TRANSCRIPT OF PROCEEDINGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

ANTI-COUNTERFEIT DRUG INITIATIVE

PUBLIC MEETING

Pages 1 thru 365

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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ANTI-COUNTERFEIT DRUG INITIATIVE

PUBLIC MEETING

9:15 a.m.

Wednesday, October 15, 2003

Four Points Sheraton

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Bethesda, Maryland

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C O N T E N T S

C O N T E N T S

P R O C E E D I N G S

MR. TAYLOR: We recognize that some people are still taking their seats, but for the purposes of sticking to our agenda as best we can, we'd like to get started. Thank you. Thank you.

I'm John Taylor. I'm Associate Commissioner for Regulatory Affairs. I want to thank all of you for coming. There's an accident on 495 that has caused a bit of a traffic back-up on Wisconsin Avenue. That's one of the reasons why people are still making their way here. So an unforeseen circumstance that we had no control over, but we want to apologize for the difficulty you may have had in getting here.

Again, thank you for coming. As many of you know, in July the Commissioner announced a major new initiative to more aggressively protect American consumers from drugs that have been counterfeited. The new initiative created an internal task force to explore the use of modern technologies and other measures, such as strong enforcement, that will make it more difficult for counterfeit drugs to get distributed with or deliberately substituted for safe and effective drugs.

As we stated at the time that we initiated this effort, the task force was slated to submit its initial findings and recommendations in approximately 60 days in an internal report, which we released a couple weeks ago, and a copy of which, I believe, was on the table outside the room. And we also promised that we would issue a final report six months from the date of inception, which means that we'll be delivering a final report on this issue in January or February of the next year.

In addition, we stated that we would plan to coordinate more closely with other federal agencies and state and local governments that shared the responsibilities with FDA for ensuring the safety of the United States drug supply and distribution system, as well as working more closely with members of Congress and industry who have worked closely with FDA in the past and we hope will continue to work closely with FDA in the future on this important public health issue.

As you know, counterfeit prescription drugs are not only illegal, but they are also inherently unsafe. Many counterfeit drugs are visually indistinguishable from the authentic

versions and, thus, pose a potentially serious health threat to Americans.

In the United States, drug counterfeiting is, thankfully, still a relatively rare event. Although FDA believes domestic counterfeiting is not widespread, the agency has recently seen an increase in counterfeiting activities as well as a more sophisticated ability to introduce finished dosage counterfeits into the otherwise legitimate drug distribution channels. FDA has likewise seen an increase in its counterfeit drug investigations, from approximately five a year in the late 1990s to over 20 per year since the year 2000.

At the same time, worldwide counterfeiting of drugs is believed more commonplace. The World Health Organization, as many of you know, has estimated that perhaps 7 or 8 percent of drugs worldwide are counterfeit, and reports from some countries suggest that as much as one-half of those countries' drugs are counterfeit.

The FDA initiative, as we discussed when we rolled the initiative out, is designed to better identify the risks and threats from counterfeit drugs, also to coordinate public and private efforts to fight drug counterfeiting and

distribution, and to develop new tools to aid in identifying, deterring, and combating counterfeiting.

Specifically, the internal task force that we created set out several goals. The goals were to develop a strategic plan to decrease the risk of counterfeit drugs entering the United States marketplace and to protect consumers from potentially harmful effects of using these products. The second goal was to continue to strengthen FDA's collaborative relationships with other federal agencies, including Customs, the U.S. Secret Service, the Department of Homeland Security, the Department of Justice, as well as other state and federal law enforcement entities. In addition, we want to strengthen our collaboration with health professionals, industry, consumer groups, and other stakeholders who could be helpful in helping us gather information regarding the best practices for dealing with drug counterfeiting in the future.

We also wanted to identify mechanisms for strengthening the nation's protections against counterfeiting including such possibilities as model practice acts for adoption by the states,

best practices for those who sell and distribute prescription drugs, and better education for patients, pharmacies and others about how to identify counterfeit drugs and alert others to their existence.

We also wanted to assess the extent to which new technologies--for example, counterfeit-resistant packaging, product identifiers such as chemical taggants, and implanted radiofrequency chips in packaging--can help assure the authenticity of drugs.

Now, although some of this technology is not currently mature enough to adequately protect the drug supply now, it may have great promise as an added countermeasure against counterfeit pharmaceutical products in the future, and that's one of the reasons why we want to be prospective in looking at this issue.

FDA believes that the increase and shift in this illicit activity has occurred for a number of reasons. These include better counterfeiting technology, including improved technology to make labeling, packaging, and products that appear real but are not; better organized and more effective criminal groups attracted by financial

opportunities; the online sales of prescription drugs by unlicensed pharmacies and/or foreign websites; and opportunities for introducing foreign-made counterfeits and unapproved drugs into large and rapidly growing import flows; and also weak spots in the domestic wholesale distribution chain, including some wholesalers who acquire most of their inventory from second sources but do not necessarily maintain effective due diligence efforts on these sources and ignore warning signs indicative of illegal or unethical behavior.

As I alluded to earlier, this is a broad effort on the part of the agency. There's representation from the Office of Regulatory Affairs, the Center for Biologics, and the Center for Drugs, the Office of the Commissioner, the Office of Chief Counsel, and others within the agency. And we feel that working internally and working with all of you that we are quite confident that we'll be able to defeat the criminal element and do a better job of protecting the American public from counterfeit drugs in the marketplace. And that leads us to why we're here today.

As a part of our mandate and/or goal, we issued an interim report a couple weeks ago that

contained potential options for a multi-pronged approach to combating counterfeit drugs. The potential options contained in the interim report are premised on three interim conclusions that were reached by the task force:

The first conclusion is that there is no single magic bullet against the growing number of sophisticated counterfeiters; rather, a multi-pronged strategy to secure the drug supply could be much more difficult for counterfeiters to overcome than any single method. It could also be less costly because a one-size-fits-all approach is unlikely to work for all parts of the complex prescription drug supply system.

Secondly, although drug counterfeiters today are more sophisticated and better organized, as I alluded to earlier, there are many new technologies and approaches that have the potential to prevent and contain counterfeit drug threats.

Thirdly, because many of these promising ideas have not been fully developed, the task force believes that an opportunity for broad public comment is essential to guide its further work.

And as part of our effort to glean this broad public--information to the public and to

enter into a meaningful discourse, we decided to organize and hold this public meeting. We announced the public meeting as part of, obviously, our effort to combat counterfeit drugs. The purpose of the meeting is to enable interested individuals, organizations, and other stakeholders to present information on all aspects of the agency's initiative against counterfeit drugs.

We're particularly interested in hearing about information related to technology, public education, regulatory and legislative issues, and from industry and health and professional organizations regarding some of these issues. The agency has also, as you know, invited vendors of anti-counterfeiting technologies relevant to the pharmaceutical industry to display their products, and there's a room next door where that is going on.

We're excited to have this meeting. Before we start, there are some housekeeping issues that I need to discuss with you.

First of all, I just want to let you know that here at the front of the room are members of the task force and members of some of the subcommittees that stem from the task force. These

are the people that have been working on the issue. These are the people who've done the work that went into the interim report. And it's their efforts that will help drive the issuance of the final report at the beginning of next year. So I want to thank all of them for their help.

I want to thank all of you for attending. We look forward to your presentations. I want to thank all the vendors.

Due to the large number of presenters, we'll need to keep to a strict schedule. Presentations will be limited to the times that were sent to you by e-mail, and the time allotted for each speaker was determined based on the size of the panel.

I also want to remind you that the meeting is being transcribed; therefore, everyone should identify themselves and the organization they represent, if any, before speaking. The transcript should be up on the website seven days after this meeting.

We have a light that will flash--and where is our light? Oh, okay. Sorry about that. We have a light up here that will flash red when the time is up. When it flashes red, we will ask the

presenter to summarize and wrap up. Task force members will ask questions at the conclusion of each panel. Members of the audience will not be able to ask questions, but I do remind you that you have an opportunity to comment on anything that goes on here as well as the agency's efforts, and that these comments will be accepted until November 3rd. And as you know, if you go to our website, you'll notice that we have a docket devoted just to this initiative.

The Commissioner is due to deliver his remarks at 11:00 a.m. at the end of the morning break. If he is delayed, we will begin with panel number 3 promptly at 11:00 and interrupt when the Commissioner arrives. So I just wanted to give you that heads-up.

At the end of the meeting, we have time allotted for members of the public who have not previously asked to make presentations, we will allow you to do so. So please be patient.

Also, note that, as I said before, our Technology Forum is right next door, and we encourage all members of the audience to visit the forum to learn more about available anti-counterfeiting technologies.

Lunch is on your own. We'll begin promptly at 1:30 p.m., and lunch is not included. There was some confusion on that point, and so I just wanted to make that clear.

We look forward to an excellent meeting. I want to thank all of you once again for attending, and I'd like to call up the first panel. Thank you.

[Applause.]

MS. KIDWELL: Good morning. I'm Carla Kidwell from the Bureau of Engraving and Printing, and we've been asked to say a few words about the technology that we use in our bank notes and in our bank note manufacturing system. So I'm going to talk about that first. I'm going to talk about a few differences between what we do and what FDA does, followed by a little bit on our public education campaign.

First of all, we want to say we have information that's available on our new bank notes which was issued last Thursday, on the 9th of October. We expect our new 50 to come out approximately one year from then, followed by the 100 the following year.

What we know is that we have one to two

counterfeits per every 10,000 genuine notes, and it's interesting and you'll see this later in the talk: This $200 note was actually accepted by someone in a Dairy Queen who gave change for $200.

All right. This is our new 20. I'm sure some of you have seen our public education that we've begun, and certainly some of the ads are on the football fields.

For our technology, we like to use layers of technology. So the first piece is the overt, which is available for the public and everyone to use, and we talk about those features and try to educate the public on those features so that they do not accept counterfeits.

