problems that have resulted from this new and emerging area of counterfeit drugs.

Our next steps are to look at what's happened in Nevada and Florida and to see if those changes can address the problem of counterfeit drugs and how our model regulations can or should be amended to incorporate what has occurred in Florida and Nevada.

To achieve this, we have commissioned a task force that will meet at the end of October, and we are inviting in all stakeholders that may have an interest in this area and continue our cooperation with the FDA to review our model regulations and to propose new regulations to the states to address this new and emerging area of counterfeit drugs.

We would hope that a similar approach could be applied as worked with the PDMA and that federal recognition of the state effort would occur, but the actual changes in the standards and guidelines would occur at the state level so that future changes could be made more easily and less cumbersome.

We believe this is the right way to go. We believe the evidence that exists since 1988 to

support this is very important. We have a good regulatory system in place that's fairly uniform among the states. The impact on the wholesale industry has been minimal, and the burden on interstate commerce has been almost nil.

So, again, we'd like to employ the same process for this problem, work cooperatively with the FDA, the wholesale industry, and other stakeholders to develop a public and private partnership.

Thank you for the opportunity.

[Applause.]

MR. RICCARDI: Good morning, almost afternoon. My name is Sal Riccardi. I am the President of the Pharmaceutical Distributors Association, also known as PDA, an association representing interests of 6,000 small licensed prescription drug wholesalers operating throughout the United States.

I am also the President and co-owner of Purity Wholesale Grocers. Our pharmaceutical division, Supreme Distributors, has been wholesaling prescription drugs for more than 20 years.

As an industry, PDA members service other

wholesalers, hospitals, retail pharmacies, doctors' offices, clinics, emergency response units, military and private dispensaries, and others who are not adequately serviced by the large national and/or regional distributors. All member wholesalers operate under the same state and federal laws as the large national and regional wholesalers. Our presence in the marketplace helps stabilize prices by creating competition.

I am here today to address the shared objective of counterfeit drug detection and prevention and to outline the public and private sector actions regarding wholesale distribution of prescription drugs that the PDA believes reasonably and effectively would help achieve these objectives without unreasonably burdening prescription drug wholesalers and putting them out of their businesses.

First, prescription drug wholesalers are required to be licensed where they have facilities, and if required, in the states into which they sell prescription drugs. State licensure laws vary from filling out a simple one-page form and tendering a nominal fee to criminal background checks, including fingerprints on individuals, physical

inspection of in-state facilities and operations system for the common-sense requirements.

Lack of strong uniform requirements for criminal background checks, training and experience, insurance and other common-sense requirements along with weak criminal penalties and other enforcement promotes an environment for criminals to enter into. PDA supports state efforts to enhance wholesaler licensing requirements and increases in state licensing fees necessary to support those requirements, along with stronger and swifter enforcement by state and federal authorities.

Florida and California are two examples of states that have recently tightened licensing requirements. PDA agrees with strengthening licensing schemes, but other requirements that burden interstate commerce--I'm sorry. Let me back up. PDA agrees with strengthening licensing requirement schemes, but these licensing schemes should not seek to impose hodgepodge of pedigree or other requirements that burden interstate commerce by imposing different pedigree or authorized distributor of record requirements in each state or for different drugs when sold within a state.

Second, criminal penalties for knowingly introducing or knowingly distributing counterfeit drugs must be raised. Counterfeit drugs pose a serious danger to the public, so the penalty for knowingly handling these drugs must be heavy. FDA's interim report notes that counterfeiting a label has a larger penalty than counterfeiting the drug itself. That does not make sense, and PDA supports legislation to increase penalties for counterfeiting.

PDA, in conjunction with the Healthcare Distribution Management Association, HDMA, has developed voluntary recommended guidelines for pharmaceutical distribution integrity. Under these guidelines, wholesalers will raise the level of scrutiny of their sources of supply. In doing so, we hope that sources with questionable integrity will be identified and that they may have no customers. Hopefully, they will also be discouraged by our due diligence from trying to enter the marketplace. The FDA is aware that private industry does not have the legal authority to impose mandatory guidelines on the industry participants or punish those that don't follow them.

The PDA believes that the FDA should consider incorporating a number of the guidelines into the present guidelines for state licensure of wholesale prescription drug distributors to become the current GMPs, or good manufacturing practices, for holding prescription drugs. To the extent that it has the regulatory power to do so, we encourage the FDA to explore this possibility.

The PDA opposed implementation of the FDA's 1999 Prescription Drug Marketing Act, PDMA, final rule that would require that pedigree go back to the manufacturer in every instance. But I want to note that the failure to have a final rule does not mean that the PDMA has been ignored. PDA members provide a prescription drug pedigree that goes back to the last authorized distributor of record and will continue to do so. And FDA and state officials have ample power to determine the further prior history from authorized distributors of record who must keep records on their own premises.

