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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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"WHAT YOU NEED TO KNOW TO ENSURE COMPLIANCE WITH
THE NEW FDA BIOTERRORISM ACT REGISTRATION AND PRIOR
NOTICE INTERIM FINAL RULES"

Thursday, April 1, 2004

Boston, Massachusetts

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1 P R O C E E D I N G S

2 MS. KOLAITIS: No one wants to be first?
3 Great. Come on up.

4 MS. KAZAM: My name is Pamela Kazam, and
5 I'm from Shaw Supermarkets.

6 We need to register our warehouses. We've
7 already done that. But is there ever a time in
8 which we can give that registration number out to
9 vendors? Because sometimes we get asked for our
10 registration numbers?

11 MR. CARSON: Yes. under the Bioterrorism
12 Act, FDA--it was stipulated that we must keep that
13 information confidential. But that registration
14 number is your property.

15 And we've heard from many people in the
16 industry who are sharing it with their suppliers,
17 and they are doing that to show that they have
18 complied with the rules, so that other suppliers
19 know that they're okay.

20 So, yes, you are free to share it, because
21 it is your property.

22 But just as Diane said, you only share the

1 registration number. That way your data base
2 information remains intact until you go in and
3 update it yourself.

4 MS. KAZAM: Okay. Thank you.

5 [Pause.]

6 MR. KATZ: Hi. David Katz, from C.H.
7 Powell. We deal with a lot of food brokers who
8 don't normally handle food, they just buy it and
9 ship it directly to the clients. But they do get
10 samples in, which come to their office. And they
11 hold them. They also send them to clients, so
12 they're distributing them. They even may consume
13 them in the normal course of testing these.

14 And the question always come up: should
15 they register?

16 MR. [PANELIST]: This has come up a number
17 of times.

18 FDA, in putting out the proposed rule,
19 estimated that there were 420,000 food facilities
20 worldwide; roughly 200,000 domestic, 200,000
21 international.

22 When we did that, we did not factor in

1 such enterprises as you've mentioned. Having said
2 that, we do know that certain trade associations
3 and others who have the same kind of functions that
4 you do on a relatively temporary basis they would
5 hold foods, just as samples and things. And they
6 have registered.

7 So, you're certainly welcome to register,
8 but the intent of the rule was certainly not to
9 cover your particular business activities.

10 Did that answer your question?

11 MR. KATZ: [Off mike.] I guess they feel
12 they're not compliant, only because they do hold
13 food, and do distribute it.

14 MR. [PANELIST]: Well, if you fall under
15 the scope--just as I showed you--the definition of
16 packing or holding a food, then you must comply.
17 But, generally speaking, we're looking at--in the
18 packing and holding foods, warehouses, silos, large
19 tank facilities and the like, and that's what our
20 main focus was.

21 So, certainly, on the fringes there are
22 holders of food. I mean, we in the FDA building--

1 we have vending machines in our facilities. We
2 have not registered. So--

3 [Pause.]

4 MS. : Hi, I'm Diane from
5 [inaudible] International. I have a related
6 question.

7 We are importers. We're not brokers. We
8 import food and own it. And we store it at a
9 public cold-storage facility.

10 We did register, because last fall I went
11 to a similar event and I was told "when in doubt,
12 you should register." So what I did is that I
13 registered and for the facility address I have my
14 company, c/o the name of the food facility and the
15 address. And the information comes to me.

16 And I feel like it was necessary for us to
17 comply, because we own the product, and with
18 registration, I'm telling you who I am; that I own
19 the food, and where I have it.

20 Is that reasonable?

21 MR. [PANELIST]: Partially.

22 [Laughter.]

1 Thank you for complying. But, again, you
2 do not own a food facility. You are using a
3 warehouse, and you are holding your product in that
4 warehouse. So it's the owner/operator/agent in
5 charge of that warehouse that needed to register.

6 Now, in one way, you've done that on their
7 behalf, but the information that you've supplied in
8 the registration should be the location of that
9 warehouse--oh, okay.

10 VOICE: [Off mike.] [inaudible]

11 MR. [PANELIST]: Okay. Fine. When you
12 said, "care of," I wasn't sure if you put that in
13 as the location of the facility.

14 Then that is accurate. Thank you. Yes,
15 absolutely.

16 [Pause.]

17 MR. SPADE: My name is Philip Spade. Do
18 pharmaceuticals need to register?

19 MR. [PANELIST]: This is a food facility
20 registration, so if the pharmaceutical is also
21 considered a food--such as when there is
22 over-the-counter products, sometimes they're

1 considered not really a pharmaceutical, but an
2 over-the-counter drug--but only if it's a food, and
3 only a type of food that I mentioned.

4 So, sometimes dietary supplements and
5 dietary ingredients might fall into two different
6 categories.

7 MR. SPADE: But generally
8 drugs--pharmaceutical drugs--

9 MR. [PANELIST]: No. There is a separate
10 drug registration requirement that's separate and
11 apart from this.

12 MR. SPADE: Okay. And one other question:
13 do the U.S. agents need to register separately from
14 the foreign facility? Or can they register
15 separately from the foreign facility?

16 MR. [PANELIST]: No, the U.S. agent is
17 part of the required information in registering a
18 facility. There is no separate record or mechanism
19 for an agent to register on their own behalf,
20 separate and apart from a food facility.

21 So whoever is submitting the information
22 on behalf of that facility must either include the

1 U.S. agent in that, or it's the U.S. agent who's
2 submitting the information, and they must include
3 it in that registration submission.

4 MR. [PANELIST]: I think the only
5 exception would be if the U.S. agent has another
6 legitimate operation that would require them to
7 register.

8 So if you had a warehouse here, and you
9 were registering as the agent for your foreign
10 supplier, then you would have to register because
11 of the warehouse, not because you're a U.S. agent.

12 MR. SPADE: I see.

13 MR. [PANELIST]: But if you're strictly in
14 the business of being an agent, you do not have to
15 register.

16 MR. [PANELIST]: He's making the
17 distinction between--if you said "U.S. agent,"
18 that's one required piece of information in
19 registration. But we also use the term "agent,"
20 when we said "owner, operator, or agent in charge"
21 of a facility.

22 So, Mike's point had to do with "agent in

1 charge" versus "U.S. agent"--two different terms.

2 MR. SPADE: Understood. Thank you.

3 MR. SILVER: Hi. I'm Mike Silver, from
4 [inaudible]. I have a couple quick questions.

5 If the company has gone out of business,
6 for instance a winery, from overseas. How would
7 you handle--or your don't handle it, maybe.

8 MR. [PANELIST]: Well, we are certainly
9 hoping for the help of friends to make this data
10 base as accurate as possible. Obviously, as places
11 of business go out of business, we are asking--but
12 obviously would have very little ability to
13 require--that they cancel their registration. So
14 we're going to have to try and keep our data base
15 up and accurate as possible.

16 one way that we're done that--and as
17 you've seen with Diane--if someone else buys that
18 facility, then we ask them to let us know if
19 someone previously owned that facility so that we
20 can go in and clean up the data base if that first
21 operator hadn't cancelled.

22 But the second way--since the lady that

1 asked the question that had to do with the foreign
2 facility--the second role that we will be talking
3 about is if products from that food facility are
4 trying to come into this country, one of the
5 required pieces of information for prior notice is
6 the registration number of the facility from which
7 that food was produced. So we would require some
8 reconciliation of that registration information as
9 part of importing that food into the country.

10 MR. SILVER: Well, I guess my point is
11 that if you have an old bottle of wine, old bottle
12 of scotch--you know, someone bringing in their wine
13 cellar--

14 MR. [PANELIST]: That's a different
15 question.

16 MR. SILVER: Okay. I should have been
17 clear.

18 MR. [PANELIST]: We've had many questions
19 about auction houses--and, as you know, in the wine
20 and liquor industry, there is--many hands handling
21 things. Things do not necessary come directly from
22 the production facility to the United States. They

1 go through Negociance, they go through other means.

2 We haven't got a good answer for that yet.

3 We do know that wine is sold to many people, and
4 they keep it for two years and then they decide
5 it's still good, they're going to ship it to the
6 United States for sale. They do not have the
7 registration number from the facility that it was
8 produced, or it was re-labeled or whatever. We're
9 still working on that with the wine and beverage
10 industry on how best to deal with that.