We also have covert features. We have detectors, machines that can pick up those features. And then there are forensic features that are available in the laboratory.

What we've determined over the years is that with technology growing at a very rapid rate, we need to change our notes every seven to ten years. And so we had a cycle that started in 1996, and now this one is starting in 2003.

BEP is a manufacturing outfit. We manufacture and secure financials. We control all

of those facilities, very high levels of security. Our Fort Worth plant is surrounded by a hundred acres of land; Washington, D.C., like a fortress.

We also are very careful about the suppliers who supply to us, and our security team goes out to those suppliers and assures that they, in fact, meet the security requirements that we have.

We sign nondisclosure agreements with selected vendors when we have these unique features we're including, and the last policy is, in fact, that for the larger denominations, we put in more features of higher level.

All right. So let me just take a minute to run through the features on our new 20. What you have is an embedded thread that you see here. You hold the note up. It's a transmissive feature. Hold the note up to the light, you can see the thread in there. The thread has text on it that says "USA 20" and has an American flag with the 20 in the star portion.

Also, when you hold the note up, you can see the paper watermark, and that watermark is supposed to match the picture that's printed on the note.

And we have optically variable ink. In this case now, depending on the angle, the color changes from copper to green.

For other public features, we tell people to take a look at the engraved portrait. Engraved portraits tend to look much different than offset or what you can scan on a computer.

We ask you to feel the notes, and, in fact, most of the counterfeits are picked up by people who detect a difference in feel. That's very normal. That's what causes people to look at the notes in the first place.

And then if you look at your notes, you'll see distinctive red and blue fibers, and you can see those in the pictures so you can look at those as well.

We have other features that are apparent with a small magnifier. We have microprinting that is in both the offset and intaglio printing, and it's shown here in the slide. And, of course, there's a blown-up picture of the thread with the USA 20 and the 20 in the flag portion. It didn't come out too good.

We have covert features, special inks with varying magnetic properties or spectral properties,

special inking patterns, unique fibers and a unique substrate.

We do have some system differences with FDA that we want to point out to everyone. BEP is a manufacturer. We can control what we put in. We can control our suppliers. FDA is a regulator.

We also control all aspects of our process. We write the contracts for our materials. We approve the security requirements at all the supplier sites. We sign the nondisclosure agreements.

The currency itself, once it's packaged, is shipped direct from the BEP to an armored carrier straight to Federal Reserve banks, and we also have each note uniquely marked with a serial number that we can track back through the process and we can determine authenticity with that.

The other piece I wanted to point out because in the report from the committee I saw the packaging issue was very much in the forefront, so I wanted to just say a couple words about our packages.

First, we strap our notes in packs of 100, and we call that a strap. It's a paper strap that goes around it since you can't see the picture.

Then we have a shrink wrap film that goes around ten of those straps, and that is called a bundle and that's a thousand notes. Then we put four of those bundles together and shrink wrap it again, and that's 4,000 notes and that's called a brick. And then we take four of those bricks, and we have a 10-mil thick film that goes around those, which is called a cash pack, and that's 16,000 notes.

Still, there's one more layer. We have skids. We put 40 cash packs on those skids, put top boards with straps and seals, and five layers of shrink film that goes around those skids.

So we control the packaging. The packaging is set up so that the Federal Reserve can break down the packages as they do their shipments to commercial banks any way they'd like to break them down.

We also have a product that can be looked at transmissively, something that FDA for the most part can't do with bottles that you would be applying labels to. We can handle our product to determine it, and feel is very important. We have labels in which you can't use the transmissive attributes, and you have the issue of whether you put your anti-counterfeit features in the pills

themselves or the liquid or whether, in fact, you put it in the label.

All right. Public education. First of all, the public education campaign for our new 20s and for this whole new series 2003 is a $53 million effort. The first order of business, to find stakeholders: Federal Reserve, commercial banks, retail outlets, gambling casinos, machine vendors, transit authorities, the general public.

We used the vendor that we hired for the public education, went out, used our focus groups to find out what people knew and didn't know about their currency, what the previous education programs had determined to be successful and which were not. And our goal was that 88 percent of the public be educated.

The first education piece was to let everyone know that your notes never go out of style. They might go and look different. They are always accepted, no matter which series.

We had targeted messages for key groups: African American, Hispanic, Asian American markets, news media. We have plans to spend 60 percent of the budget the first year since this is the first note out. We have a number of brochures, and I

brought I think about 150 of them, if anybody is interested in looking at the brochures. They're printed up in 25 languages. This is a worldwide education plan. We have articles and photographs in 90 of the U.S.' largest newspapers. We also use trade journals.

In addition, we used direct mail outreach, e-mail and post. We have a database of 28,000 businesses and organizations that represent cash handlers.

We have a website called MoneyFactory.com. The information is downloadable 24/7 in 25 different languages.

We've also used some paid media placement in more than ten countries. What you see up there is the Times Square billboard that was up for our introduction last Thursday, airport, subway, taxi toppers in major cities, and 1,300 prime-time spots over a two-week period to make everyone aware of the change.

We also got some help from some corporate partners which provided us with some free advertising. Wal-Mart did their own education of all of their employees, had special messages throughout the stores. Ace Hardware set up a

contest with the winner coming to Washington, D.C., and getting a tour of the BEP. They also set up a wind tunnel, which is probably a lot more exciting than our tour, in which they sent people in to grab as many of the new 20s as they could in the wind tunnel. So people had a lot of fun with that.

And we had a partnership with Pepperidge Farm, and actually, I brought some goldfish today. They're advertising new colorful goldfish, so there's a school contest on here in which you can win cash and those new $20 bills.

We've also gotten a lot of partnership with a number of shows. Our note was displayed on the "Wheel of Fortune" for a week. It's been on--well, you can read the list of some of the programs that we have on, stories that include our new $20 note. And I also brought along for the panel and anyone else who's interested a list of all of these TV shows that will, in fact, feature the 20, and there are quite a number of them, a very large list.

Bottom line that I want to close with is that U.S. currency will change, it will continue to have multiple layers of security, but that it will always maintain that distinctive look and feel that

make it uniquely American.

So thank you very much.

[Applause.]

MS. FORTUNATO: Good morning. I'm Sue Fortunato. I represent the Secret Service, and we are also now a part of the Department of Homeland Security. So I wanted to address you and tell you what we are doing with FDA in product counterfeiting cases.

Very briefly, the mission of the Secret Service, as everyone knows, we protect the President, Vice President, families, dignitaries, numerous people, as well as we are in charge of protecting the monetary system of the United States.

The Forensic Services Laboratory is the Secret Service's crime laboratory, and this is where we look at all evidence to determine whether things are genuine or counterfeit and link counterfeit documents together. Particularly, I wanted to point out that we are not a full-scale forensic lab. We're not like "CSI." We don't do DNA. We don't do trace evidence. We are specifically tasked with looking at financial types of documents and threatening types of documents.

So that means letters, monetary types of items, credit cards, currency, traveler's checks, even identity documents. These are the types of things that we look at, and as a laboratory we've gotten very, very good at some of the things that we do. And as a result, we open up our laboratory to other federal, state, and other local agencies to be able to use our services.

A few of the questioned documents examinations that we will conduct include looking at handwriting and authorship. Obviously, this comes into play with threat cases as well as financial crimes cases. We look at indentation analysis trying to find information that's been unknowingly indented into documents. We restore altered and erased material. Oftentimes in financial crimes, documents are dummied up after the fact to try and make them look like they were doing genuine business transactions. So we look at those documents also.

The next two items, to determine the age and whether they're genuine or counterfeit, are unique to the Secret Service. There are no other federal agencies that analyze documents to this extent, and for that reason, as I said, we open up

our laboratory to other federal agencies, state, and local for criminal types of investigations. And, finally, we do provide investigative leads and courtroom testimony if necessary.

I'm going to skip the stories. We're short on time. But this is an example of a threatening letter. Obviously, we will look at this to try and identify the writer based on suspect writing, as well as when we do get threatening cases, it is important for us to consolidate cases together to try and identify one writer who wrote numerous letters.

This is an example of a financial crimes type of case where we have a document that's dated and it has signatures on it. We'll look at not only the authorship, but we will also look at the document and what comprises that document--the ink, the paper, the ink jet printing, the toner that appears on it--to determine how old that document is.

And, finally, the oldest reason why the Secret Service is in existence is because of counterfeit currency. We were initially founded in 1865 because one-third of the currency in circulation at the time was counterfeit. And so

for the last 140 years, we've been looking at not only currency but also all the other types of financial documents.

And as you can see, there are a lot of them. Today we've got traveler's checks and credit cards and birth certificates, as well as identity documents. Nowadays the identity documents go hand in hand with the financial documents because the counterfeiters are creating packages or sets of identification. You can now buy a birth certificate, a driver's license, and a number of business checks, and you're ready to go.

What we do is we look at these documents and compare them to one another, and we try to determine, first of all, if it's genuine or counterfeit; and then, secondly, can we link the counterfeits together? Can we say that multiple items are all the result of the same group of people or the same source? And that's what we do here. This is giving you an example of looking at documents that are printed on paper. Currency is printed on paper, as are traveler's checks and birth certificates. So we're very good at looking at items that are printed on paper.

We're also very good at looking at items

that are printed on plastic. It's a completely different type of a substrate, and the printing appears very differently. But what we can do is, as we take a closer look at things, these two items were found in completely different areas of the country. But as we take a close look at them, we can see that not only is the hologram a very crude imitation of an original, but the Visa logo has also got a lot of problems in it as well. And by comparing these two items together, we can say that they are identical, and as a result they came from the same source.