PDA opposes the implementation of the 1999 final rule because authorized distributors of record are exempted by the PDMA from providing a pedigree. Ninety percent of the drugs in commerce

start at the big three prescription drug wholesalers who are all authorized distributors of record under the PDMA. And, therefore, 90 percent of the drugs in commerce are sold, including the wholesalers, without a pedigree requirement. Implementation of FDA's final rule, as currently written, will, therefore, effectively jeopardize the businesses of over 6,000 small wholesalers who will be faced with the choice of either demanding pedigree from the major wholesalers who are legally exempt from any requirement to provide it, to going out of business because the drugs heretofore have been distributed with a lack of the requisite pedigree, or operating their businesses in violation of law. This, of course, is really no choice at all.

PDA supports the efforts to strengthen the requirements for who may be an authorized distributor of record and voluntarily will be implementing definitions and submitting them to the FDA for your consideration.

But PDMA was not designed to address counterfeiting issues that confront the industry. PDMA is antiquated, but it is the law. Not surprisingly, our position is that the best

solution to the counterfeit problem is one that involves mandating that manufacturers incorporate tamper-evident technology into their products to enable wholesalers, dispensers, and consumers alike to identify authentic versus counterfeit products.

In arriving at a solution to prescription drug integrity verification, FDA and manufacturers need to work together to require and utilize technology that can conform integrity at any point in the system--wholesale, retail, and dispenser. And it must be uniform technology that can be utilized in a cost-effective manner throughout the distribution system to the dispenser.

And in the meantime, manufacturers should consider counterfeit deterrence. Overseas and domestic manufacture and sale of United States approved drugs for sale in other countries is the same color and shape and at prices deeply discounted from prices here does not make good sense to counter counterfeit deterrence. The current practice of one color and shape for all is an invitation for smugglers to bring those drugs back into the United States, and we agree with the FDA that smugglers are the avenue to inject drug counterfeits into United States commerce.

Additionally, anti-counterfeit and tampering technologies could be used today and used only for the United States market, and we believe their use as well would achieve a substantial deterrence to smuggling and counterfeiting.

To conclude, PDA supports strengthening state licensing requirements, but there needs to be uniformity with respect to commerce. Easy, logical measures can be implemented by wholesalers that will make entry to the marketplace much more difficult for unscrupulous individuals and the authorized distributor of record can be redefined to include stronger objective parameters. Penalties for counterfeiting can be enhanced. Manufacturers can take logical measures to make their products less susceptible to counterfeiting and smuggling, and the FDA can mandate uniform pharmaceutical integrity verification technology that can be used throughout the distribution chain.

Thank you for your time today.

[Applause.]

MR. TAYLOR: In keeping with the first panel, I'm going to ask the task force members if they have any questions.

I'd also like the task force members,

before they ask a question, to also give your name and also identify what part of FDA you're from, and that will help the transcriber as well as others in the audience, including the press, to match a question to a person. So, Bill?

MR. McCONAGHA: I'm Bill McConagha with FDA's Office of Chief Counsel, and I have a question for Mr. Borschow first. And is Mr. Bostian still here or did he--he fled? I don't blame him. So I might then in turn address it to Mr. Catizone.

What I'm curious about, gentlemen, is your view or perception as to the appropriateness or need for strengthened federal oversight by the FDA with respect to this problem. We heard from Ms. Wagner. She suggested that there were certain behaviors that we ought to encourage but not necessarily make mandatory. Mr. Riccardi talked about potentially federal oversight in terms of strengthening GMP and maybe requiring certain things of manufacturers.

I'm curious, each of you in turn, what your own views are as to the role of FDA and federal oversight, mandatory oversight in terms of addressing these issues.

MR. BORSCHOW: Well, we agree very much with the Commissioner that what we need to have and to continue to have is an effective partnership between the government and private enterprise. It has been very successful thus far, and we have been able to maintain a very high integrity in our system.

Certainly, as we stated, we endorse the idea of looking both at the licensing process that goes on and finding ways to improve that to exclude, you know, potential threats through the licensing process. And we also believe that we should work towards, you know, increased penalties, where appropriate, criminal penalties. And these are clearly areas where government in one form or another should intervene.