11 It also has come in with U.S. returned
12 goods; goods produced in the United States, shipped
13 abroad have come back with salvages, or
14 consolidators to re-sell into the United States.
15 They don't have access to the registration numbers
16 either. How do they supply that information?

17 We are still--and you'll see, we're
18 working with those industries now to see what is
19 the best solution to that. But I don't have an
20 answer for you right now.

21 MR. SILVER: The other question I had is
22 on chemical additives. If a food broker is buying

1 a chemical additive some of it may go into a food,
2 it may not. They're selling it to, maybe, a
3 facility that it may go into soap, it may go into
4 chewing gum.

5 MR. [PANELIST]: Yes, we've had that
6 question in the past. And if you know that your
7 product can be used as a food product, then we ask
8 you to register it.

9 We've certainly come up with that in the
10 harmonized tariff codes that we have issued,
11 especially for foreign facilities who produce many
12 different ingredients that are shipped to the
13 United States for further processing. We've tried
14 to capture all of those that would be used as food
15 ingredients. So it is important for them to
16 register--if their product may be used--

17 MR. SILVER: Possibly used--okay.

18 MR. [PANELIST]: Yes.

19 MR. SILVER: Okay. Great.

20 [Pause.]

21 MR. [PANELIST]: This kind of goes into
22 prior notice, but what would happen there, to is if

1 the end customer was like a drug manufacturer, it
2 wouldn't even go through prior notice necessarily
3 in that case. It's depending on the product--you
4 know, the end use.

5 MR. O'NEIL: Hi. Steve O'Neil. You
6 mentioned just a few minutes ago about nutritional
7 supplements. My understanding is that they're
8 considered a food, so ingredients would fall under.
9 That is the case?

10 MR. [PANELIST]: Yes, they are considered
11 food. The point the gentleman raised was about
12 pharmaceuticals, and I was trying to dance around
13 whether a pharmaceutical was a food or not a food.

14 But certainly, if it's a nutritional
15 supplement or a nutritional ingredient, that is a
16 food.

17 MR. O'NEIL: Okay.

18 MR. [PANELIST]: And it is covered by the
19 scope of this rule.

20 MR. KENNEDY: Good morning. Bob Kennedy,
21 from FedEx Trade Networks.

22 One question, if you could put it on hold

1 for the section portion, to follow up on the
2 gentleman's question about what would you use for
3 the registration on the liquor in that case that he
4 brought up--you know, what do we show if we do
5 bring in liquor that's several years old, and we
6 don't know the manufacturer.

7 So, again, that question goes toward your
8 second--on the pre filing.

9 MR. [PANELIST]: Well, they're not going
10 to have an answer, like I didn't have an answer.

11 MR. KENNEDY: Okay.

12 [Laughter.]

13 MR. [PANELIST]: So we'll hold it for
14 longer than the second session.

15 MR. KENNEDY: So we just leave it blank
16 and bring it in.

17 MR. [PANELIST]: We will--we're going to
18 update--we're dealing with that question. I just
19 said that we're still trying to come up with a
20 solution. We haven't found a solution yet.

21 MR. KENNEDY: I'm just concerned that when
22 we do the pre-filing, we won't have anything to put

1 in there. So I'm assuming you're going to just
2 release it.

3 Just a question on--we had a previous FDA
4 meeting prior to December 12th. We were
5 instructed, or led to believe, that each
6 manufacturer--each foreign manufacturer--when
7 there's subsequent manufacturing process, had to be
8 registered up to and including the port authority.
9 But today it seems you're clarifying that it's only
10 the final manufacturer. Is that correct?

11 MR. [PANELIST]: That is correct.

12 MR. KENNEDY: Thank you.

13 [Pause.]

14 MS. ALVATELL: Hi, I'm Susan Alvatell with
15 Hasbro.

16 We had an incident where we were trying to
17 do a prior notice--I know that prior notice is
18 going to be--but we have a guy in our quality
19 department that registered Hasbro.

20 We went into the system, under his ID and
21 password, and it was changed. And, unfortunately,
22 he was out for the day and through the weekend and

1 the following Monday. So we couldn't get into the
2 system.

3 Is it possible that maybe more than one
4 person can register?

5 MR. [PANELIST]: Yes--not more than one
6 "person" can register, but Diane showed you
7 accounts. The company can have an enterprise
8 account, and then you can have sub-accounts, with
9 more than one person having access or authority to
10 use that information.

11 So, obviously, however you want to conduct
12 your business, you could either have in a secure
13 location the registration number for your facility,
14 or you can have other employees, or a senior
15 official, have access to that system. And you can
16 set that up yourself.

17 MS. ALVATELL: Okay. And as the password
18 changes, everybody that's within that--

19 MR. [PANELIST]: No.

20 MS. ALVATELL: Who would be notified of
21 the--in other words, if someone from our facility
22 updated the password, and they never notified us,

1 how could we get back on to the system?

2 MR. [PANELIST]: They would only update
3 the password for their sub-account.

4 MS. ALVATELL: For their sub-account.

5 MR. [PANELIST]: The master
6 account--whoever held the master account holds that
7 password. So if you create for 10 employees, each
8 of those employees has their own password.

9 MS. ALVATELL: Okay. So we'd have to go
10 in--now that we're registered once, can I go in
11 there and make those changes?

12 MS. SCHMIT: Yes.

13 MS. ALVATELL: Okay.

14 MS. SCHMIT: Each person gets their own
15 account, their own password. They can be
16 sub-accounts of a master account.

17 MS. ALVATELL: Okay.

18 MS. SCHMIT: But each person--if you have
19 the registration and PIN numbers, they can all be
20 linked to each other; or the master account can
21 decide that this person can have access to these 10
22 facilities; this person can have access to those

1 10; the master account--I can have access to all of
2 them.

3 So, you can have it so multiple people can
4 get to the registrations.

5 MS. ALVATELL: Oh, great.

6 MS. SCHMIT: One way or another--however
7 you want to do business.

8 MS. ALVATELL: Thank you.

9 [Pause.]

10 MS. SCHMIT: Yes, I can show that to you
11 afterwards, when we take a break. I'll bring that
12 up on the screen.

13 MR. [PANELIST]: Any other questions?

14 MR. DAWSON: My name is Kim Dawson. I
15 work for the Department of Education, and we
16 oversee the National School Lunch Program and the
17 Commodities Program, and we distribute food to
18 schools and residential homes, and prisons and
19 homeless shelters.

20 And I was wondering how this act affects
21 us.

22 MR. [PANELIST]: Well, you are preparing

1 foods sold directly to consumers, so you would be
2 considered under the retail provisions.

3 So--now, there are central kitchens that
4 sell to other businesses that provide that
5 function, so it all depends on how you do business.
6 But if you're selling directly to
7 consumers--children, nursing homes, whatever--then
8 you would be considered a retailer and exempt.

9 But if you're selling to other businesses
10 that are, in turn, selling to consumers, then you
11 would be covered by this ruling. And your
12 commissary, or wherever you prepare the food,
13 should register.

14 MR. DAWSON: Okay.

15 MR. [PANELIST]: So, depending on how you
16 do your business--

17 MR. [PANELIST]: Are you a State agency?

18 MR. DAWSON: Yes.

19 MR. [PANELIST]: Wouldn't they come under
20 the general non-profit? If they're a State
21 government--

22 MR. [PANELIST]: Not per se, no. Because

1 we've had meetings with a school lunch program, and
2 each program actually does it a little bit
3 differently. So there is not a blanket yes-or-no
4 to the answer.

5 But I would say, just looking at the
6 definitions and material we gave you, it's likely
7 that you need not register, because you are a State
8 or a Federal institution. But, again, it depends
9 on your business practices, if you're covered or
10 not covered.

11 MR. DAWSON: Okay. I thank you.

12 [Pause.]

13 MR. : One more question. The
14 part of transportation or holding goods in the
15 normal course of transportation is kind of
16 confusing to me.

17 As an MBO, we tend to get goods into our
18 warehouses overseas that may be held for four or
19 five days for consolidation. We have containers
20 that will be held at importers because they cannot
21 unload the containers in a timely manner, so they
22 may be held there for three or four days.

1 Is that--what is the definition--

2 MR. [PANELIST]: That's covered under the
3 normal course of business.

4 MR. : So there's no time--I
5 thought 24 hours was--

6 MR. [PANELIST]: No, there is no time--if
7 you read the rule, there is no time element on
8 holding. We had no time element as far as the
9 definition of holding.