Just to give you a couple of other examples of the typical types of cases that we look at, this was a situation where we had two maps that were being contested. One source showed their map on the left as being very different from the map on the right, and they wanted to know whose was genuine and authentic. Comparing the two, the one on the right you'll see the red circles. Those are areas where there are remnants of that line that originally appeared there. What's happened is someone has taken an image, either a digital image or a photograph of the original, and they've removed those lines, and now they've reprinted it

again. But in doing so, they've been fairly sloppy, and this is what we find with a lot of counterfeiters, and this is what we look for forensically.

Another example of a type of case that we've done, Nazi war criminals cases are very popular lately, and this case, we looked at not only the ink, the paper, the typewriting, and determined that everything was legitimate with respect to the date of 1945. Of course, once we render that opinion, they come back and say, well, then, obviously the photo has been altered, can you look at that? So we were able to do that type of examination as well and determine that, no, this is the original photo that appeared here.

And, finally, as a last example of the types of cases that we've been involved in, this is an art theft off of the West Coast. This was 17th and 18th century drawings and paintings that we looked at. And the gallery had said that they had stamped all of their items with a unique marking. And so we set about looking for that mark, and we did find it not only obliterated under black ink, but also under some very thick tape. So we were able to illuminate that original seal and say that,

yes, this is originally their product.

So now that I've told you who we are and what we do, let me tell you why we're involved with the FDA. Just like our own cases, the product counterfeiting type cases do affect the monetary system. And I already mentioned we frequently receive criminal cases from outside agencies. Because of our unique capabilities in looking at documents to the extent that we do, we've opened up our services to other agencies. And they are submitted by FDA. We for at least ten years now have had a memorandum of understanding with the FDA to analyze cases of this type, and we have successfully been in business with them for ten years, and we hope to for the next ten and onward.

I'd like to show you some examples of the types of counterfeit products that we've received from the FDA. There are three general categories: one is an altered genuine product, the second is an all-out counterfeit product, and the third is counterfeiting just the shipping containers.

Now, I'm only giving you these examples because that's what we've seen from FDA. I'm sure that there are some others that I may be missing. Before I continue, I also want to let you know that

we do not do any evaluation of the drugs themselves or the food products themselves. We don't look at the ingredients to determine their quality or quantity of the ingredients. We simply look at the packaging and the printing that's done on the outsides.

And one last note. I apologize if there are any manufacturers of these particular products in the audience. This is not an indication that your packaging is not secure enough. What it is an indication of is the counterfeiters are attacking the products that they are going to get the most bang for their buck off of. So what you're going to see is these are the expensive products that are out in the market that are being counterfeited.

This is an altered genuine product. What I've done and typically what I do is I open up the box the very first thing when I get it, so it's laid out flat so you can see the whole thing or at least most of it.

On the end of it, it has a lot number and an expiration date. And if you look closely that lot number and expiration data, that blue box, is not registered and it's not aligned with the top black writing. So that was the first thing that

tipped off someone at the pharmacy or in the distribution chain.

So we took a look at this, and if we look really closely at it, that's actually a blue box that's been reprinted and it's affixed, it's taped down to this box. And all it is, it's altering the genuine product to say that rather than expiring the year 2000, this product now expired in 2002. So they expanded its life span a little bit. So that's an altered product.

This is a counterfeit product, an entirely counterfeit product. This is Nutramigen, Enfamil. About five years ago, this product was $20 to buy in the supermarkets, and I know from personal experience, I should have bought stock.

[Laughter.]

MS. FORTUNATO: But this product, when it came to us, inside the cans it was not only expired product, but it was also different types of product. It was soy or the regular infant formula that most infants can handle. My daughter decided to go the designer route, so we had to buy this.

This is very expensive. It's also for colicky babies and it's semi-broken down, so it's very expensive to buy.

What the counterfeiters had done is they simply took the products, the soy products and the other types of products, photocopied an original or a genuine Enfamil, Nutramigen label, and simply pasted them around these cans and sold them as Enfamil.

Our Latent Fingerprint Section did do an analysis on these as well, and we were able to find fingerprints on the undersides of the labels identifying a male and his girlfriend as the perpetrators behind this case.

Here's another all-out counterfeit. Now, this one I want to show you a little bit more detail on how it's printed, because this one is printed not by using an ink jet printer or a color copier, which is the easiest way, but by using the same methods that the genuine manufacturers employ, the commercial types of printing processes using offset lithography.

Generally, the genuine is on the top and the counterfeit is on the bottom, or the genuine will be on the left and the counterfeit will be on the right. But the next few slides show a comparison of the two.

In this slide, you'll see that at the top,

the genuine is much more--it's a much better quality print. The bottom has got all this stairstepping. And so the counterfeiters aren't as concerned with how nice it looks, just by--they're just interested in mimicking the product.

And here, notice the style of the lettering that they've chosen. It's not even the same as the genuine. The genuine registered trademark, the numeral 6, and even the information at the bottom, it's all different fonts and styles.

And when we get to the vials of that particular product, they've done the same thing. They are not looking at the style or the quality. They're just interested in reproducing the name where it should be very basically.

And here's another comparison of the genuine product versus the counterfeit. The counterfeit is on the bottom. You'll notice that the registered trademark doesn't even hardly show in the lower picture.

The other thing that I wanted to point out with this picture is that the counterfeiters are not--don't pay that much attention to their alignment. If you notice in the bottom slide, the blue and the yellow and the black don't necessarily

register very appropriately. And in this slide, the same thing. The green and the black are not in alignment.

Lucky for us the counterfeiter's sloppiness helps us forensically identify them. If you notice, this is a comparison of two counterfeit products, and what we've done in this case is look at all the sloppiness and compare it and be able to identify another product and say that these two are the result of the same operation. If you look in the "l" of "Tablets" at the top and also at the bottom, as well as in the "t" and the "s," there are dots and dashes and different defects that appear. And those appear to us as a printed fingerprint, basically, that allow us to connect things together.

Again, this is another comparison of a counterfeit to another counterfeit, and you can see how truly sloppy they get. Sometimes it's difficult for them to get pictures of a round vial, and so what they do is take a picture, move the vial a little, take another picture, move it again and take another picture, and end up stitching all those imagines together. So that appears to have been what happened here. Right through the "c" and

the "r" was maybe one of those areas where they had to stitch two negatives together.

And this is the final slide, just showing you the different defects and how we can identify that product. And these are some of the examples of information that we will give back to the FDA and let them know to look in these areas, these specific areas to see if this is the same product.

And the final example is the counterfeit shipping containers. The shipping containers were sent to our laboratory. They were cardboard boxes. We also received the printing plates that were used to produce them.

What I learned happened in this case is that the genuine product was stolen off the streets, and there were drug addicts that were given money for those products. They took the products and their counterfeit containers, the cardboard boxes that they had produced, and sent them both off to the Institute of the Blind, asked them to repackage the boxes, and then they sold them to retailers, whether they were knowing retailers or unknowing. And then any damaged products in the process of all of this they donated to women and children's shelters. So they

certainly have an operation going. It's just that, you know, they were dealing with original stolen product.

So we were able to look at the containers themselves and the printing plates and say that, yes, these plates were used to produce these boxes, and that is the printing operation source.

We're continuing our cooperative effort with FDA to analyze drug products as well as food products, like I said, the labeling and packaging only. And we have also made an offer to the FDA to accommodate them in a database that I'd like to just briefly preview. Our database contains genuine samples as well as counterfeit samples, and it is available on the Internet for law enforcement.

It began in the 1990s. Our latest version was just finished the other day. This year we put $400,000 towards it, and now what we have is all counterfeit and genuine documents, both identity type documents, driver's licenses, identity cards, credit cards, traveler's checks, all kinds of different documents in here, not only the text on them, their numeric information that appears on them, but also graphic images of each one. It's a

Web-based application, and it's available through the Internet, but it's a private website that you need an access and a password to get into and then from there you again need another user password and--I'm sorry, user name and password to get into our database as well. So there's two levels of security there.

The enhancements that I'd like to mention are particularly the alerts and the hot sheets. For law enforcement it's fairly obvious, but what that means is that any investigator can go onto this database and pull up either a genuine item or a counterfeit item, such as the new $20. If you wanted to print posters around your office or in your store, you would be able to pull down those images and make a poster and say here are the new security features of this document and be on the lookout, you know, we're going to begin to see this. Or if you're getting hit particularly hard with any kind of a counterfeit, you could post these alerts to say look out for this and look in these areas to see if this is a genuine product or not.

There are a number of different options as far as searching this database, not only from

suspect description to where it was passed to how it was made, and then once you find that particular item of interest, it will give you all the information, including additional cases that are linked to that.

Once you click on any particular item, you bring up that item as well as enlarged either security features, such as microprinting, that we would want you to be able to read what it says, or particular areas of interest with a counterfeit to denote here's a misspelling, you know, you can look in this area to see if this is the counterfeit that you may have.

Some of the things that we've shared with FDA as far as anti-counterfeiting techniques include the following, and many of them have already been voiced. It is a multi-layer approach. There is no silver bullet, just as Mr. Taylor had mentioned earlier. We have suggested things to the pharmaceutical industry as well as the infant formula manufacturers, things like increased graphics, unique fonts, and sometimes deliberate mistakes are kind of nice. Sometimes when the counterfeiters are reproducing things, they see that and think that it's a problem and they want to

change it and make it look correct. So that can also be used as a security feature.

There are things that you could use such as color, anything other than cyan, yellow magenta, and black, which are what color copiers and color ink jet printers use. So we'd like to try and stay away from those as much as possible. Obviously, they can be used, but should be used in combination with other true colors.

Security features, there are overt and covert types of features that can be used as well as security packaging. All of these things can be implemented at any stage in the distribution chain.

The final item that I'd like to bring out is education, and the BEP has really done a great job with the new 20s and showing you their education program. This is really a very important piece to any kind of security. If the recipients don't know what to look for, you've spent a lot of money for no particular reason. So we try and educate people as much as we can on our end. We're going out and instructing law enforcement on what to look for, and we're giving them this database and allowing them to look up certain things and give this to them as a tool.