In addition to that, the work of the FDA in terms of exploring with industry and identifying the necessary process and technology changes has been very effective. We salute the work of the Anti-Counterfeit Task Force, which is, of course, in progress. And we at our association have a task force, a Product Safety Task Force, which is working very closely on this. So that I think that the role of government as a collaborative partner

is the one that we really endorse. We don't feel that a specific technology should be mandated but, rather, because of the multi-pronged approach that needs to be addressed, the industry should be encouraged to pursue all of the appropriate methods and technologies, and that FDA in a sense has served as a gathering place and a sponsor of the type of dialogue that can help advance these processes and make them happen much more quickly. In many instances, it's a matter of dissemination of information and developing understanding. Our industry is a large industry, and a great deal of information needs to flow.

So we salute FDA for its initiatives and believe that the work that it's doing is very effective.

MR. CATIZONE: Carmen Catizone with NABP. We believe that the regulatory model that was employed for PDMA has worked quite well, and we'd like to see that model implemented while continuing to deal with counterfeit drugs. And that model basically was for federal legislation to establish the ability of the states to regulate at a much more specific practice of pharmacy type level.

We'd like to continue that as well as

identify areas that we think federal legislation needs to be developed or strengthened, and two areas that immediately come to mind probably would deal with the technology issues, because there needs to be uniformity among the technology or technology requirements; and, two, the ability to attain a national injunction relief or national injunction against wholesale distributors that may be operating illegally that would curtail the ability of people to move from state to state to avoid this type of enforcement or regulation.

MR. TAYLOR: Peg?

MS. O'ROURKE: I'm Peg O'Rourke from the Center for Drugs. I have a question for all of the panel members, any or all. We were talking earlier about the electronic pedigree and the electronic trace and track technology. While that is several years away, it sounds like it would eventually evolve into a sort of universal pedigree.

But given that's a distance away, to level the playing field, which this might do, what is your opinion on having a universal pedigree requirement implemented now, even though it would be on paper or a combination of paper and electronic?

MS. WAGNER: Our organization doesn't believe that the technology is really ready yet. We think that certainly is the solution, to have an electronic pedigree all the way from manufacture to patient. But it's our understanding that many of these technologies are not complete yet, so we would hate to see something mandated that would either add costs to the system or decrease efficiencies to the system.

MR. CATIZONE: This is Carmen Catizone, NABP. We think something needs to be done in the interim because the incidence of counterfeiting seems to be increasing. And it's interesting to us and somewhat confusing that people would buy prescription drugs from unknown sources and that the paperwork would not exist for those people to authenticate or verify those products to the other consumers down the line in which they sell those products.

So we would support some system, whether it be paper or a combination of paper and electronic, that provides the documentation that would be needed to at least substantiate the sources of these products and to determine whether or not there's a trail of evidence where

counterfeiting could be detected or fraud be detected.

MR. BORSCHOW: Among the voluntary guidelines that our own association has been developing is the issue of, in fact, being able to ascertain the origins of products. And so we're very much attempting to make sure through these guidelines that product is not introduced of an unknown origin.

However, we, on the other hand, believe very strongly that track and trace technology is actually closer, and we believe that an industry initiative can, in fact, make it happen in a much shorter time period than many might believe. We have seen just in the last six to nine months enormous progress in this area, and there's a considerable effort, part of it sponsored by our own association through our Collaborative Commerce Committee and our Product Safety Task Force, which we believe will help to advance that. And we do have a group of industry players and stakeholders, including some of these technology providers, who are working very arduously on making this happen.

As I alluded to in my testimony, we believe that at the simplest level this technology

is, in fact, very close to being available and practicable, and I once again remind all of our listeners that both Wal-Mart and the Department of Defense have in unequivocal terms stated that they expect that technology within a matter of on the order of 18 months. So I think that we should not for one moment believe that we're talking about something that is a decade or more away. On the other hand, we do have to understand that we are a large industry and we are talking about many, many tens of thousands of products, and certainly it will take some time for even a fast-paced technology to be completely ubiquitous. And certainly we as an association, through our voluntary guidelines and through our support of FDA's multi-pronged approach, have attempted to address the interim period. But certainly we believe that the sooner that these types of track and trace technologies can be brought into place that we can really create an additional level of security in our system.

MR. RICCARDI: Our association, the PDA, believes that some of the prongs of the multi-pronged approach can happen rather quickly, that being the licensing requirements be increased.

I was able to sit on the ad hoc committee in the State of Florida, and we had a subcommittee in that state specifically focused on licensing. And one of my colleagues here had mentioned earlier that one of the states had over a thousand wholesale licenses given out. And from one of the agency member's mouth to my ears, they said it's basically a rubber-stamp approach, and that's wrong.

That needs to be changed, and that can be changed quickly. I believe that the criminal penalties need to be looked at. The pedigree--and also the third thing would be to increase the definition of what an authorized distributor is and what the requirements are for you to become an authorized distributor.