10 And so we're exempting--"in the normal
11 course" if you're doing transportation. In talking
12 with railroads and others, much of the
13 transportation is not a straight-line proposition.
14 Many of these things are staged in different parts
15 of the rail line, so that they can consolidate,
16 rearrange trains and the like. And this is all
17 part of their normal transportation. Likewise, as
18 you have mentioned, for an MBO.

19 So, when we considered that question, and
20 we put it out in January and February, we did
21 consider the entire normal course of business to
22 include what you're just mentioned.

1 [Pause.]

2 MR. [PANELIST]: Now, the difference--and
3 let me just mention one thing--some of the same
4 facilities have secured storage areas. Marine
5 terminals do, railroads do, others do. Those
6 facilities, which are secured storage facilities
7 for that sole purpose, should be registered,
8 because that is their function. That is not the
9 normal function of transportation. That is a
10 different function.

11 So if you do have those types of
12 facilities, then we would ask you to register
13 those.

14 [Pause.]

15 MS. KOLAITIS: Are there any other
16 questions--for registration?

17 Remember, this is registration under the
18 Bioterrorism Act. So just to go back to the
19 question on pharmaceuticals--if you're a
20 pharmaceutical manufacturer, you're required to
21 register with FDA under the FD&C Act. But under
22 the BT Act you're not required. It's only for

1 food.

2 Sharon, are we ready for the break?

3 [Taping stopped; taping resumed.]

4 MS. KOLAITIS: --allotted some time for
5 questions and answers. And we'll ask you to come
6 up to the microphone, and ask any questions that
7 you might have on prior notice.

8 MR. O'NEIL: Hi. Steve O'Neil. I have a
9 few questions, if it's all right?

10 The first one--legal and civil penalties?
11 Who's responsible? The importer, the U.S. agent,
12 the manufacturer?

13 MR. [PANELIST]: One of the reasons why
14 the prior notice is as complex as it is is that
15 specifically at the request of the brokerage
16 community, they wanted to distinguish the
17 "submitter," meaning the person who supplied the
18 information, from the keypuncher, if you will.

19 MR. O'NEIL: Right.

20 MR. [PANELIST]: So the person who
21 submitted the information is essentially is
22 attesting to its accuracy.

1 MR. O'NEIL: Okay.

2 MR. [PANELIST]: So the submitter would be
3 the liable party.

4 MR. O'NEIL: Okay--for a foreign exporter
5 who fails prior notice? Who would be
6 responsible--if they have a U.S. agent? If they
7 shipped without any notification to their U.S.
8 agent, who--

9 MR. [PANELIST]: They don't have to notify
10 the U.S. agent--prior notice has to be submitted.
11 Whether they give that information to the broker,
12 or they file it in PNSI and then just give you a
13 confirmation number.

14 MR. O'NEIL: Okay.

15 MR. [PANELIST]: That's not a criminal
16 penalty issue at this point. That's a refusal at
17 the border and, you know, "Hi. Welcome to FDA."

18 [Laughter.]

19 MR. O'NEIL: For international mail--there
20 is an exception for international couriers like
21 DHL?

22 MR. [PANELIST]: No.

1 MR. O'NEIL: No?

2 MS. [PANELIST]: [Off mike.] [inaudible]--
3 international mail.

4 MR. [PANELIST]: Mail is--

5 MS. KOLAITIS: [Off mike.]
6 [inaudible]--definition.

7 MR. O'NEIL: But you still have to do the
8 two-day prior notice.

9 MR. [PANELIST]: Yes.

10 MR. O'NEIL: Okay.

11 For registering and prior notice for--if
12 you had a shipment of--everything with the same
13 package size, but different lot numbers, is it two
14 prior notice, even if it's one shipment?

15 MR. [PANELIST]: If lot numbers are
16 required, you can glom, using those PK-0 through
17 PK-9 to separate them with a, you know, semicolon
18 or something. Lot number does not break down for a
19 separate BTA; packaging size does.

20 MR. O'NEIL: Okay.

21 MR. [PANELIST]: We recognize like a
22 typical canned goods shipment may have two or three

1 lot numbers in it--of the same size merchandise.

2 MS. KOLAITIS: [Off mike.] And the same
3 company.

4 MR. [PANELIST]: Yes. Right.

5 MR. O'NEIL: And just for myself, when we
6 have a holdup due to prior notice, or if we're on a
7 Customs hold before--under BTA--who do we go to?
8 To either get an update--90 percent of it, our
9 broker does the work for us. But we do some of our
10 own. We've already run into where we've tried to
11 get further information from the local FDA office,
12 and we can't. We run into a standstill on where to
13 get it.

14 MS. KOLAITIS: [Off mike.] But not for
15 prior notice. The prior notice is not processed by
16 your local FDA office.

17 MR. O'NEIL: Well, whoever our contact
18 person was. Is there someone--

19 MR. [PANELIST]: The local office--if you
20 question an entry, and you say, you know, "Where's
21 my 'may proceed'?"--which is your typical question
22 on this, they'll say, "It's not in our in-box."

1 They can tell you--it's in prior notice status.
2 And then, you know, if there's a hold, we don't
3 communicate that information in general.

4 MR. O'NEIL: Okay.

5 MR. [PANELIST]: Particularly so when
6 you're dealing with a land border.

7 MR. O'NEIL: Right.

8 And then, do you guys know if
9 there's--just for us to allow lead times for
10 import, what we should allow--additional time for
11 prior notice clearance? Is it two weeks? Four
12 weeks? Eight weeks?

13 MR. [PANELIST]: No. You can submit prior
14 notice up to five days in advance.

15 MR. O'NEIL: No, I know--once it hits the
16 port.

17 MS. KOLAITIS: [Off mike.] Before it hits
18 the port.

19 MR. O'NEIL: Well, before. But once our
20 material comes, if prior notice is accepted, it
21 should clear--

22 MR. [PANELIST]: Right.

1 MR. O'NEIL: --in the same amount of time
2 it normally--

3 MR. [PANELIST]: Well, there's--it's a
4 two-hurdle process. Essentially what happens now
5 is, let's say for sea cargo, eight hours after it
6 arrives--when we start enforcing timeclock
7 management, it will have either been satisfied or
8 we will have set the holdup for Customs to, you
9 know--or to go out and look at it, or to hold it
10 for us to look at.

11 But after that eight hours--assuming that
12 has not happened--and that is not--you know, we're
13 not--that's going to be a rarity; a relative
14 rarity, the BTA holds. Then our system will let it
15 go, and it jumps from the one screening
16 process--the prior notice screening process--into
17 our regular 801(a) screening process, and you know,
18 for an air cargo shipment, typically, two hours
19 after you submit it, if you get a system "may
20 proceed," you should be seeing it--two to
21 two-and-a-half hours.

22 MR. O'NEIL: Okay. Thank you.

1 [Pause.]

2 MR. : I have a comment and a
3 couple questions.

4 I mean, first of all, I think, you know,
5 we all agree that the point is to keep terrorism
6 and keep, you know, the food supply safe. But the
7 registration part I really understand. I think
8 that's important to know who the players are,
9 commodities. But I have a real problem with prior
10 notice. It just seems that there's other--I know
11 the ship's already moving--but, you know, it seems
12 to me if you had another way; for instance, if you
13 just say, "Well, we're not going to release your
14 shipment."

15 I mean, most people are just regular
16 business people. And in this case, I mean, the
17 submitter in most cases becomes the broker--

18 MR. [PANELIST]: Mm-hmm.

19 MR. : I mean, we're--you know,
20 they're expecting the broker to take care of this
21 information; you know, we're the experts with the
22 Customs system and, you know, the go-between.

1 MR. [PANELIST]: You're basically picking
2 up a couple of additional pieces of information.
3 You're picking up the registration number, which
4 you didn't have.

5 MR. : That's true.

6 MR. [PANELIST]: What I would truly advise
7 you to do is query those MIDs. You know that there
8 are many manufacturers have multiple MIDs--you
9 know, due to variations in address; the fact that
10 we don't know U.S. geography, forget foreign
11 geography. Half the people put the city in as the
12 province, the province in as the city.