And, finally, I just wanted to thank you for your attention, and I wanted to thank FDA for the invitation.

Thank you.

[Applause.]

MR. THIROLF: Good morning. I'm going to go through this as quickly as I can, so hold on to your hats, if you have hats.

OCL has been around for 30 years. We represent FDA, FTC, CPSC, national highway transportation agencies. We've been doing it a long time, and these are my views, not necessarily those of the Department of Justice. This is who I am and my phone number. This is the office. This is where we are in the CFR. The point of contact policy, we are in contact with every U.S. Attorney's Office around the country through their fraud coordinators. Our monograph is on the DOJ Web page.

I thought, first of all, we're dealing with the Food, Drug, and Cosmetic Act. What are the elements of the offense? When these cases are indicted and presented to a trier of fact, jury or judge, we've got to meet the elements of the offense. Rather than give you a long jury

instruction, here's the statutory definition. I want to point out one particular point. The violation is bearing the identifying mark of another drug manufacturer. One of the keys to this is being able to find that mark and present it. The Secret Service obviously is critical in being able to show how the bad guys are falsely representing the drug to be the product of that manufacturer.

There are other statutes. We use 18 U.S.C. 2320, which is the trademark statute. We use mail and wire fraud, which has been enhanced. Mail and wire fraud is now a 20-year max. The Sentencing Guideline has been amended. More than 250 victims adds an automatic six to the sentence, and we've gotten 18-year sentences under the mail and wire fraud statutes.

I want to go through this. When Paul asked me to talk about this, I said we ought to at least give a very brief statement about what the history is. And let's go very quickly.

Jamieson-McKames was a drug wholesaler on the edge of the distribution system. They were making some money. Motrin had just come out. Motrin was a very popular, in-demand product.

There wasn't enough supply. What did Jamieson-McKames do? They bought 200,000 doses of magnesium salicylate to look like Motrin, and they put Motrin out on the market through their own wholesale operations. The Eighth Circuit Court of Appeals in a very strong opinion from Judge Arnold supported the conviction and the eight-year sentence each of those folks got. In that time, 1981, an eight-year sentence for a Food, Drug, and Cosmetic Act violation was unusual.

The next one I want to talk to you about is Ovulen. Searles' Ovulen product was on the market. It was new, it was effective, it was successful. There wasn't enough of it, so what did Shelly Harwin do? Shelly Harwin went out to his Spanish manufacturer of Ovulen, brought it into the United States, repacked it, sold it through what was his own connections with a fairly on-the-gray-line drug distribution operations, and it was very successful and they made a lot of money.

The problem was Shelly was in trouble with the Federal Government on other fraud issues, was arrested, so his accomplices, Alfonso and Villone, went off and they had to find some Ovulen. They found some in Central America. They sold it. On

the counterfeit they made a lot of money.

The next item was they couldn't find any active ingredient, so they went to a Central American manufacturer, and they made an Ovulen look-alike with no active ingredient in it, sold it and made a lot of money. They were caught. Judge Keough, over a two-and-a-half-week trial, heard all the evidence and sentenced them to 26 years in jail, which I think is still the longest food and drug sentence out there.

I'm going to go through these even quicker. Nahdi was a guy who was trying to counterfeit antacid. He got 12 years. He was arrested in England, and there's an international flavor to these cases that follow here. He would never have been caught if we hadn't been able to convince SmithKline to offer a letter of credit which brought him out of hiding and into London. Flavine is an animal antibiotic. Drugs are being counterfeited that just aren't for humans but for animals. Four years' imprisonment. The main guy would not have been caught but for the fact he and his girlfriend went to Paris for a vacation. They got off at Frankfurt. They left Frankfurt. They went to De Gaulle airport. They were arrested at

the airport and were extradited to the U.S.

Roussel Uclaf, this relates to--it's not counterfeit in the classical sense, but it's product made where it's not supposed to be made, represented to be Cefaclor that was made in a particular way according to the drug master file. They were convicted, $23 million fine, $10 million forfeiture credited to FDA. Again, that operation was overseas in Italy.

Milstein is a recent prosecution for Eldepryl. Four-year imprisonment. Again, a guy who was operating on the fringes of drug distribution, a wholesaler out of his house, and also involved foreign operations involving Israel and everywhere else.

Look, early communication to FDA is essential. The sooner that FDA can know that there's a problem, the sooner that OCI can begin to look at the issue, the sooner that we can make a judgment on the public health consequences.

Undercover work is essential for industry and OCI to be working closely so that you are able to pursue that undercover lead. These are guys who are hiding and they aren't going to come out.

There is a potential for bioterrorism

exploitation, the terrorism section in Main Justice, there are terrorism officers in each U.S. Attorney's Office. Any of that will be closely and very effectively dealt with.

There have been and will continue to be, I submit, public health issues which are going to affect the investigation. If this is a product which can hurt people, the balance between when do we tell the public that this is a problem which affects the company, a victim in this situation, when do we stop the investigation in order to go forward to deal with a public health issue, has been a theme.

The final line is follow the money. It's going to cost millions. Anybody who is going to go into this business in the U.S., in my estimation, who is not a one-time operator is going to be dealing in large quantities of dollars.

How do we decide when we pursue a case? Well, this is a standard you'll hear from every U.S. Attorney's Office. What's the deterrent value? What's the guideline range? The guideline range for counterfeit drugs, I submit, can be very substantial. If they are charged under mail or wire fraud, that's a 20-year max. Does the statute

need some attention? I think it does. And over the years, we have been blessed in this country by not having major counterfeit operations. But my fear is that the value of the American pharmaceutical market is so attractive that we have to be on guard for these.

What are DOJ's priorities? I will tell you that for our office, if FDA says this is a priority, it will be done. U.S. Attorney's Offices I think will be responsive when we will be able to show the consequences that these cases have caused. In Jamieson-McKames, in Ovulen, there were situations where people were put at very serious risk.

Can the defendant help the government to prosecute others? We are always looking to go up the chain, and finding the local guy who is dealing out of the back of his car isn't the focus necessarily.

Prosecution I think is essential to deter these folks. There are unscrupulous markets out there. The prescription drug market had a positive influence, but I still submit there are unscrupulous markets which permit these sorts of on-the-edge characters to sell drugs through a

network that saves money for the bad guys.

Cooperation is key between FDA and law enforcement and prosecutors. The sooner the criminal focus is there, the sooner you will get results, and I submit you will get outstanding results.

Thanks very much.

[Applause.]

MR. TAYLOR: Is Ms. Hofmeister here? If not, we will open it up for questions from task force members to the panel members. I have one question. This is for Ms. Kidwell. Obviously, you have done a lot of thinking about your outreach, and I notice that some of the shows that you picked have an enormous audience, and I actually saw it at the Michigan-Minnesota football game.

But I guess my questions is: How do you track how many people you are actually reaching? Is it an extrapolation based on the ratings and the reach that you know some of these shows currently get? Or do you monitor the outreach over time to see whether or not your efforts are making a difference? And are you tracking how many people you're actually reaching?

It's something we've been trying to think

about ourselves in refining our message and refining our status.

MS. KIDWELL: We use focus groups in the field, and we'll be going back to focus groups to find out how well our message has actually been received due to the public education campaign. As you're talking about this, obviously it's very difficult to find out how many people actually understand what the message is and are people using those features that have been provided them to determine authenticity. And it's always difficult to tell. We see notes and I know my colleague here from the Secret Service sees notes in terms of counterfeit notes that are--the counterfeits are mostly terrible and, really, most of them, if people paid any attention at all, are missing very essential features, whether it's the watermark or the thread, because if they're put on on a computer, which for $20 notes is where most of them are counterfeited, then counterfeits are very, very poor in this country in particular. And the $100 is the most counterfeited note overseas, so what we try to do, again, is keep the information coming in from the Secret Service, from Interpol, to find out what kind of issues we're having over there,

whether people appear to have a good understanding of what we've been trying to teach them.

MR. TAYLOR: Any other questions?

MR. McCONAGHA: I have a quick question to address to the panel generally. We saw some very dramatic examples of clear counterfeits in terms of actual product labeling and, in fact, it looked to be product labels, the actual container's unit of use. I'm just curious. In your experience, can you give us a sense in terms of the counterfeits you see as to what layer of packaging, for lack of a better term, you see most of the counterfeit materials appearing? Are we talking about kind of large-scale shipments in which people are counterfeiting the labels, the labeling that might appear on, you know, lot-size packages? Or do you find more typically that you're dealing with unit-of-use distribution vials and that kind of a situation?

MS. FORTUNATO: I think I can only speak based on the different types of cases that we've seen from your agency so far, and they are attacking any portion of that chain that they can get to. We had the example of the cardboard boxes. We've had cases where it's the genuine product in

the inside, and then they just counterfeit the label. And then the other was--let me think. Well, it's either just the label--or it's the genuine that they take and then they alter the packaging.

So at any stage that they can get to in the distribution chain, it appears as though they're willing to attack it. I don't know that anything is more vulnerable than anything else. In fact, there's a current case that I'm working that old vials--genuine vials were retrieved from the hospital refuse, and they were collected and then reused with nothing in them but tap water.

So there are a lot of different attacks to the different drugs and products, so I don't know that anything in particular is being attacked.

MR. THIROLF: Basically you'll see the whole range of things over the history of this, but anybody who's in it to sell tens of thousands of doses will counterfeit every piece of the item, from the package insert down to the packing material or the shrink wrap or whatever. Someone who's going to be doing a much smaller item will cut it down, obviously, but anybody who's seriously going to counterfeit large quantities has to do it

from the beginning all the way to the end of the process in order to have it salable.

MR. McCONAGHA: And you've seen that, Gene?

MR. THIROLF: Yes.