There's a catch-22 in PDMA. The authorized distributor is not required to pass on pedigree past the authorized distributor. But if we increase the licensing requirements, the criminal penalties, and the definition of who is an ADR, and in short order, I believe that you're going to eliminate a lot of the bad people that may want to enter this environment.

And so I would like to see those things

occur and allow the good wholesalers, the ones that operate their businesses every day for many years in the past, not be jeopardized with the requirement of paper pedigree, because if you don't increase the licensing requirements, the criminal penalties, and the AD definition, you're still going to have criminals entering in and falsifying paper pedigree, and that's not the answer.

MR. TAYLOR: Don?

MR. VASBINDER: My name is Don Vasbinder. I work in the Office of Regulatory Affairs. My question is for Mr. Riccardi.

You mentioned applying GMPs to wholesalers, and I was wondering if you could elaborate on that a little bit, what you had in mind, any particular details. And if anybody else wants to comment.

MR. RICCARDI: We intend to supply our written comments as an association, but it has to do with consistency and it has to do with raising the bar. And we will supply that to the FDA task force.

MR. VASBINDER: Okay. Thank you.

MR. BORSCHOW: I'd just like to add something to that. We should know that wholesalers

today are one of the most highly--drug wholesalers are one of the most highly regulated industries in the entire nation and, in fact, are subject to a constant and continuing scrutiny, not only from FDA but from a whole other alphabet soup of government and state agencies. And it's fair to say that wholesalers have a pretty respectable level of practices, but as I stated in my testimony, we have very definitely been putting our heads together to try to further enhance those practices through our own voluntary guidelines in response to the evolving threats that we must address.

And so we would place a particular emphasis on that, and at the same time convey the understanding that wholesalers and certainly our association members are very, very carefully scrutinized and have some very stringent practices in place. And the result of that is the fact that, as I stated, we distribute literally billions upon billions of units almost without, you know, any exception in the most correct fashion.

MR. TAYLOR: Thank you.

Ilisa?

MS. BERNSTEIN: I'm Ilisa Bernstein in the Office of the Commissioner, the Office of Policy.

I have a question for Carmen.

We've said that it's pretty clear that the state laws need to be strengthened. We're looking at the laws. You said you're looking at the laws and have developed a task force. Can you give us a sense of where the states, the Boards of Pharmacy or the regulatory authorities, what their thoughts are and where you think that they would come down o this?

MR. CATIZONE: As other members of the panel have indicated, although we have more uniformity in this area than in others, there are still some variations. And I think some of the states employ registration processes that may not be as stringent or as significant as licensure processes. And I think the threat of counterfeit drugs has opened their eyes to say we have to take a closer look at this and probably a stronger regulatory approach.

So I believe that the state boards would be in favor of enhanced state regulations to deal with this issue.

MR. TAYLOR: Okay. Well, I want to thank the members of Panel 2 very much for your thoughtful comments, and I'd like Panel 3 to please

come to the table. The first speaker will be John Gans from the American Pharmacists Association.

MR. GANS: I don't know whether to say good morning or good afternoon. I knew I was going to do good afternoon, but we've changed the schedule a little bit.

Thank you for the opportunity to present the views of the American Pharmacists Association. Founded in 1852 as the American Pharmaceutical Association, we were the largest national professional society of pharmacists in the nation, representing more than 50,000 practicing pharmacists, pharmaceutical scientists, and student pharmacists. Also, our reason to be was really about the integrity of the drug supply back in 1852. It's interesting how we have now come almost full circle on that, but there are a lot more players and this responsibility falls really in the hands of the FDA and for our part the USP.

First, let me provide APhA's support of FDA's goal to combat counterfeiting through advance technologies and the coordination of efforts of all parties, including manufacturers, wholesalers, pharmacists, and patients. The protection of our medication supply is of vital interest to

pharmacists, including efforts to prevent an introduction of counterfeit products into a system, and the quick identification and elimination of such products from the system if the medication supply is infiltrated.

Pharmacists rely on a safe, pure supply to help patients make the best use of their medications. My comments today will address three basic areas: the patient and provider education; two, packaging and distribution technologies; and, three, areas of public and private sector collaboration to this important agenda.

Pharmacists have a role in this agenda as educators, purchasers, and protectors of the medication supply which they work with. As the agency further develops this agenda, APhA encourages you to consider two things:

First, we must keep in mind the goal of all of our efforts should be to increase the integrity of our drug supply and never move off of that goal.

Second, we must consider the reality of every member in the pharmaceutical system, and that is the issue of limited resources.

While these things cost a lot of money,

when they move through the system there are very limited margins in many of those areas. Therefore, in determining your directions, you must look at reasonableness, and reasonableness, we think, must consider cost.

