through the FDA Web site, it doesn't have to be in our system yet.

MS. : So you want them to be

the same.

MR. : Just about the electronic filing, will we be able to electronically file a prior notice and then later electronically file a Customs entry?

MR. : I would think so. It would depend on the software system.

MR. : I mean in the ABI system.

MR. : It depends on how your software is set up. Everybody's software is set up differently.

MR. : But you don't need a Customs entry in order to accept the prior notice?

MR. : No.

MR. : Okay. All right. Thank you.

[Whereupon, the conference was concluded.]

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