MS. KAO: My question is for Ms. Kidwell. I wanted to mention that there seemed to be a lot of potential parallels between our public awareness campaigns. We both have to raise awareness among the public that there is potentially a problem, and we have to educate them on how to respond when there is a problem. And all the while we have to reassure them of the integrity of our products out there.

You mentioned a lot of collaborations, a lot of collaborative efforts that you're involved with. I was just wondering if you can tell me a little bit about the dynamics of those collaborations, some lessons learned perhaps on how best for a government agency to collaborate with outside groups. Are you the driving force, or are you merely consultants? Or what have you found to be most productive?

MS. KIDWELL: Well, I think one of the things that we know has helped us greatly is hiring

a contractor who, in fact, has the context to allow us to develop these partnerships in the first place. And that becomes absolutely critical if we're trying to get a partnership on a television show and so on, which, of course, is how much of--many of the people in the U.S. are reached. So if you're trying to reach individuals, that's certainly a powerful medium. And I know our lesson learned from before--we've had public education campaigns before. We've never spent this much money before. But what we found out is that just printing up all of these brochures or having articles in newspapers does not reach all of the public that is necessary to reach.

So we also had tried to use just the public service announcements on television so that we wouldn't have to pay out all of this money. And what happened is those spots ran at, you know, 2:00 a.m. or some other really good times when no one is watching. And so what we learned is that we do need to get the message out prime-time, and some of the partnerships and the contacts that we had to make the partnerships that have allowed us to work with a Wal-Mart or an Ace Hardware, I mean, nationwide facilities that reach an awful lot of

people. It's been a very good experience for us, and some of these little games that are played, whether it's "Wheel of Fortune"--I mean, that was another one. We got free publicity, basically, a partnership with the game shows where you just get it laid out. And so what was essential for us was having a contractor who had those contacts, knew how to reach those particular groups.

And I'll also say that the other very big success this time--and I think we've done a lot better with this--is targeting to specific groups, whether it's the Asian American community or African American community, and through various media to target different age groups, because it's sometimes also very difficult to reach some of the young people, too. So there have been specific targets there as well.

MR. TAYLOR: Any further questions?

MR. RUDOLPH: This is for Ms. Kidwell. You had mentioned that there were differences in federal oversight between money and drug products when it comes to development and use of anti-counterfeiting technologies in packaging and kind of initial, if you will, distribution of product.

Do you think then there are any

implications for the actions that would need to be taken by FDA and by members and participants in the drug distribution chain or in the roles that those different members would play as a consequence?

MS. KIDWELL: Well, I think FDA has very difficult task in front of it, considering, again, you don't control the manufacturing of all drugs--some come from overseas--and you don't have any real control over all of the various stages of repackaging. And certainly what our experience is is that the controls up front are what makes the system work for us. What we know is if you are going to include specific anti-counterfeiting methodologies in there, you know, having control over the manufacturing facilities so that they're not available to anyone and everyone, and to have the packaging so that you know it's consistent. We have rules, when people do open packages in which, for example, in a shortage--and there are sometimes a shortage or overage in some of the notes. It doesn't happen very often, but there are specific rules when someone breaches the packaging that, number one, someone else has to be in the room, someone else has to testify that the package--the original packaging must be kept intact. The Secret

Service would be looking at that and so on.

So, you know, the lesson for us has been, you know, very good controls. Doing the security surveys of the plants that manufacture the anti-counterfeiting pieces for us is a crucial piece of the puzzle, and I don't know enough about FDA's regulatory authority, whether you, in fact, could get some additional authority to begin to take over some of those tasks.

MR. TAYLOR: Any other questions?

MR. RUDOLPH: I just have one other. Sorry.

Mr. Thirolf, you had mentioned that the mail and wire fraud statute was pretty good, but that it does need some attention. And I don't mean to put you on the spot, so if you want, you can take the Fifth, if you will. But I wanted to see if you might be able to elaborate on what changes you all thought should be made and whether there were any other either new authorities or changes to existing authorities that should be undertaken.

MR. THIROLF: I've made a career of not taking the Fifth Amendment, so I'm not going to change now.

[Laughter.]

MR. THIROLF: I think there are two points. Obviously, this is an issue which has gained more attention because of the opportunity that the United States market provides for the bad guys. And I think that we are relying on statutory provisions that have been in existence a long time, and I think FDA is the appropriate agency to make some judgments about whether those statutory provisions need some update in terms of bringing those definitions into compliance with the technology, for example.

I also think that we are much more international drug production operation today than we were 20 years ago when Jamieson-McKames was being prosecuted. And I think FDA--and this is my personal opinion. FDA should have some additional authorities to be able to obtain from the foreign manufacturers or distributors the information they need not only for regulatory purposes but for whatever enforcement purposes FDA should pursue.

We have communicated to the House Oversight Committee in the past that giving FDA explicit extraterritorial authority in the statute would be a good idea.

I think that you all at FDA know better

than I what sort of tweaking the statute needs to give you the tools you need, and we would be happy to try to work with you and give you what insights we have.

There has been, as you can see, a limited number of these counterfeit cases brought, and I think we learn a little bit each time. And I hope we don't ever have to do a lot of them. That's my hope. And if we do, I think using the tools that we have to get as large a sentence as we can is possible.

MR. TAYLOR: All right. I want to thank the members of the first panel for their thoughtful comments--we really appreciate it--and call up the members of the second panel. The first speaker will be Mary Ann Wagner from the National Association of Chain Drug Stores. Thank you very much for your thoughtful presentations.

MS. BERNSTEIN: To speed things along, if the panelists for Panel 2 can come up and sit at these two tables in the front, that would be very helpful.

MS. WAGNER: Good morning. My name is Mary Ann Wagner, and I'm Vice President of Pharmacy Regulatory Affairs with the National Association of

Chain Drug Stores.

NACDS and its membership consists of 210 retail chain community pharmacy companies. The chain community pharmacy industry is comprised of 20,500 traditional chain drug stores, 8,800 supermarket pharmacies, and nearly 6,300 mass merchant pharmacies. Our pharmacies fill over 70 percent of more than three billion prescriptions dispensed annually in the United States.

We wholeheartedly agree with the FDA when they say there is no magic bullet to solve these very serious counterfeiting problems, but we stand ready to work with the FDA to develop solutions that will work. It is critical to the chain drug industry that the consumer have confidence in the pharmacist with whom they place their trust. It is equally important that our pharmacists have confidence in the integrity of the drugs that they dispense. We depend on the FDA and their scientific expertise to approve only those drugs that are safe and effective for the American consumer. Anything less should not be allowed in our distribution system.

It is a concern that some of the potential options laid out in FDA's interim report would have

a counterproductive impact on our industry. In our final report to the FDA, we will point out options that are not realistic or affordable.

NACDS's Leadership Council, which is made up of manufacturers, wholesalers, and retail pharmacy chains, has taken on prescription drug counterfeiting as a priority concern to be addressed by every segment of the drug distribution system. We have formed three working groups to target specific policy issues relative to counterfeiting. We have the Regulatory and Enforcement Measures Group, Business Policies and Practices, and Technology Prevention Measures. We will be looking at both federal and state laws and regulations on drug distribution as well as criminal penalties for counterfeiting. We will examine current business practices and consider potential guidelines for the future. We will study technology solutions that are available today and into the future and consider the costs involved to the drug distribution industry.

Retailers in an effort to keep distribution costs to a minimum and prices to the consumer as reasonable as possible utilize secondary distributors when appropriate. We would

not want to see these distributors completely eliminated.

Many of the options that FDA presents have the potential to disrupt a complex and, for the most part, efficient system. The distribution system should be free of disruption, but at the same time safe and effective. We will be looking at the current penalties for counterfeiting and suggesting that they be increased.

State licensing regulations should be tightened up, but the Florida model referred to in the report is not the answer.

Florida has been suggested as the answer for the country; however, Florida had some very serious problems that needed a very targeted solution. Pedigree papers that they are requiring are ineffective because they, too, can be counterfeited.

Our industry, because we cannot maintain such histories down the lot and container, will no longer be able to return overstock, errors, and outdated drugs. It is not realistic to expect distributors to perform inspections on one another. Rather, that should be the responsibility of the entity granting the license.

It was never the intention that chain distribution centers be considered secondary wholesalers, and we hope to correct that in the next legislative session. But that is how the language currently reads.

Repackaging operations are a benefit to pharmacies and the consumer because they reduce costs and are often packaged in very convenient and manageable quantities. One of the options implied direct purchasing for certain products. We realize that there are distribution systems now in place for specialized products, but we feel that any pharmacy willing to abide by necessary guidelines should be allowed to carry specialist products. Likewise, wholesalers should have this ability as well. Paper pedigrees are just not realistic. As we said, they can be counterfeited, and they are also very burdensome to maintain.

The Commissioner has praised unit-of-use packaging. We, too, find such packaging very useful for some products. However, for the majority of prescription products on the market, a quick migration to such a system would be unworkable.

Likewise, the concept of pharmacies using

one wholesaler exclusively might be feasible for 95 percent of the products they order, but not for the remaining 5 percent.

We all agree that electronic track and trace with authentication is our dream for the future. There are many business applications that would benefit from this technology, as well as anti-counterfeiting advantages. But we must consider that the technology is not yet ready for full implementation. The tags, readers, and savants, or collection devices, are ready, but we will need the O&S and PML elements to make the system work for us. We strongly believe that the FDA should encourage but not mandate the use of technology to prevent counterfeiting and diversion.

Much needs to be discussed by the industry as this technology emerges. Questions regarding the data, who owns the data, where it is stored, for example, need to be resolved. Standards need to be developed and adopted. The process has begun but completion is a long way off.