The cost of this new system should not outweigh the benefits, and the cost/benefit analysis of any new activity should be considered. One approach to maximizing the use of our resources would be creating standard processes for identifying medications most likely to be counterfeited and to focus our resources on those drugs. Obviously, this review process would have to be updated frequently to ensure that it remains current.

One theme in the report and in today's hearing is that staying ahead of very sophisticated counterfeiters will require sophisticated counter-measures. Technology is an important part of that sophistication. APhA agrees with FDA's assertion that new covert and overt technologies must be implemented in combination to provide the strongest system possible. Additionally, technologies must be flexible to adapt to ever changing counterfeiting activities.

To improve the integration of these technologies in pharmacies, we recommend the agency use practicing pharmacists to evaluate anti-counterfeiting technologies and that they be used at the pharmacy level. But technologies are only a part of the solution. As medication experts on the health care team, pharmacists play a leadership role in identifying counterfeits and preventing their introduction into the system, the distribution system and educating consumers about counterfeits and how to address a suspected counterfeit product. We believe that pharmacists and consumers are critical.

Recognizing this reality, APhA supports efforts to increase the understanding by pharmacists of the role they play in preventing counterfeit medications from reaching patients to help improve pharmacists' baseline understanding of the regulation of our prescription drug supply. Most pharmacists today I don't even think understand all the licensing that's involved, so we are publishing a continuing education piece in the next few weeks that will address this issue.

APhA also supports the profession developing and pharmacists implementing best

business practices for buying medications to help them identify legitimate buyers. These simple steps can move us closer to a better system, and it can be done very quickly.

Another essential role pharmacists play in protecting the medication supply is reporting routine problems with products. Pharmacists are the first health care provider notified by patients of suspect medications and have an important role in alerting the FDA and manufacturers about suspected and counterfeit medications. But to facilitate the reporting, pharmacists need timely, accurate, and pertinent information. Such notification should take place in a priority order, with an optimal situation for notifying the pharmacy community first, not the consumer press, and an immediate subsequent notification to the public and the rest of the health care system. By communicating first to the pharmacy community, both pharmacists and pharmacies, the agency will prepare the community most likely to receive communications, to receive products back.

When a counterfeit medication is suspected, pharmacists need the following information: product name; lot numbers, including

the suspected scope of the problem; three, the source and distribution and route of administration of the product, how the product is suspected to be counterfeit; and information on the level of risk to the patient.

This information helps the pharmacist determine the relative risk of the drug supply which was infiltrated by the drug in question.

Consumers are essential to our efforts. Patients need to be educated about how medications differ from other goods, and other steps must be taken to protect themselves. I recently worked on an international paper that talked about medications as being special. At first, I didn't like the term, but as we moved into it, I began to realize that the public through direct-to-consumer advertising and some other steps, they may begin to look at medications differently than they've looked at them in the past. So we need to go back and educate them that they have a role here.

To fulfill their role in identifying counterfeit medications, patients must learn about the importance of reporting and where to report their concerns. They must understand how easily drugs can be counterfeited and how difficult it is

to detect counterfeit drugs. Patients must understand that medications are different from other imported goods, and counterfeit drugs are not necessarily evident to the human eye. They need to know that they should tell their pharmacist when the drug looks, smells, feels, and tastes different than what they previously experienced.

All that being said, the consumer's best protection from counterfeit medication is using legitimate, trusted sources of supply--a licensed U.S. pharmacy.

Moving to the area of packaging and distribution, APhA agrees that pedigrees are an important tool to consider adding to the kit of anti-counterfeiting devices. In concept, pedigrees may be an appropriate tool to track the preparation of drugs from manufacturer to wholesaler to pharmacist. However, we have significant concern about cost, potential benefits, and the potential benefits of a paper-based system which may only provide a track record of product movement or simply provide a counterfeit record of product movement, a trail as fake as the product that it accompanies.

The value of the paper-based system is

limited by the ease of counterfeiting paper pedigrees. If an entity is sophisticated enough to counterfeit a product, we believe that the entity has the same and equal capability of counterfeiting a paper pedigree. APhA recommends that the agency consider alternate formats, such as an electronic pedigree system. If such a system automatically created a pedigree, it could be implemented with minimal administrative burdens and would be less likely to be falsely produced by counterfeiters.

In addition to the pharmacist's direct role in reducing the risk of counterfeit products, there are other components of the draft paper that warrant comment, specifically unit-of-use technology. Although there are many questions that need to be addressed with this technology, APhA supports the use of unit-of-use packaging because of its potential to enhance patient safety, patient adherence, and drug distribution efficiencies. Efficient implementation of unit-of-use packaging requires state laws to authorize the pharmacist to modify prescribed quantities. Little issues like "Is a month 28 days, 29 days, 30, 31, or is it 35 days?" need to be standardized.