13 And the MID you may be using may not match
14 your registration information--

15 MR. : Sure.

16 MR. [PANELIST]: --and then it's going to
17 bounce at some point--you know, when we go into
18 full enforcement, you're going to start getting
19 rejections.

20 MR. : It just seems to me that
21 we're punishing the wrong people. I mean, I can
22 tell you I know what's going to--everyone's going

1 to be late. It's happening now. I mean, you're
2 having a problem getting people registered. And
3 I'm sure the late percentage must be huge. And
4 it's going to continue to happen because
5 things--you know.

6 And I don't even think that when it's sent
7 is the point. I mean, the point is: are the goods
8 contaminated? You know, is it going to harm the
9 food supply? That's kind of the point of--you
10 know. As a terrorist, you know--I mean, I doubt
11 there's any terrorists in the room. You know, we
12 all want a safe food supply.

13 And the point--whether--you know, that we
14 get penalized because we didn't tell you timely
15 about a food product that most business people are
16 just trying to do their business, doesn't seem
17 fair.

18 MR. [PANELIST]: Yes. I think what's
19 going to be happening is, first of all, a large
20 majority of the business is repeat and routine
21 business. The shipments--

22 MR. : That's true.

1 MR. [PANELIST]: --the same stuff comes in
2 week after week. Those people will be registered.
3 Those people--you know, they'll get hit once.
4 They'll register, and from that point on,
5 hopefully, things will work smoothly for them.

6 I think--but that's one of the reasons by
7 the BRASS went away. I mean, we--there were
8 shipments we did not find out about until 10 days
9 after they were in the country, and long gone. You
10 know.

11 MR. : Yes. Sure. Well, I mean,
12 but that's part of the release. I mean, if you get
13 a "may proceed"--I just don't think prior notice is
14 the answer, I'll be honest with you.

15 MR. [PANELIST]: Well, if I could just
16 make a comment--I notice you mentioned the term
17 "punish," and that's not the intent.

18 MR. : Well--

19 MR. [PANELIST]: And I'd also point out,
20 we have the situation where--you know, forget about
21 BTA. We have a prior notice on all shipments
22 coming through now. And I understand your concern,

1 and I understand the difficulty.

2 But as I said starting out, this is a
3 fairly complex load that's been put on the trade
4 and also on FDA and Customs.

5 MR. : Sure.

6 MR. [PANELIST]: And I think--as was
7 said--I think as the repeat nature of a lot of
8 these goods, it's going to get easier. It's like
9 everything--it's like a lot of other programs.
10 It's going to fall into place. And I understand
11 it. It's got to be very difficult for you sitting
12 there, you know, trying to get this stuff in.

13 But we're not penalizing people just for
14 not getting it in on time, you know. You're going
15 to be delayed. You're not going to see penalties,
16 you know, for that.

17 I think it's just a question of getting
18 used to the system. And then if you take a look at
19 non-BTA merchandise, the same sort of principles
20 are applying. You say a determination has to be
21 made. Well, what we need to make that
22 determination is advance information. And that's

1 what we're asking for--not through BTA, or for
2 advance notification, for all types of transport.

3 MR. : I mean other than--I guess
4 my other point is: has any consideration been made
5 into CT PATs? If someone is a CT PAT? You know,
6 if they've done all their security things and the
7 background, it seems to me that, you know, what's
8 the point of prior notice. They've done all
9 the--they know who their suppliers are, they keep
10 secure facilities. You know, they keep good
11 records. They know their employees.

12 MR. [PANELIST]: Right. To the
13 extent--first of all, I think the prior
14 notice--we've been looking at, I think, at CT
15 PAT--Customs has been asking us to do it. I think
16 it will still require the prior notice information.
17 I think the key there is that you're, you know--the
18 key there is going to be the sophistication of your
19 filer software to memorize transactions so that you
20 have a minimum amount of information to update with
21 each new shipment.

22 It's also going--the CT PAT type of logic

1 may also get put into our screening, you know, so
2 that the odds of a CT PAT getting a bioterrorism
3 hit or stop at the border would be, you know, slim
4 to none, because of the same logic. We have a
5 secure supply chain. We know all the elements.
6 The data still gets provided, but the odds of a hit
7 are far less than, you know, somebody who is
8 not--where we don't have that information.

9 MR. : Okay. I guess my point is
10 that because a prior notice is late, and could
11 possible go into this constructive GO, it doesn't
12 mean that the goods are contaminated--

13 MR. [PANELIST]: No.

14 MR. : --and the whole issue of
15 having to export it--and then you have another
16 point, which is, you know, a lot of shippers and
17 importers they--you know, they depend on their
18 broker, or their freight-forwarder to do it, and
19 maybe there's mis-communication--

20 MR. [PANELIST]: Mm-hmm.

21 MR. : --and then all of a sudden
22 you've got this \$100,000 shipment of pickles or

1 something--who knows--you know, and it's like--
2 okay, I'm going to sue you because you were
3 supposed to--you know, we had an agreement that you
4 were going to take care of this, and the broker
5 says, well, you know, I guess I slipped up, and--

6 MR. [PANELIST]: Well, unlike the
7 801(a)--and that's--you know, what you're used to
8 generally, unless we flat-out made a mistake and we
9 refused line 1 when we meant to refuse line 2. But
10 generally, on 801(a) we do not rescind refusals.
11 They're final.

12 Refusal under 801(m) is not--(m) or
13 (l)--is not final and, basically, you either let
14 the timeclock run out, depending on how the
15 Customs--they may just have you, you know, pull
16 over on a lot and say, well, you know, at the end
17 of two hours we should have our notice back that
18 you're satisfied--or less.

19 The two hours is not--you know, that's the
20 minimum you have to give us. Our screening system
21 may say, "Okay, we took that data you gave us under
22 PN. It's not timely, however we looked at the

1 criteria--it's fine. Go." It's not going to be,
2 "Oh, no, you didn't give us two hours. You're
3 going to sit here for two hours until--even though
4 I know the decision already, I'm going to make you
5 sit here--"--no.

6 Electronically, we're going to process
7 that right back when we get it. If it's PN
8 satisfied, then it goes through the regular 801(a)
9 process.

10 MR. : I would just hope that,
11 you know, the FDA is lenient. Because most people
12 are not trying to introduce poisonous goods into
13 the--you know, into the community. That's really
14 it.

15 [Pause.]

16 MS. : Hi. I'm Connie. I work
17 at Hasbro.

18 I just have a couple of questions. On the
19 9801-1097, it doesn't work in the ABI system. It
20 doesn't accept prior notice.

21 MR. [PANELIST]: That's one of the things
22 we have to work on.

cac

1 MS. : Okay. So you know about
2 that.

3 MR. [PANELIST]: Yes. We know about that.

4 MR. [PANELIST]: I was going to say I'm in
5 probably weekly meetings with the ABI people, we
6 are working on the ability to accept data on
7 non-flag codes, and also to allow a partial
8 disclaimer.

9 The original logic was an FD-3 was that if
10 it was an FD-3 flag, both BTA and FDA--either both
11 are required or neither are required. People have
12 come up to us with some examples where they truly
13 are not subject to BT, but they're still subject to
14 FDA. But the tariff code kind of needs to have BTA
15 capability for other products in there. So that's
16 why one of the things that's currently--should be
17 coming out shortly, is the ability to do a prior
18 notice disclaimer on an FD-3, and still submit the
19 801(a) data.

20 MS. : Because you can do it on
21 the website. Okay.

22 I also have candy that has two different

1 kinds of candy; a lollipop and a powder--one
2 manufacturer, two FDA codes. Is that two prior
3 notices?

4 [Pause.]

5 [Laughter.]

6 MR. [PANELIST]: It's two--oh, because
7 it's a combined--

8 MS. : One's a powder and one's a
9 lollipop.

10 MS. KOLAITIS: [Off mike.] One
11 manufacturer.

12 MR. [PANELIST]: It's one manufacturer,
13 but if it's two separate product codes--

14 MS. : I couldn't find another
15 way to do it. I had to do it as two prior notices.

16 MR. [PANELIST]: I don't know. I--umm--

17 [Laughter.]

18 --talk to me afterwards. I'll try the
19 candy.

20 Umm--there may be--that's something we may
21 have to look into, where we may have to come up
22 with--like we do have codes for the multiple

1 food--you know, like the medical foods which are,
2 you know, 20--and we have a "gift basket" code.