When the FDA is ready to implement an alert system on counterfeit products, it should seriously consider chaindrugstore.net as a proven tool that can quickly reach many of the

stakeholders. Chaindrugstore.net is a targeted retail pharmacy industry platform that will ensure real-time communication of critical information from the FDA the moment it is released. Education of the pharmacist and of the consumer is crucial when it comes to counterfeiting and recall issues. Chaindrugstore.net could easily relay educational information from the FDA and the manufacturers to the targeted audience. It has always been an embarrassment to corporate headquarters when pharmacists start calling right after the store is open to gain information in order to respond to customers' questions about something they read in the paper that morning. There has to be a better way to get the right information to the right people in a timely manner.

We hope to submit a comprehensive industry report to the FDA in early December. We appreciate the opportunity to discuss these important issues with the FDA before requirements are put in place that would disrupt our industry. We look forward to FDA's final report that we are confident will take into consideration the market-driven forces that are in place today and will be emerging in the coming years. We are eager to achieve a foolproof

method of ensuring the integrity of prescription drug products from manufacturer all the way to the patient. But it is important to take a multi-pronged and phased-in approach over an appropriate length of time that will cause the least disruption to the current system.

I thank you very much for your attention today.

[Applause.]

MR. BORSCHOW: Good morning, and thank you for allowing me this opportunity to speak. I'm Jon Borschow, President of Borschow Hospital Medical Supplies, Inc. I'm here today, however, speaking as Chairman of the Healthcare Distribution Management Association. HDMA is a national trade association representing 89 distributors of pharmaceutical and health care products. These distributors constitute nearly 100 percent of the pharmaceutical wholesale distribution market, totaling more than $140 billion in annual sales.

HDMA members are responsible for ensuring that billions of units of medication safely make their way to tens of thousands of retail pharmacies, hospitals, nursing homes, clinics, and other provider sites across the United States.

HDMA's mission is to secure the safe and effective distribution of health care products, to create an exchange industry knowledge affecting the future of distribution management, and to implement standards and business processes that produce efficient health care commerce.

With that mission in mind, I am delighted to have this opportunity to highlight HDMA's perspectives on FDA's interim anti-counterfeit report and to tell you about HDMA's ground-breaking work to help fight the public health threat of counterfeit drugs.

HDMA is very pleased to see that the FDA is concerned about state licensure. There's a high degree of variability among the states regarding the type and intensity of oversight they carry out both in issuing a license and in following up after a license is issued. Some states also are too lax when it comes to penalties for counterfeiters. It is essential that all regulatory bodies be cognizant of their responsibility to enforce the law and to protect against the entry of adulterated product in the pharmaceutical supply chain.

Some states have thorough and effective programs for examining the credentials and

qualifications of those who wish to become wholesale distributors and for inspecting distribution facilities. Yet other states have licensed hundreds of wholesales to distribute pharmaceuticals, although HDMA's 89 members constitute nearly 100 percent of the wholesale distribution business.

That said, it is clear that stronger licensure and inspection programs are critical to the success of any anti-counterfeit initiative.

HDMA is also pleased that the FDA recognizes that there is no single magic bullet solution to the counterfeit problem and that a multi-pronged, total supply chain strategy is needed to protect the safety of the U.S. pharmaceutical supply.

HDMA has closely studied this problem, and we were in full agreement that this effort cannot be accomplished by one part of the industry alone. Federal regulators enforce anti-counterfeit laws. States serve as the licensing entities that initially approve, inspect, and regulate the firms doing business. And manufacturers control the packaging or other anti-counterfeit characteristics of the drugs they supply.

Counterfeit drugs are a supply chain issue, and we are all invested in solutions. We wholeheartedly agree with the FDA that safeguards are needed in all of the transactions processed in the supply chain. With this in mind, our members have developed a set of voluntary best practices that we call our recommended guidelines for pharmaceutical distribution system integrity. Pharmaceutical wholesalers have been following similar business practices for a number of years, but recognizing our unique position in handling pharmaceutical products, we decided it was time to come together, pool our combined knowledge and experience, and raise the bar even further regarding our own due diligence.

Aside from our guidelines, HDMA does support covert, overt, and forensic packaging features as well as industry adoption of track and trace technologies that uniquely identifies the product units wholesalers ship to providers as part of a complete and effective security strategy.

With this in mind, HDMA's Product Safety Task Force, a broad-based coalition of pharmaceutical supply chain stakeholders, is examining the business requirements needed for the

implementation of track and trace technology.

Track and trace technology supports the unique identification of each individual product unit, allowing distributors to easily identify and locate specific items in the supply chain. The technology HDMA believes holds the most promise is radiofrequency identification, or RFID. Using RFID technology, a tiny radiofrequency chip containing essential data in the form of an electronic product code will allow supply chain stakeholders to track every unit of medication in the country on an individual basis. By tying each product unit to a unique ID, any item can be tracked through the entire supply chain with an unalterable electronic pedigree. The EPC chip, which can be thought of as a product's DNA, will be equipped with high-technology security protection that will make it impossible to duplicate or steal the identity of an authentic unit.

Even if criminals develop the technology required to create an exact replica of the EPC, the technology's ability to track product movement from the manufacturer to the patient would detect duplicate drugs in an incorrect location within the supply chain. In addition, EPC has other patient

safety features built in. EPC has the ability to constantly monitor the temperature conditions of each unit of medication as it travels through the system to ensure proper storage and handling. The technology also can track product expiration dates, simplify the process of product recalls, and reduce the number of medication errors by uniquely matching the specific product to a specific patient. Further, because the technology represents an opportunity to improve efficiencies, EPC is far more cost-effective than other pedigree solutions.

The technology for case-level implementation of track and trace, as Wal-Mart has mandated, could be accomplished in as soon as six months. Such implementation would allow the industry to perfect the application of the technology and lay the groundwork for expanding track and trace to encompass the individual product units wholesalers ship to providers. Perhaps most importantly, a track and trace technology would take the burden of having to authenticate products off the providers. Providers would merely purchase product through an authenticating distributor with the assurance of product safety.

HDMA is working closely with standards bodies to further the awareness, adoption, and implementation of EPC in health care distribution, and we recommend that this technology and others that improve patient safety be implemented in the shortest possible time frame. In the case of EPC, we are encouraging our manufacturing partners to put this technology in their product packaging and to commit to early adoption. We also have approached other industry trade groups to create broad-based support for our efforts.

HDMA members dedicated to this issue have started working with pharmaceutical manufacturers, packaging suppliers, technology providers, wholesalers, and health care providers to provide a compendium of strategic and tactical information on EPC. HDMA also plans to craft an industry-wide position statement in support of EPC in an effort to continue the momentum behind a safe and efficient supply chain.

HDMA is a strong advocate for ensuring a safe and secure supply chain from would-be counterfeiters. Patient safety is our number one priority. It is with this in mind that we advocate for technology-based anti-counterfeiting solutions,

guidelines recommending thorough due diligence of all business partners, member commitments to report suspicious activity to authorities, strong enforcement of state and federal law, and impeccable licensure requirements. With the successful implementation of these technologies and the active efforts of our members, we should be able to build a high enough wall around our pharmaceutical supply chain to prevent any unsafe product from entering our domain.

Thank you for your time.

[Applause.]

MR. TAYLOR: Before we start with the next speaker, it's 10:45. We recognize that we're running behind because we started late in an attempt to make sure everyone was in the room.

Dr. McClellan is here, and he will be speaking at 11 o'clock. However, his window is fairly short. So if we could take a 15-minute break, return back to the room at 11:00, and once he is done speaking we'll resume with the speakers on the second panel and continue through and make adjustments during the day to ensure that we get back on track.

Thank you.

[Recess.]

MR. TAYLOR: Can everyone take their seats? Thank you.

Okay. As I discussed earlier, I told you that the Commissioner of the Food and Drug Administration would have an opportunity to speak at 11 o'clock, and he is here. It is my pleasure and honor to introduce Dr. Mark McClellan, Commissioner of the Food and Drug Administration.

[Applause.]

COMMISSIONER McCLELLAN: John, thank you very much.

It's always a pleasure to be introduced by John. He definitely has a way of getting people's attention, quite a presence. And he's also been very busy lately. We are facing a number of new challenges to keeping the products that FDA regulates safe and secure. So from new food security regulations to keep our food imports secure, to dealing with new problems with prescription drug safety and security like those that we're talking about today, John and his team and FDA's enforcement activities have been very busy. I want to thank them for the great work that they are doing.

I also want to thank you all for coming today to meet with us and share your ideas and views on how we can do as effective a job as possible of keeping the American drug supply safe and secure. The United States has a very safe prescription drug supply, and FDA is working hard to keep it that way.

This is not something that we can take for granted. If you look around the world, in many countries a quarter or even a half or more of the prescription drugs that people take are not legitimate products. They may not work as intended, and that's a real public health concern. And although counterfeiting of drugs is not widespread in this country, we have seen an increase in counterfeiting activities. Our number of investigations has gone from about five per year in the 1990s to over 20 per year in the last several years. And even more worrisome, we have seen an increase in the sophistication, the cleverness, the technical capabilities of counterfeiters that are trying to get drugs into the U.S. distribution system.

This is a real public health threat. As we have seen from the counterfeit cases that we've

already encountered and in many cases solved and put people in jail, counterfeit drug products may contain only inactive ingredients, they may contain incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, or they may be contaminated. The result is risks to patients' health, either risks to their safety directly if the products are dangerous, or risks from people suffering from complications from the many diseases that prescription drugs can treat today. So this is a serious concern at FDA.

With these more sophisticated drug counterfeit operations, FDA and all law enforcement activities that are partnering with us need to be even more effective in meeting these new challenges.

I just got through touring some of the technology vendors next door, and for those of you who haven't had a chance to go over there yet, I highly recommend it. For those of you from the various companies that are coming up with innovative solutions, in many cases that have been applied to other industries besides pharmaceuticals, and in some cases they're starting to be applied to the health care industry, I want to

thank you for your efforts. We need these fresh, innovative ideas for keeping our drug supply secure at an affordable price today more than ever.