When considering collaboration with the

role of the Boards of Pharmacy, it should always be considered in developing an anti-counterfeit agenda. Currently, many State Boards of Pharmacy are faced with a challenge of regulating store-front operations which facilitate personal importation of pharmaceuticals. APhA firmly believes that one of the greatest risks to patients receiving counterfeit drugs is through personal importation. These facilities are clearly participating in the delivery of medications to patients and practicing pharmacy. Unfortunately, some of these store-fronts operate in a gray area of the law.

APhA applauds FDA's work with the Boards of Pharmacy and NABP and individual state regulators to rein in these illegal and unscrupulous distributors. We support efforts to update NABP's rules, reviewing the 50 state practice acts, and moving forward.

Finally, APhA recommends the agency collaborate with private stakeholders in designing communications strategies among stakeholders. The private-public partnership could facilitate a standard anti-counterfeit communication which would be very helpful. The agency knows that "Dear

Doctor" and "Dear Pharmacist" letters are not always read. APhA recommends using a website of resources for pharmacy professionals, pharmacists.com, to deliver FDA's message on counterfeiting. Pharmacy.com is a single-source site for professional resources that are vital to the continuous development of pharmacists' needs about professional development.

Pharmacist.com is a joint venture between the National Association of Boards of Pharmacy and APhA. And it assembles in one place resources that pharmacists need. We now know that each pharmacist in the country, over 200,000 unique visits have occurred to this site, and it is well used. The site also could be used to help pharmacists link directly to MedWatch to facilitate and ease the reporting of suspected counterfeits.

As medication experts and the most accessible health care provider for patients to go to with questions about medications, it's essential that pharmacists play this role and be, in fact, empowered to do it. APhA is pleased that the FDA is addressing this important issue. The review of current policies and systems is timely given the recent increases in counterfeit medications and

importation by individual patients.

APhA looks forward to working with the FDA as we collaborate to provide patients with quality pharmaceuticals and the education to make the best use of this valuable technology.

Thank you.

[Applause.]

MR. SCHECKELHOFF: Good afternoon. My name is Douglas Scheckelhoff, and I am the Director of Pharmacy Practice Sections for the American Society of Health-System Pharmacists. ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals, HMOs, long-term care facilities, home care agencies, and other components of health care systems. I am pleased to provide you with ASHP's views on the serious problem of counterfeit drugs entering the nation's drug supply chain.

In June of this year, ASHP adopted a policy that encourages the FDA to develop and implement regulations to restrict or prohibit licensed drug distributors from purchasing legend drugs from unlicensed entities and to accurately document the original source of drugs and chain of custody from the manufacturer to the pharmacy. My

comments today and ASHP's written comments in response to the Federal Register notice will discuss how that policy relates to the work of the FDA Counterfeit Drug Task Force.

Over the next few minutes, I would like to comment on four areas that are addressed in the interim report. These include regulatory and legislative issues, industry and health care professional issues, technology issues, and public education.

First, regulatory and legislation issues. Most consumers have no idea of the scope and complexity of the drug distribution chain in its business components, particularly the buying and selling of products between wholesalers. ASHP remains extremely concerned about vulnerabilities in the pharmaceutical supply chain, particularly with respect to secondary distributors. While these entities may perform a role in providing needed medications in some situations, ASHP believes that stronger state and federal oversight may be needed.

Any changes to federal law and regulation should be patterned after recent legislation enacted in Florida. Florida's new law begins to

address the lack of authenticating and documenting the chain of custody of a product from the originating manufacturer. This is particularly important with respect to the high-risk drugs identified by the state as being prone to counterfeiting.

Recent discussions by ASHP's policy recommending councils noted the need for uniformity in state regulation of a national standard in order to maintain the integrity of the drug supply. However, we should be sensitive to the unintended consequences of the creation of new barriers in distributing prescription drugs, particularly with respect to legitimate returns of unused product from pharmacies.

ASHP does not believe that paper pedigrees are an optimal solution to the counterfeiting problem. However, ASHP believes that the development of a limited uniform list of drugs considered to be at high risk for counterfeiting and determined by the FDA should be a priority. Products on the list should not be shifted around among wholesalers. This list should be maintained through a paper pedigree system in the interim, with the eventual goal of developing an electronic

pedigree for these and other drugs.