3 Something like this may--you know, it may
4 be something that we may need to add to add a
5 product code to cover that situation.

6 But, seriously, do talk to be afterwards.

7 MS. : Okay.

8 Also, when I was doing a prior notice on
9 the FDA website, it says that you put the
10 registration, all you need is the city and the
11 country. And I couldn't do that either. And I was
12 on the phone with FDA a few times--on the Help
13 line. I tried all different ways. And I had to
14 put the whole name of the company, the address--

15 MR. : [Off mike.] [inaudible]

16 MS. : Everything. Yeah.

17 MR. [PANELIST]: [Off mike.] Does that
18 mean the links are frozen [inaudible]?

19 MS. SCHMIT: I can check on that and get
20 back to you.

21 MS. : I've tried a few times; a
22 few days.

1 MS. SCHMIT: Talk to me afterwards.

2 MS. : Okay.

3 And, the owner--is that the--we have a
4 candy that goes from--we get it from one person, it
5 goes to another person in China. They put the
6 candy together--we have like lollipop with a toy.

7 MR. [PANELIST]: Mm-hmm.

8 MS. : Is that the owner?

9 MR. [PANELIST]: The owner--we only put
10 owner, I think, on the website because Congress put
11 it into the Act.

12 [Laughter.]

13 The owner, I think, in most cases, is
14 going to be the importer or the consignee.

15 MS. : The importer? Because
16 that's not what I was told on the Help line. I was
17 told that the person that puts it together.

18 MR. [PANELIST]: Who has the title to it?

19 MS. : Excuse me?

20 MR. [PANELIST]: Yes--who would have the
21 title to that shipment?

22 MS. KOLAITIS: Hasbro.

1 MS. : Yes, Hasbro.

2 MR. [PANELIST]: So you're the owner of
3 it.

4 Lou, do you have any--?

5 MR. CARSON: [Off mike.] Hasbro is the
6 owner in this case. You should be putting
7 [inaudible].

8 MS. : Okay. Because that's what
9 I was doing, and then they changed my mind.

10 MS. SCHMIT: There was, just a few days
11 ago, put up on the Help Desk web page, some
12 additional phone numbers for the prior notice
13 center for policy questions.

14 MS. : Okay.

15 MS. SCHMIT: And that just went up just a
16 few days ago. So some of those could be answered
17 there, if they're not answered by the industry
18 system's Help Desk, which is more "how to," as
19 opposed to the policy.

20 MS. : Now, also the airlines in
21 China, they won't accept our shipment without a
22 prior notice. Is that something that you're

1 running into? Because the shipment--actually air
2 shipments don't come in for like three days. So I
3 actually have two days to make a prior notice after
4 an air shipment leaves.

5 MR. [PANELIST]: I guess the carriers may
6 be doing that out of self-protection. They--since
7 they bear the cost of anything, so that's their
8 requirement, not ours.

9 MS. : Yes. Okay.

10 And what happens if I need an IT? It's
11 going to want an IT. you don't know the IT number
12 until after it leaves.

13 MR. [PANELIST]: Under the--

14 MS. : For air shipment.

15 MR. [PANELIST]: Under the WP process, you
16 can give us the airway bill.

17 There are three or four different
18 identifies that can be used in that process--

19 MR. [PANELIST]: [Off mike.] [inaudible]--
20 airway bill and--

21 MR. [PANELIST]: Yes.

22 MS. : So you don't need the IT

1 number.

2 MR. [PANELIST]: Right. In fact if you
3 already know the consumption entry number from your
4 broker, that can be used--although--

5 MS. : We do our own brokerage.

6 MR. [PANELIST]: Yes--you do your own?

7 MS. : Yes.

8 MR. [PANELIST]: At the moment--for the
9 next few weeks I'd prefer you wouldn't do that--

10 [Laughter.]

11 --until we get another piece of software
12 in place.

13 MS. : Now, one more question. I
14 have freight that goes from L.A. to Oakland. USA
15 now have to clear it in L.A. or do the prior notice
16 in L.A.

17 [Multiple simultaneous comments.]

18 MS. : Oh--no, no IT.

19 MS. KOLAITIS: [Off mike.]

20 [inaudible]--far as L.A., and then after that it
21 goes--

22 MR. [PANELIST]: Oh, this is freight left

1 on board.

2 MS. : Yes.

3 MS. KOLAITIS: Freight left on board, I
4 believe, is file at, really, the port where it's
5 going to be discharged.

6 MS. : Okay. That's what I
7 thought it was.

8 Okay. Thank you.

9 MR. : I think the Customs
10 definition of "port of arrival" is intent to
11 unlade. So that--in that case, it is where the
12 ship is going to unlade the cargo. Because we had
13 that question awhile ago on that. It's not the
14 first port that the ship hits the United States,
15 it's where it's going to unlade the cargo--which
16 could be three or four ports in a rotation.

17 I hate to tell Jim about WP's, but WP's at
18 a port like Boston are extremely important, since
19 about 75 percent of our freight moves in-bond. And
20 the problem that we have--and this will get to a
21 question eventually, is that because the way the EI
22 and HN system was set up, we have to certify for

1 cargo release to get that information submitted
2 through ABI to OASIS.

3 Now, the funny thing: if something moves
4 in-bond, that doesn't happen until 48 hours until
5 the arrival at the port of entry. So you have
6 goods coming into L.A. that are going to take five
7 days to cross the country. You try and file it
8 before the ship arrives in L.A. Customs is not
9 going to do any selectivity which will transmit the
10 information to FDA until 48 hours before it arrives
11 into Boston, so you automatically have a late file
12 on your PN.

13 MR. [PANELIST]: Because for sea cargo,
14 it's eight hours.

15 MR. : Yes, but--

16 MR. [PANELIST]: So you've given your 48
17 hours, when it's first coming in.

18 MR. : But there is a problem at
19 Customs--not a problem, but their policy at Customs
20 is not to do selectivity until 48 hours on in-bond
21 freight; 48 hours before cargo arrives at the port
22 of entry--entry--and not the port of arrival.

1 MR. [PANELIST]: All right, I--

2 MR. : And the fact is, they
3 don't send the information to Food and Drug until
4 they do selectivity. So forget the fact that we're
5 certifying it for cargo release. So WP's pretty
6 important.

7 An air-freight WP can be important because
8 you may not want to certify for cargo release on
9 entry, because you don't have full facts on an
10 air-freight shipment until the goods are arrived
11 and the importer tells you exactly what you have.
12 So WP is another important thing.

13 The problem we're running into is this
14 pen-and-ink changes, and this has been a major
15 problem. We've had cases where a value
16 changes--we've made a mistake in a conversion and
17 we want to change a value--that's not a pen-and-ink
18 change that's allowed under BTA--under your FDA.
19 So we have to re-file an entry, which is onerous on
20 all of us, and also makes a late file.

21 MR. [PANELIST]: [Sighs.] I--

22 MR. : So--I know there's an

1 update to pen-and-ink changes, but I think--

2 MR. [PANELIST]: Yes, I think we're trying
3 to come to an agreement with Customs on what pen-
4 and-inks they--to allow on their side, and where
5 they do not have to tell us. And pretty
6 much--well, some of the stuff like the PNSI
7 stuff--Prior Notice System, web-based--is, if you
8 will, cutting- or bleeding-edge, depending on your
9 point of view. The fact that we were able to take
10 ACS, which is a vintage system, and get it up to
11 running to transfer this data, certain things had
12 to be done or else you would have had to wait until
13 you got into an ACE environment and it's totally
14 rebuilt

15 And pen-and-inks was one of the
16 casualties.

17 MR. : Right. And I understand
18 that. I was kind of involved with headquarters on
19 that issue.

20 But the problem you have to realize is
21 that pen-and-ink changes, and the fact that we have
22 to cancel entries, is a huge burden, and is

1 actually invalidating PN's that are really valid.
2 I mean, what do you care if something's \$1,000 or
3 \$1,100. Does it make a difference?

4 MR. [PANELIST]: Umm--I thought that
5 Customs was allowing that--those changes--and not
6 sending them--value--because value isn't
7 even--it's--

8 MR. : Well, you just put
9 down--up there what changes were allowed. Value is
10 not one of them. As a matter of fact, there's
11 quite a few changes that are not allowed under
12 prior notice that have really no affect on
13 admissibility or what you would be doing for any
14 screening.