There are many promising technologies out there. I had a chance to see some radiofrequency identification techniques, new applications of bar code labeling, new approaches to doing track and trace technology so that we can reliably, in ways that cannot easily be fraudulently faked, identify whether a product really is a legitimate one, it's come from a legitimate source and has not been tampered with along the way.

I've seen new technologies for packaging, new color-based technologies that embed multiple different layers of protection.

I've seen new anti-tampering technologies for drug packaging, even the tops of injectable drugs that can help keep the product secure.

And I've seen new technologies that can be used on the drugs themselves, from new color technologies to bar codes embedded, not just unit-of-dose packaging but actually on the drug, to other taggant and chemical technologies that are not harmful for patients but that can make it very easy to determine whether a product is safe or not.

They do everything from make it easy for us or others to do chemical testing on the product's legitimacy to making it easier for patients to identify whether the product is a legitimate one or not by a distinctive taste.

So a lot of potentially valuable technologies out there that are in development right now, and in some cases are starting to be applied to the pharmaceutical industry. In some ways, the pharmaceutical industry is behind other industries where secure track and trace approaches and secure anti-counterfeiting technologies have become more widespread.

I heard some this morning about the fragrance industry where many of the technologies that might potentially be useful in pharmaceuticals can be applied.

And I want to thank our colleagues from other government agencies, such as the Department of Justice, the Bureau of Engraving and Printing, and the Secret Service, for sharing their expertise on counterfeiting technology with us.

I think as a result of meetings like this that we can really speed up development, the testing, the feasibility testing and the cost-

effectiveness testing, of many of these technologies that are in development today. And as we are trying to do in other areas of FDA activities where there are new technologies that can be valuable, we want to bring them to benefit patients as soon as possible. And while many of these technologies do seem a few years away from widespread application, while they have not been fully tested yet and demonstrated to be feasible, I think that through meetings like this and through further steps that FDA will take to speed along the development and application of these technologies, we are on the cusp of a potentially much more secure drug supply using 21st century technology in the years ahead.

But as our colleagues who are also experts on counterfeiting technology have told us, there is no single magic bullet. Not only do many of these technologies need to go through some further developmental steps, counterfeiters are very sophisticated today, so this is a moving game. We constantly need to be finding ways to update our technologies. We constantly need to be thinking about whether we've got enough layers in place. There's no one magic bullet. We need to think

simultaneously about a coordinated approach that involves tracking and tracing and product packaging and product-embedded technologies and others, multiple layers to keep our drug supply safe.

Our money supply, just the paper money, has more than 20 embedded technologies, both overt and covert and some that are only known to the Treasury Department that handles the money. We need multiple layers like that to assure security in prescription drugs as well, and we're going to be working to bring these proven technologies, to develop the proof for these technologies, and to bring them to improving our drug supply as quickly as possible. And this meeting and your input into that process is an essential part of getting there as soon as possible, getting to a secure drug supply based on up-to-date and constantly improving 21st century anti-counterfeiting technology.

I also want to highlight briefly a few other areas that FDA has stressed in our recent interim report from our Anti-Counterfeiting Task Force where we think we can do a more effective job in protecting Americans from unsafe counterfeit drugs, an even more effective job than we are doing today to keep our drug supply safe and secure. And

I hope all of you here will help us both with your formal comments at this meeting, questions, comments, and other input that you send us. We have an open docket right now, and we really do want input from everyone who is interested in maintaining the security of our drug supply.

Let me just run through a few of these areas very quickly. One of the things that is evidenced to us in this work is that all of the participants in our drug distribution system, from manufacturers to wholesalers and distributors, to pharmacies, to patients, have a responsibility to help us prevent and detect the introduction of counterfeit drugs into our drug supply.

In particular, the businesses that are involved in the pharmaceutical manufacturing and distribution industry can help by adopting secure business practices. We think from what we've seen so far that some of the business practices in existence today can be improved as a means of deterring and detecting counterfeit drugs.

We've heard from and we've gotten a lot of feedback out to wholesaler organizations, for example, that are moving forward with developing more secure business practice models as a standard

for their industry. And we're looking forward to working with all of the other stakeholders in the prescription drug distribution system to make sure that we have identified and are doing all we can to encourage the adoption of secure business practices to minimize vulnerabilities to counterfeit drugs.

It is also important that we rapidly receive and are able to disseminate information on counterfeit drug introductions when they do occur. As I said, the number of cases of counterfeiting is on the increase, and an important part of an effective anti-counterfeiting strategy is to be able to identify and limit the damage from counterfeit drug introductions when they do occur.

Our task force has recognized the need to strengthen the systems that are used for reporting suspected counterfeits and for alerting stake-holders and the public when these counterfeit drugs do enter the drug supply. So we're interested in hearing about the best approaches and networks and other steps that can be taken to support this important goal of rapid notification and response capability.

It is also essential for consumers, pharmacists, and other health care professionals to

know how to identify counterfeit drugs and what to do when they believe that they've encountered a counterfeit drug. This includes recognizing the anti-counterfeiting technologies that are introduced. There are a number of steps in place today for anti-tampering provisions, for legitimate packaging and the like. As I said before, we need to do more, but there are steps that can be taken even now to help recognize when packages, labeling, and the drug products themselves have been compromised.

And while we are already trying to get a message out to consumers and while we've worked closely with pharmacy associations and other health professional groups to get the word out and educate health professionals about these problems, I think there's more that we can do, and our task force is seeking guidance on how best to tailor and deliver these important education messages to help us prevent damage from counterfeit drugs.

Finally, counterfeit drugs are a global problem. We're seeing an increasing number of cases that involve not just a few people manufacturing a fake product in their garage, but well-organized international criminal operations

that are trying to make use of the latest technologies for making a product that looks like the real thing but isn't. And we need help of international law enforcement, health and regulatory authorities, as well as private stakeholders internationally to help us address this problem effectively.

So we want to hear about new and better ways to work with other nations to deal with this global threat to the security of prescription drugs.

To all of you who are participating, I want to thank you for your contribution to dealing with this significant emerging public health threat. I am confident that working together we can stay ahead of those who are out to make a fast buck at the expense of the health of Americans. And I'm sure that we will be able to work together to keep our drug supply safe and secure and the safest in the world if we do remain vigilant through steps like this.

Thank you all for your contributions.

[Applause.]

COMMISSIONER McCLELLAN: Maybe if there are a few questions for me--there are a lot of

other people here who are more knowledgeable than I am on all of the intricacies of counterfeit drug technology and response systems, but if there are a few questions from press or others for me, I'd be happy to take them right now.

QUESTION: Can you talk about the role of--[inaudible, off mike].

COMMISSIONER McCLELLAN: Well, our main focus here today is on counterfeit drugs. Importation is a different problem. Many of the steps that we are identifying here to take involving counterfeit drugs are over parts of the drug supply where we have authorities and resources to deal with them. Drugs that Congress has deemed illegal are ones that are outside of the scope of our regulatory system, where we don't have any legal authorities, for example, to go into other countries and determine whether these products are safe, and we don't have the resources to back that up either. So that's a different kind of problem, and I'm certainly concerned about any threats to the integrity of our drug distribution system. But our focus here is on anti-counterfeiting steps that we can take when we've got the resources and authorities to deal with the problem.

Yes?

QUESTION: Can you comment on how you see the balance between private sector action on this issue and FDA regulatory action?

COMMISSIONER McCLELLAN: I think it's a combined effort. You know, we do have a primarily private prescription drug manufacturing and distribution system, and that has many advantages in flexibility and competition and the like. It does mean that any of our efforts need to be coordinated well and need to take account of responses that the private sector can take as well.

As part of our task force activities, for example, we're working on model secure business practices that could be adopted by each and every component of the private drug manufacturing and distribution system. We're looking at steps that states have taken through their regulation of wholesalers and distributors that might help contribute to making the drug supply more secure as well. And we're also looking at steps that we can take through regulatory action or identifying solutions that could be widely adopted on a voluntary basis to address the problem.

One of the main points of having this task

force effort is this is a big problem with a lot of good ideas to help us deal with the problem, and we want to make sure that we're getting full input from the private sector, from our partners, and government law enforcement and anybody else who's interested in coming up with the best combination of solutions. But it is going to be a private-public joint effort.

QUESTION: Dr. McClellan, is there any kind of estimated time where you think that all of these things could be coming together and that there would be something in place that would be a measure or--I think you know where I am--you know, some sense of, yes, now we've solved the--or we've treated or we've stopped the major problem.

COMMISSIONER McCLELLAN: That we've addressed the problem.

QUESTION: Right.

COMMISSIONER McCLELLAN: We are trying to move as quickly as possible, and I am expecting a final report from our Anti-Counterfeiting Task Force in January. So this is a very fast-track, high-priority effort from the agency, and I'm hoping--I know it's a lot of work for the guys who are involved in this effort, but I'm hoping that

that is going to lay out a fairly comprehensive set of ideas on steps that we can take on all of these fronts that I mentioned--technology, response networks, new business practices, and the like--to help address the problem.

But one of the things that has been made very clear to me by both the sophistication of the counterfeit operations that we're seeing and by the expertise that groups like the Secret Service and the Bureau of Engraving and Printing have shared with us is that this is never a problem that's over; that we need to be taking steps constantly to review what the counterfeiters are capable of, constantly review what new steps we can adopt, what new technologies, other new approaches may be available to respond to the latest threats, and keep ahead of the game.

This is a problem that requires a multiple-layer approach, and it requires constant vigilance to make sure that we're staying ahead of some increasingly sophisticated criminals.

QUESTION: Would there be a time when the anti-counterfeiting measures were good enough that you could allow or feel more comfortable with importation from other countries?

COMMISSIONER McCLELLAN: I think that's certainly possible. I mean, there are technologies out there that may one day make it possible to do, for example, reliable tracking and tracing and have embedded in the product, and not just in the package, technologies that are two steps ahead of the increasingly sophisticated counterfeiters that we're facing.