In terms of augmenting state pharmacy practice acts, ASHP believes that attempting to rely on State Boards of Pharmacy to improve control over wholesalers will require 48 or 49 additional states to take actions similar to Florida and, therefore, be inconsistent and potentially delayed. In the meantime, counterfeiters will simply move to states with fewer restrictions and controls. Many Boards of Pharmacy and Health Departments do not have the resources needed to effect the needed changes at the state level, and effective anti-counterfeiting measures will be slow in coming. The FDA should become more involved in controlling wholesalers.

Now onto industry and health care professional issues. Electronic means and systems for alerting pharmacists to counterfeit products already exist through professional organizations. For example, ASHP maintains an e-mail list of over 23,000 members who receive news items from us on a weekly basis. The development of a new independent counterfeit drug alert network is not needed since other systems already exist, and the cost of populating and keeping a system such as this

current would be prohibitive.

ASHP stands ready to provide rapid alerts to members and hospital pharmacy departments about counterfeit drug incidence, which is in keeping with our longstanding partnership to the FDA's MedWatch reporting system.

Pharmacists should be the focal point for patient contact, education and follow-up when a product is suspected of being counterfeit. Training materials should also be developed to educate pharmacy and product receiving staff with information on how to screen product packaging and what steps to take when they find a suspicious product.

Now, the technology issues. ASHP believes that applying technology for overt security methods will be of limited value to most pharmacists as a means of verifying authenticity. The reality is that most hospital pharmacies stock more than 1,500 distinct products from hundreds of vendors. It would be virtually impossible for pharmacy staff to be knowledgeable about the specific overt methods for each company and product. In addition, many experts agree that overt security methods should be changed at least annually to keep ahead of

counterfeiters. All of these factors contribute to the complexity of the problem. Covert security methods may be of some value as a means of authenticating product but only when the product is suspect. Whatever technologies are adopted need to be practical and inexpensive for the use at the pharmacy level. Funds might be better spent on technology for a universal electronic pedigree for drug products facilitated through some sort of machine readable coding on drug packaging.

Finally, public education issues. Public education activity should focus on overall public awareness of the counterfeiting problem, but generally not focus on specific products. Messages should alert patients to be on the lookout for problems such as a different look, taste or packaging of a drug, and instruct consumers to bring these problems to the attention of their pharmacists. Perhaps public education programs focusing on product integrity could be the focus of next year's National Pharmacy Week public service campaign.

ASHP appreciates the opportunity to present its views at this meeting, and we applaud the FDA's efforts. Thank you.

[Applause.]

MR. MAYBERRY: Greetings. My name is Peter Mayberry, and I am here today on behalf of the Healthcare Compliance Packaging Council, a not-for-profit trade association established in 1990 to promote the many benefits of unit dose blister-in-strip packaging.

For anyone not familiar with unit dose packaging, it is widely used throughout most of the rest of the world as manufacturer's original packaging to dispense pharmaceutical drug products. In the United States, however, unit dose formats are primarily used for over-the-counter drugs and only one class of Rx drugs, oral contraceptives or birth control pills, is dispensed in unit dose formats as the manufacturer's original packaging. It is also used with some individual drug products, but by and large, most drugs in the United States are dispensed in bulk rather than in manufacturer's original packaging.

Now, while unit dose formats can take many forms, the distinguishing characteristic of these packages is that each dosage unit is housed in a separate compartment. For solid oral dosage drugs such as pills, capsules and tablets, unit dose

packages typically take the form of a blister card which houses multiple single dosages in separate cavities, but unit dose packaging can also take the form of strips, ampules, pouches, or any other configuration in which each dosage unit is kept separate from all others. I should also point out that unit dose packaging is non-reclosable so it's only used one time.

Corporate members of the Healthcare Compliance Packaging Council include manufacturers of the film, foil and paperboard used to create unit dose packaging, as well as manufacturers and machinery use in the production of unit dose formats. HCPC corporate members also include contract packaging firms who are hired by pharmaceutical manufacturers to put drug products into specialty packaging, and repackaging firms who purchase drug product from pharmaceutical manufacturers, put that product into unit dose formats and resell it to hospitals, inpatient facilities and others.

My message today is to commend FDA for recognizing the role that unit-of-use packaging formats can play in deterring counterfeit drug products as noted in the recently released interim

report from FDA's Counterfeit Drug Task Force. Unit dose formats are a subset of unit-of-use packaging, and as such, FDA should strongly consider action that would result in greater use of unit dose formats as manufacturers original packaging. The HCPC also supports FDA task force findings regarding the need for pedigree requirements for repackaged drug products, use of tamper-evident packaging, and the incorporation of covert and overt anti-counterfeiting technologies in pharmaceutical packaging and labeling.