15 And that's something I think you have to
16 work out.

17 MR. [PANELIST]: Yes. And my guess--and
18 you know from the ABI people, but my guess is
19 that's going to be something that's going to wait
20 for ACE.

21 We're going to try and look at what
22 pen-and-inks--I think the big piece is where we can

1 sit down with Customs and say, "Certain
2 pen-and-inks we don't want to know about." You
3 know, we don't make admissibility decisions based
4 on tariff codes. I mean, we really don't use them
5 terribly much. And usually, a lot of pen-and-inks
6 are--they're changing the last digit on that--you
7 know, tariff classification, which has no bearing
8 on us.

9 And that's probably the bulk of the
10 pen-and-inks we see, is--that's what's happening.
11 If they're doing a pen-and-ink because the
12 manufacturer's changed, we definitely want to see
13 it.

14 MR. : Right. That's
15 understandable.

16 MR. [PANELIST]: Yes. So, again, that's
17 something that is in discussion. There's a lot of
18 program that involved making this work. And, you
19 know, pen-and-inks is one of the items that's on
20 the table.

21 [Pause.]

22 MR. PEPPER: Hi. My name's Leo Pepper,

1 and I have a question about the counseling of
2 importers that submit inadequate or a lack of prior
3 notice altogether.

4 How will that counseling take place? Will
5 that be done directly to the importer? Or through
6 ABI to the broker?

7 MR. [PANELIST]: It should--well, because
8 this is difficult sometimes in the environment, but
9 there some--actually, a couple of handouts are out
10 there, and the prior notice glossy that's out on
11 the desk is excellent.

12 We also should be working through the
13 brokers, and we are tracking some of these things
14 in--headquarters is tracking these. So some filers
15 have already gotten notices generated by
16 headquarters but distributed by the ports, telling
17 them, that, you know, "You're having some problems
18 here."

19 And I have to tell you, the number is
20 limited. But I can see that going up, and we will
21 be tracking those.

22 So--and the border environment's a lot

1 easier. I know up there there are certain--it's
2 easier to take one of those glossies, or a handout,
3 and hand it to the trucker, and say "Give this to
4 the importer."

5 MR. : Sure.

6 MR. [PANELIST]: It's a little bit harder
7 in a big port like this.

8 But you should be--you know, you should be
9 aware that it is being tracked through out systems,
10 and you're probably going to be notified in a
11 letter. I wouldn't wait for the letter. You know,
12 I'd try to say to them, "If you have any question,
13 please give me a call and I'll put you in touch
14 with somebody who can help you or get the
15 information to you."

16 But, ideally, we want to get the
17 information out. In fact, that's--you know, that's
18 what happened here, and I'm sure that's why we--

19 MR. [PANELIST]: We have been providing
20 Customs with data, in terms of data quality.
21 Because there's things Customs can see. Customs
22 can see that, hey, people are not submitting a

1 registration number; you know, it's not there.
2 They can't tell you off-hand if that's a good
3 number or if it's even a right format.

4 I mean, we've got people submitting a
5 registration number with "0000," because we're in a
6 discretionary enforcement mode, that is, you know,
7 currently being taken. But, you know, when we go
8 into full enforcement mode, that's not going to
9 work. But we are--you know, some of the data that
10 our contracts are providing to Customs are the
11 people that are routinely giving us bad data.

12 MR. : I see. And, I'm sorry,
13 you mentioned that that was done possibly through a
14 letter of some port--to the importer directly?

15 MR. [PANELIST]: But we also--I mentioned
16 in passing--we've had some outreach to the trade.
17 We had it from around Thanksgiving 'til just before
18 Christmas. And, you know, that's the type of thing
19 that we're trying to get the form compliance part
20 of this done.

21 As far as the individual counseling,
22 that's something we're going to have to think

1 about. Because, as I say, you're already pretty
2 far down the road by the time you get one of those
3 letter. You know, I know--I'm very comfortable
4 with what's happening on the northern border. I'm
5 more comfortable, now that I'm back in the Port of
6 Boston, about what's happening here. But I will
7 look into it.

8 MR. : I see. I'm only concerned
9 about a scenario where I can envision where an
10 importer provides a broker with more than adequate
11 information, and in a timely manner, yet maybe the
12 broker submits it late, and they don't want to tell
13 the importer for, you know, whatever reason--maybe
14 they don't want to be reprimanded for submitting a
15 late prior notice on their behalf. And if the
16 importer isn't directly communicated to by Customs
17 or FDA, then maybe they may not know that that's
18 being done untimely. And therefore, all of a
19 sudden the penalty shows up in their office.
20 That's what I'm kind of concerned about.

21 I guess I'm just hoping that Customs and
22 FDA will communicate directly to the importers, as

1 opposed to something maybe through ABI or something
2 like that.

3 MR. [PANELIST]: I see what you mean.

4 MR. [PANELIST]: It's now the importer
5 working through an intermediary--

6 MR. : Exactly.

7 MR. [PANELIST]: --and they may not be
8 getting that information.

9 MR. : Exactly.

10 MR. [PANELIST]: That's the point.

11 MR. [PANELIST]: [Off mike.] Can we just
12 try to answer that, as well.

13 Remember, we ask for affirmation on the
14 owner and ultimately the consignee as part of this.
15 And that had to do with being notifying that there
16 was a problem where put it into storage
17 [inaudible]. We would have a way to notify
18 importers in that way as well, if we did have
19 problems with the broker. So we will that comment
20 back.

21 MR. : Thank you.

22 MR. [PANELIST]: You know, my

1 recommendation is keep good records of what you
2 send forward.

3 [Pause.]

4 MS. : Hi. I am a customs
5 broker, and I just wanted to kind of clarify
6 anticipated questions I'm sure I'm going to get
7 from my importers.

8 When the freight comes into the first
9 port, prior notice is required, yet an IT is
10 allowed to move without that; that's avoiding the
11 general order.

12 MR. [PANELIST]: No. When you do an
13 IT--if you're doing an IT, the prior notice is
14 submitted at that time. It has to be submitted.

15 MS. : I thought I heard--

16 MR. [PANELIST]: I know--and that's, I
17 think, something that's--I think our policy people
18 and Customs have to get together. I think we have
19 a discrepancy on that slide. It has to be provided
20 and satisfied, really, before the goods move under
21 that bond.

22 MS. : Okay.

1 MR. [PANELIST]: You know, with the eight
2 hours or whatever.

3 MS. : And following suit to
4 that--I think someone made reference to
5 it--invariably the left hand doesn't know what the
6 right hand's doing; the supplier doesn't give
7 information, the information's not available all
8 the time.

9 How do you anticipate penalties? Will
10 they be fairly automatic? At some point, you're
11 going to have to crack down on late filing, because
12 it's going to be a problem. Is there an idea on
13 how you're going to handle that?

14 MR. [PANELIST]: I can't speak for the
15 FDA.

16 MS. : Okay.

17 MR. [PANELIST]: I don't think it's--I
18 think it's unexplored territory for us.

19 MS. KOLAITIS: [Off mike.] But I think
20 we're going to take a look at a broker's history, a
21 filer's history, and make a case-by-case decision,
22 just like we do with all of our compliance actions.

1 And see is it intentional or is there a history
2 here. We have recalcitrant filers, too. We take
3 action now. We issue warning letters.

4 MS. : Excellent.

5 MS. KOLAITIS: [Off mike.] So, you know,
6 we're going to take a look at what the enforcement
7 issue is, and--but the first thing--I mean, if
8 prior notice is inadequate or it's not filed, well,
9 they're subject to refusal. You refuse the
10 shipment at the port of arrival. And that's
11 [inaudible].

12 MS. : Okay.

13 MS. KOLAITIS: [Off mike.] I mean that's
14 [inaudible].

15 MS. : Okay. And my other
16 question is regarding personal effects. I thought
17 I heard that personal effects were excluded from
18 this? But that didn't really make sense to me, so
19 I assume I heard wrong.

20 MS. KOLAITIS: [Off mike.] No, we said
21 they're not excluded.

22 MS. : They're not excluded.

1 Okay. I mis-heard that. Excellent. Thank you.

2 MR. [PANELIST]: Eat before you go.

3 [Laughter.]