That day is not here now. Many of the technologies that we're hearing about are still in development, and one of the main purposes of this meeting and of our whole anti-counterfeiting effort is to speed up the development of more effective, automatic, reliable, inexpensive approaches to assure drug safety, both domestically and abroad. But we're not there yet. It's going to take some real work in the months and years ahead.

Yes?

QUESTION: Do you have a handle, Dr. McClellan, on what percentage of the drug supply is--how big a problem this really is? And what leads you to say that this is a growing problem?

COMMISSIONER McCLELLAN: Yes, I want to be very clear about that. You know, people in this country have traditionally enjoyed the benefits of

being able to walk into a pharmacy and be very confident that the drug that they're getting is the real thing, it is going to work as intended, it's a legitimate product. That has not changed. Our drug supply itself, when you buy within the regulated FDA-, state-regulated system, is very safe and very secure, and only a tiny fraction of drugs in that system are not legitimate, are counterfeit agents.

However, there are growing threats to the security of that system. As I mentioned, we are engaged in an increased number of investigations reflecting increased criminal interest here. It's not surprising to me. I mean, criminals are going to go where the money is, and they're also going to go where the technological opportunities permit them to go. So there are well-financed operations that are investing in better technologies because they can make a fast buck, they think, at the expense of the public health. That's why we need to stay vigilant. The game is changing, and we want to stay ahead of it so that our drug supply does remain safe and secure.

QUESTION: Is there any evidence [inaudible].

COMMISSIONER McCLELLAN: Well, the growing number of investigations reflects a growing number of criminal operations involved in counterfeit drug production and distribution. And as I said, we're seeing more operations that aren't just a few people, you know, working together locally but multiple locations, well connected via the Internet and other communications means, financed well enough to develop and implement technologies that look a lot like the real drug products. We're seeing this on an increasing scale. There have been a number of high-profile investigations just this year that have gotten a lot of public attention in this regard.

Now, that doesn't mean that people who are buying drugs--you know, who walk in the pharmacy and buy a drug need to have a real worry that those drug products are safe and secure. Again, the chance of any particular drug people who buy within the U.S.-regulated system is illegitimate is extremely small. But we've got to be vigilant to keep it that way. There are more criminals that are better organized with better technologies, better abilities to communicate, who are out to make a buck this way. And I want to keep our drug

supply secure. We owe that to the American public.

I think I have time for one more. Yes?

QUESTION: [inaudible, off mike.]

COMMISSIONER McCLELLAN: Well, the PDMA did view having a drug pedigree as one important step towards assuring the security of the drug supply. There's no question about it. If we could have reliable, you know, with no possibility of fraud, methods of making sure that a drug can be tracked reliably and can be traced back if there is a potential problem, that would add immensely to our ability to secure the drug supply.

Congress, though it passed the law, has also expressed some strong concerns to us about the feasibility of implementing the PDMA as written. And as you said, this was a law written 15 years ago in a different era of both counterfeiting technology and anti-counterfeiting technology. It envisioned paper records and so forth, and it didn't even extend to all parts of--the requirements didn't even extend to all parts of the drug distribution system.

In contrast, today we have the potential, perhaps in the next few years, to come up with an electronic version of dealing with this problem

more cheaply, more reliably, more securely in a way that can't be faked, like paper records. And so I think there is a new--you know, in this near era there's new, some potentially valuable opportunities for addressing the problems that PDMA intended to solve. Those are serious problems that need to be addressed.

Okay. Thank you all very much again for coming.

[Applause.]

MR. TAYLOR: All right. Let's resume Panel 2. I understand that Carmen and Larry are going to be reversing order. Is that correct? Okay. So Larry Bostian from the National Consumer League is going to speak, and then Carmen Catizone is going to follow. Thanks, guys, for being so flexible.

MR. BOSTIAN: The National Consumers League, America's oldest consumer advocacy organization, is pleased to speak today about the problem of counterfeit drugs. I'm Larry Bostian, Vice President for Development of the National Consumers League, here on behalf of our President, Linda Golodner.

Many speakers today have talked about the

problem from the perspective of the pharmaceutical supply chain. We thank FDA for inviting us to come and offer some thoughts from the consumer perspective.

There are several developments that combine to make the problem of counterfeit drugs. Pharmaceutical research has brought a wide array of drugs to market, offering new treatment options for many illnesses and conditions. The population is aging, and the elderly just take more drugs. Changes in the health care system have placed greater responsibility on individual consumers to manage their own health care, and this makes it vital that they have access to the information and the tools they need to do that wisely. And, finally, we recognize that the cost of prescription drugs places a real strain on many families and can sometimes lead consumers to make the wrong decisions about their health care.

We've been working for more than a hundred years to ensure that consumers have access to safe products. A panel of National Consumers League volunteers staffed a booth at the 1904 St. Louis World Exposition where they demonstrated that canned green beans had been adulterated with green

dye. This is before the 1906 Safe Food and Drug Act.

Today, we work in partnership with government, FDA and many other agencies, labor, nonprofits, and business to make sure that drugs are safe and effective and consumers have access to the information they need, in forms they can understand, to choose wisely for themselves and their families.

We also have experience helping consumers deal with fraudulent products and services. Since 1992, NCL has operated the National Fraud Information Center, a toll-free hotline and a website where consumers can get information about telemarketing and Internet fraud. We talk regularly with consumers about fraud, and we reach out through the media to remind consumers to be alert to fraudulent offers. We've been exploring the connection between counterfeit drugs and our expertise in Internet and telemarketing fraud.

Having said all that, we think it's a lot to ask of consumers to be on the lookout for counterfeit drugs in their pharmacies. In our experience, to be successful, consumer education really has to be simple, messages have to be very

clear, and consumers need to see and hear these messages through many channels.

Consumers need good, solid general information about this particular issue presented in a way that persuades them that it's serious but doesn't unduly alarm them. The League believes that the FDA and industry have a special obligation to explain the issue to groups that are most at risk. Senior citizens, for example, those with poor vision of reading skills, or poor health literacy need to be able to read and understand any messages that are meant to convey and persuade the public.

Consumers need to be aware of the source of their drugs and how to minimize the risk, as Dr. McClellan mentioned. We encourage consumers, for example, on our website who are looking to buy drugs online to look for the VIPS seal.

As a small nonprofit organization with limited resources--and, believe me, ours are really limited--the National Consumers League example might be useful. When we undertake an education initiative to generate the maximum possible media attention, we often start by commissioning a telephone or online survey of consumers' knowledge

and attitudes about a particular health issue. And then our outreach efforts, although we do some work on the Web, are typically pretty low-tech. We'll do a national press release. We'll place new content on our website, nclnet.org, and our fraud websites, fraud.org. We'll often prepare a VNR and B roll for use b local news outlets. We often do radio media tours during morning drive time. We'll do map releases that are distributed through Pennysavers and other small circulation outlets.

We also do outreach to long-lead publications, and we occasionally luck out. I mentioned the National Fraud Information Center. In August--here's the National Enquirer from August 5th--there was a two-page article, "Beware Telemarketing and Internet Scams," that is based entirely on an interview with my colleague, Susan Grant, who runs our Fraud Center. Now, we couldn't buy that kind of exposure, pardon the phrase, but we think that's a very effective way. Parade Magazine and others reach millions and millions of consumers, and as I said, consumers need to be reminded a lot. Consumers are going to need guidance to be able to tell whether a drug might be counterfeit.

At the risk of stating the obvious, messages need to reach consumers where they are. In terms of counterfeit, for example, pharmacies could present color photographs that depict what the genuine drug or package looked like compared to what the counterfeit drug or package looked like so consumers would know what to look for. Many area groceries are introducing scan your own checkout lines, and those screens have tremendous potential for conveying this kind of information.

The checkers at my grocery store have a flip chart that lists in pictures all the different vegetables and fruits so they know what code to push. A flip chart like that while you're waiting in line to pick up your prescription could have a lot of that same kind of information.

Again, this is a pretty low-tech suggestion, but consumers, especially those who have poor health literacy, might take advantage of an outreach technique like that, and that would just reinforce the messages that are coming through the media, public service announcements and so forth.

It's important, especially if the FDA is going to issue an alert about a counterfeit, that

consumers know what they should do if they've actually bought a counterfeit drug. It may be important for consumers to know that it's important not to just discontinue the drug, but to consult with a pharmacist or health professional, and they need to know when and how to report it as well.

These days, consumers shoulder a heavy burden. Increasingly, they're responsible for managing their own health, often taking multiple drugs on an ongoing basis. The range of available drugs is large and growing. Many of them are expensive. It's regrettable that on top of all that, consumers have to worry about counterfeit drugs, too, but there we are.

The National Consumers League's bottom line is one shared by everyone here today. Consumers need access to safe and affordable drugs, and we all need to work together to help them.

Thank you very much.

[Applause.]

MR. CATIZONE: Good morning. I want to make sure no one else wants to speak. Are we all set? Okay.

Again, thanks to the FDA for allowing us the opportunity to participate in this public

meeting. We'd like to extend our thanks to the task force and the FDA for your efforts to combat counterfeit drugs. NABP and the state boards find the interim report informative and critical to the process of managing this crisis. The partnerships with the State Boards of Pharmacy through federal-state relations of the FDA have developed and maintained to combat this crisis and other crises are extremely important to the State Boards of Pharmacy and will prove even more useful as we embark on this path to deal with counterfeit drugs.

NABP's mission is to represent all the state agencies regulating pharmacies and pharmacists. As indicated in the interim report, we develop model regulations that assist the states in developing their own regulations and practice acts. Our model regs on wholesale distributors serve as the basis for the almost uniform regulatory scheme and structure that's in place among the states. It was also used by the FDA in developing their federal requirements and guidelines under the PDMA.

Currently, NABP is involved in analyzing all the state practice acts to determine what areas need to be changed or what areas don't address the