4 MR. [PANELIST]: No, the rule is household
5 goods?

6 MR. [PANELIST]: [Off mike.] Yes, when we
7 asked our compliance policy [inaudible]--and the
8 different types of problems that might occur, what
9 actually we will say. And that is our best
10 information to provide you as to how we're going to
11 proceed, just as Diana mentioned. We're going to
12 do warning letters and other things. But right now
13 what we forecast for prior notice is using CBP
14 civil money penalties if there was an egregious
15 act, or, obviously, if you fail to provide prior
16 notice then you'll be subject to refusal and
17 [inaudible].

18 We haven't [inaudible] and explained
19 things in those terms, and we're probably not going
20 to explicitly give you any [inaudible] detailed
21 arithmetic way of how we're going to come up with a
22 fine.

1 MS. : [Off mike.] Which is
2 fine-- [inaudible].

3 MR. [PANELIST]: But I would think that
4 normally CBP deals with problems of this
5 nature--CBP civil money penalties, we'll follow
6 that procedure if that's the proper course, or if
7 FDA needs to send the importer or broker a letter
8 because they're failing to comply with [inaudible],
9 and then we'll just ratchet it up each time
10 [inaudible].

11 MS. : I just had a quick
12 comment. I just wanted to explain that Hasbro, of
13 course, would hate to have an import of food or
14 whatever it is that we import--and for some reason
15 it's carrying bioterrorism material. That would be
16 something that we'd want to make sure that we don't
17 do that.

18 But just to bring to your attention what's
19 happening with the food that we fly in, when we go
20 ahead and we make entry because we do our own
21 entries in-house--when we make entry, we're doing
22 it once we receive an authority from the forwarder.

1 They tell us where the freight is going to be
2 located, and that happens after the freight
3 arrives.

4 So, we're able to put all that information
5 into the ABI all at once. When we have to do the
6 prior notice, prior to arrival, we don't have all
7 that information. So what we're doing now is
8 working with our Orient office--the Hong Kong
9 office--so that they put in the prior notice, which
10 is basically the same information that's put into
11 the ABI. So we're duplicating information.

12 Is there something that FDA can work
13 around with us so that we make sure that we do it
14 within a reasonable amount of time? Because the
15 forwarders are not giving us the flight information
16 and the arrival destination until it actually
17 arrives. And there's like a chicken-egg situation
18 going on with us.

19 MR. [PANELIST]: Well, when you're saying
20 your "Hong Kong office," how are they--they're
21 putting it in through the PNSI?

22 MS. : Yes, they are.

1 MR. [PANELIST]: And then how are you--are
2 you just--are you duplicating the information, or
3 are you just giving the confirmation number.

4 MS. : We're getting the
5 confirmation number, and we're putting all the air
6 freight information, of course, into the ABI also.

7 MR. [PANELIST]: You don't have to. If
8 it's in the PNSI--if you--if they've issued you a
9 confirmation number, the only affirmation you have
10 to give us is the PNSI number.

11 MS. : Right. That's correct.

12 MR. [PANELIST]: So you only have to give
13 it a one piece a day. You don't have to re-do all
14 the registration and all the other stuff.

15 MS. : What we are trying to do
16 is have everything done in-house, including the
17 prior notice. But we found out when we go on the
18 FDA website, all the data elements that are there
19 are also duplicated in the ABI.

20 MR. [PANELIST]: Yes.

21 MS. : And we're trying to make
22 it more efficient, if possible--when it comes to

1 data entry.

2 MR. [PANELIST]: We don't have the ability
3 to do it half-and-half.

4 MS. : Okay.

5 MR. [PANELIST]: And I don't see that
6 happening, you know, for the foreseeable future.
7 It's really just--unfortunately, the onus is on you
8 to kind of work on your freight forwarders to
9 provide the information--

10 MS. : Okay.

11 MR. [PANELIST]: --in a more timely
12 fashion. And that's--you know, we all recognize
13 that this is going to make you change in the way
14 certain business practices are done, and that
15 certain information that has always been available
16 just has to be communicated in a more timely
17 fashion.

18 MS. : Okay. Thank you.

19 [Pause.]

20 MR. WALLACE: Hi, I'm Jim Wallace from
21 C.H. Powell Company.

22 Listening to a few of the comments made by

1 some of the attendees, and working day-to-day for a
2 number of years in the business, lately it's been
3 kind of a crisis mode on food imports. And we
4 handle about, I'd say, 20 percent of our imports
5 are food-related. So it's very important to us, as
6 brokers, to be able to provide this service for the
7 importers that are basically depending upon us to
8 file the prior notifications.

9 Because of commercial realities, a lot of
10 times you may not have a notice of arrival, so
11 therefore you don't know there's a shipment in
12 transit; you don't have the documents; it's a new
13 supplier--I mean, there's a variety of issues that
14 come up at the time where we're attempting to make
15 the entry in the prior notification.

16 Friday afternoon a set of documents comes
17 in with 25 commercial invoices on a consolidated
18 shipment of wine from France, and maybe you're
19 missing two invoices; maybe you're missing a
20 registration number, and you're trying to put all
21 that together. And it's a virtual impossibility.

22 What should we do, as brokers, in cases

1 like this to prevent penalties? Is it an
2 eight-hour requirement, that we have to file this
3 eight hours--if the shipment's coming in on
4 Saturday or Sunday, what's going to happen to the
5 entry down the road?

6 MR. [PANELIST]: The requirements--in the
7 case of--especially in the sea cargo, I think
8 you--you know, probably a late shipment would
9 probably not be that big a deal because it will be
10 held inside the port and you can do it on Monday.
11 The only difference is you're going to have to go
12 to the web to add the secure location.

13 The other issue is that you may have to
14 let your suppliers know that there's going to be an
15 additional cost, because what you're do is break
16 that out into two entries; that that's complete,
17 and that which you cannot enter.

18 MR. WALLACE: So we would break it out
19 into what you have information non and what you
20 don't?

21 MR. [PANELIST]: Yes. You know, that may
22 be--that's a business decision.

1 MR. WALLACE: Yes. But when you say "a
2 secure location," it came into, say, Carley Durmel
3 in Boston, and it's not going to move from there.

4 MR. [PANELIST]: Then that--yes, that's
5 okay, because the BTA just says you cannot leave
6 the port unless you go to a secure facility, or
7 held in the port. And it's at the discretion of
8 the port director.

9 MR. [PANELIST]: And it can be held to
10 [inaudible]

11 MR. [PANELIST]: Yes.

12 MR. WALLACE: I'm sorry?

13 MR. [PANELIST]: It's being held by the
14 carrier--at the carrier's premises.

15 MR. [PANELIST]: Yes. So--

16 MR. WALLACE: So if, out of a thousand
17 imports a year, and an importer has 10 or 15
18 shipments where an eight-hour prior notification is
19 not accomplished, he's not going to be brought up
20 on civil charges, or penalties issued to him or the
21 broker?

22 I mean, I know you maybe can't commit--

1 MR. [PANELIST]: I can't commit, but I--

2 MS. KOLAITIS: [Off mike.] That's part of
3 why we're doing this education and outreach. If
4 you haven't done prior notice since December 12th,
5 I think Jim is stressing--start doing it now.

6 MR. WALLACE: Oh, we've been doing it from
7 day one.

8 MS. KOLAITIS: [Off mike.] [inaudible] by
9 the time August rolls around, we're hopefully going
10 to have [inaudible] what the criteria for
11 enforcement will be. And I think--that's why
12 you're better off trying to get some of [inaudible]
13 involved now, during this interim time period, when
14 there is a lot of discretion. There's going to be
15 the comment period, it's going to reopen, so that
16 you'll be able to get comments into that docket
17 again, with some real-life experiences and get that
18 included again in the re-look at the final rule.

19 But this is the time to try to test all
20 this out, because there is this enforcement
21 discretion that is going on.

22 MR. WALLACE: Great. We have--

1 MS. KOLAITIS: [Off mike.] We're going--

2 MR. WALLACE: --commercial realities. I
3 mean, you're talking with--literally have a
4 thousand registration numbers for one import
5 account. And if you have that many potential
6 registration numbers, and that many potential PN's
7 during a week, I mean--you know, things aren't
8 always going to work the way you'd like them to
9 work.

10 You know, I'm just trying to anticipate
11 what's down the road, and what type of--

12 MR. [PANELIST]: One think I would urge
13 the filers to do is check with your software
14 vendors. One of the changes that came about that's
15 an improvement on the BTA is on rejects.
16 Previously, you got a general message that said,
17 "FDA's rejected your stuff. Go figure it out."

18 MR. WALLACE: Right.

19 MR. [PANELIST]: I mean, that's
20 effectively--because it was at an entry level.

21 We are now sending line-level rejects with
22 a reason for reject. So, you know, up on the

1 norther border we still a fair number of "foreign
2 consignee." Customs has issued this admin more
3 times than, you know, they can count, saying: if
4 you are filing an FDA entry, do not use a foreign
5 consignee--unless you give the--you know, there is
6 a way out of it, but it's painful. You know,
7 you've got to do an FEI on each line to avoid the
8 "foreign consignee." But that's probably our
9 biggest single cause of rejects.

10 MR. WALLACE: How is the trade handling it
11 in general? I mean, have you done any analysis as
12 to how many timely PN's are file on imports?
13 Or--and if I don't have any answers back, and my
14 entries have been rejected, and I have "may
15 proceeds," do I assume that we're doing everything
16 properly?

17 MR. [PANELIST]: You can't really at this
18 point, because, again, trying to marry the--you
19 know, the ABI system--they're going--I think
20 they're going to start passing the warning messages
21 now. You'll start getting, you know, "accepted"
22 with warning messages. But certain things, like

1 for example, if the--where we would send rejects
2 back, and you're not even going to be allowed to
3 submit the information--Customs, can, I think put
4 in 'til Phase IV.

5 So, some of that stuff--you know, in order
6 to get the IT system--the fact that we were able to
7 get ABI working is truly an amazing thing. And
8 this is not a knock on Customs, believe me. This
9 was the fact that the initial rule went out with
10 FDA prior notice website only. We got a lot of
11 comments saying, you know, why don't we use the ABI
12 system? We finally got to a point where both CBP
13 and FDA agreed and we had--what?--probably about
14 four to five months to put this together and live
15 within the strictures of what is in the existing
16 thing so that we did not have to force a total
17 rewrite of brokers' software, a total rewrite of
18 their data bases. And, you know, for data bases
19 the size that we're talking about, to do what we
20 did in four months is--and, you know--are there
21 things that aren't working? Sure. That fact that
22 it's working as well as it did is amazing.

1 MR. WALLACE: Okay. Thank you.

2 MS. SCHMIT: I think part of what you
3 asked is an analysis of the prior notice. There is
4 a summary document that will go up on the web,
5 either today or tomorrow, I think--certainly by the
6 beginning of next week. It's been approved. It
7 might give an overview.

8 [Pause.]

9 MS. KOLAITIS: Do we have any more
10 questions? We'll take one final question, if there
11 is?

12 MR. : [Off mike.] I just had a
13 question--that was a good point about weekends.
14 You know on air-freight, you have a shipment that
15 you're meeting Friday, it's been consolidated in
16 London or wherever, and you have to put everything
17 together before it's going--I mean, all of a sudden
18 the broker becomes a 24-hour, seven day a week
19 operation.

20 And it just seems that this program is
21 going to put a lot of pressure on the broker. The
22 brokers are typically going to be the submitters.

1 MS. KOLAITIS: It's putting a lot of
2 pressure also on FDA. We've had--

3 MR. : Oh, I'm sure.

4 MS. KOLAITIS: --to establish a 24/7
5 review center.

6 So we're there to review it--

7 [Laughter.]

8 MR. : [Off mike.]

9 [inaudible]--the execution of the [inaudible].
10 It's going to put a lot of pressure on brokers.

11 MS. KOLAITIS: I understand. And that--I
12 mean, these are the comments you need to be
13 submitting with the docket. Your experiences,
14 suggestions on how it can be done, based on the
15 practice--either at the broker or the filer.

16 I think you mentioned it, or someone
17 mentioned it--you cannot assure the security of the
18 supply chain from the shipper to the consumer. And
19 that's where we are at the realities. We are in a
20 security situation. We are not talking about
21 adulteration or mis-branding under the traditional
22 FD&C Act.

1 MR. KENNEDY: [Off mike.] Joe Kennedy from
2 [inaudible]. I've got one question for you.
3 Interfacing with AMS for the arrival times on
4 vessels and aircrafts, otherwise how do you
5 determine whether or not something is eight hours
6 ahead, and two hours ahead and four hours ahead,
7 etcetera?

8 MR. [PANELIST]: Yes, my
9 understanding--there is an interface with AMS. I
10 assume they're using those times and dates, Joe.

11 [Pause.]

12 MR. : [Off mike.] So is the FDA
13 [inaudible]?

14 MR. [PANELIST]: I'm not sure.

15 [Discussion off mike.]

16 MR. [PANELIST]: I think we're currently
17 not getting the time data. And it's probably going
18 to be a post-audit enforcement.

19 MS. : [Off mike.] Again, I don't
20 always hear what I think I heard.

21 I thought I heard that a broker, even
22 though you do the transmittal for prior notice, is

1 not necessarily the submitter. So we can actually
2 go into the system on behalf of our employer, and
3 keystroke all the information in, having our
4 importer be the actual submitter [inaudible].

5 MR. [PANELIST]: Oh, yeah. That's the
6 whole idea of transmitter.

7 MS. : [Off mike.] And this goes
8 back to--you don't have to carry the burden--are
9 you following me?

10 MS. KOLAITIS: You're part of the chain.
11 You're part of the chain.

12 MS. : [Off mike.] But the
13 brokers seem to be concerned about being held
14 responsible as a submitter, but we're not the
15 submitter [inaudible]. And that's a liability.

16 MS. KOLAITIS: Right. When FDA decides
17 who to look at, they'll have to look at who was the
18 responsible individual.

19 MS. : [Off mike.] [inaudible]
20 information in incorrectly, you know, and putting
21 it--not incorrectly, but putting yourself in the,
22 you know, hot spot as the submitter, then--

1 MR. [PANELIST]: I think he's talking in a
2 business sense, not in a legal sense.

3 MS. KOLAITIS: Right.

4 MR. [PANELIST]: Okay? you're in the
5 hot-spot as a broker in a business sense. That's
6 the reality.

7 MR. : [Off mike.] Well, I'm
8 worried about that. I'm worried about a lot of
9 things.

10 [Laughter.]

11 But, I mean, I'm worried--

12 MR. [PANELIST]: If you want to work 24/7,
13 I think we have a job for you in Virginia.

14 [Laughter.]

15 MS. KOLAITIS: Okay.

16 MR. : [Off mike.] Talk about
17 business realities, and being held responsible--not
18 only for your penalties, but possibly the value of
19 goods. I mean, if we don't have prior notice, so
20 now we have to go to our insurance company and say
21 that we have--you know errors and omissions
22 coverage for food. And we've got to

1 start--[inaudible] you're going to be held
2 responsible for my \$100,000 [inaudible].

3 MS. KOLAITIS: It's a lot of
4 responsibilities with bringing food into the United
5 States, and it just got bigger. I mean, that's
6 just--

7 End Tape Side A.]

8 MS. KOLAITIS: --remain the same as it is.
9 But this is what we've started, and this is how we
10 have to continue.

11 MR. [PANELIST]: I think your concerns
12 about the weekend arrivals and stuff with air cargo
13 is definitely things you should submit to the
14 docket. Because that really is--that puts it to
15 the policy-level people to make decisions.

16 MS. KOLAITIS: Okay. Yes?

17 MS. : [Off mike.] I just wanted
18 to say one thing. I think this outreach program is
19 absolutely excellent, and very beneficial to the
20 importers and brokers. And I really appreciate it.
21 I wish it was sooner--like way back in
22 December--but, I mean [inaudible]

1 MS. KOLAITIS: Well, we did have them in
2 October. And if you want to go on-line, you can
3 see the satellite downlink. There's a lot of
4 information on the websites, if you have access.
5 There are tutorials to do the registration. So
6 there's a lot of outreach information--and more and
7 more is being added. Because we do recognize: no
8 one can do this overnight.

9 So--I mean, just you're being here, I
10 think is just evidence enough that you're interest,
11 that somehow the outreach is beneficial.

12 And, with that, we're going to wrap it up.
13 Thank you for taking the time to attend today. We
14 hope that it was informative.

15 [Session concluded.]

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