Simply stated, the growing problem of drug counterfeiting in the United States could be deterred significantly if counterfeiters have to replicate drug products as well as the manufacturer's original packaging, or replicate the professionally repackaged pharmaceuticals in unit dose formats that bear the products pedigree. This is especially true with unit dose formats where counterfeiters would have to have access to expensive form, fill and seal machines used by pharmaceutical manufacturers, contract packagers and large-scale FDA-licensed repackaging operations. Moreover, unit dose formats can be designed with multiple features that deter

counterfeiting. While it would be inappropriate in a public setting for me to outline exactly what sorts of anti-counterfeiting features are currently available, I can say that unit dose formats can include features that are incorporated into the packaging materials, printed on the packaging, adhered or embedded int packaging or otherwise used in such a manner that consumers and counterfeiters alike may never even know that the features are present.

On behalf of the entire HCPC I thank FDA for this opportunity to present our views. I also volunteer the expertise of our industry to meet with FDA officials and demonstrate some of the anti-counterfeiting features which are currently available.

Thank you.

[Applause.]

MR. TREALEAVEN: My name is Carl Trealeaven. I am the Vice Chairman of the Pharmaceutical Printed Literature Association. The Pharmaceutical Printed Literature Association, known as the PPLA, plays a key role in the supply chain for pharmaceuticals, linking product manufacturers with pharmacists, and upon occasion,

patients. We're responsible for printing the majority of package inserts distributed in the United States today. Our close association with the pharmaceutical manufacturers qualifies us to comment on packaging and security technologies that can strengthen supply chain integrity. To that end, we offer the following recommendations.

First, the FDA should encourage the use of specific security technologies in product packaging. As has already been discussed today, these technologies can be characterized as both overt and covert. And overt security tools are the ones that are easily identified, and the covert ones are not and require a highly-trained eye or even sophisticated tools to detect them. We believe that both methods ought to be used. Examples of some of the overt technologies are holograms, radio frequency ID tags, paper watermarks and intentional print error on the package. And examples are some of the covert features are invisible markings or threads that are embedded into paperboard, micro print, micro tags in the paper stock or packaging adhesive and security inks.

Common manufacturing practices in printed

packaging should be leveraged and expanded to better utilize the authentication and track-and-trace technologies. The pharmaceutical industry is served by a group of printed packaging suppliers that currently operate under the CGMPs. And although not audited by the FDA, suppliers that are held to the highest standards by the most demanding customers adhere to policies and procedures that can be expanded to utilize authentication and track-and-race technologies.

Second, the PPLA supports findings by FDA's Anti-Counterfeiting Task Force regarding the role that unit-of-use package formats can play in deterring counterfeiting. The most effective means of incorporating and preserving package security technologies throughout the distribution chain is through manufacturer provided unit-of-use packaging. Without such packaging the integrity of the supply chain between manufacturer and consumer is broken at the pharmacy stage and counterfeit product can more easily be inserted into the distribution chain.

Fourth, the PPLA reiterates our testimony before the FDA on July 31st that mandatory FDA-approved manufacturer produced printed information

for consumers can help fight counterfeiting and empower consumers as the last line of defense in combating counterfeit drugs. Overt and covert security features can be incorporated into patient package inserts, package inserts and medication guides to maintain the security of the supply chain all the way to the end user. Patient-facing security enhancements also can be accomplished via manufacturers' self-adhesive labeling and folding cartons that require special equipment to produce and are therefore difficult to unlawfully duplicate.

The PPLA applauds the FDA in its efforts to aggressively address drug counterfeiting and stands ready to assist the Agency in employing security technologies and packaging to advance anti-counterfeiting strategies.

I thank you.

[Applause.]

MR. TAYLOR: Okay. Any questions from the task force members? It's Michael. Just state where you're from.

MR. ROGERS: I'm Michael Rogers. I'm in the Officer of Regulatory Affairs, and I'm the Director of the Division of Field Investigations.

I guess I have a general question for the panel, and that is whether or not you all see any opportunities to enhance the reporting requirements for those who receive suspected or counterfeit products?

MR. GANS: I think that your systems work fine. It's pharmacists knowing about those. I don't think it will ever get to the point where consumers would know about their access, et cetera, and I think you need to be constantly working with professional associations of pharmacists to advertise those links, how to make those reports. That needs to be constantly done to put it top of mind to a pharmacist.

MR. SCHECKELHOFF: I would agree that it's largely an awareness issue I think for pharmacists. The other part is really having a system where pharmacists can authenticate or validate whether it's a real problem product or not, so that there's not a lot of reporting of things that shouldn't actually be reported and ending up with a system that's flooded with false reports.

MR. MAYBERRY: My association doesn't have any expertise in this area, but my personal view is that consumers should be involved and should have

knowledge of who to report counterfeits to.

MR. TAYLOR: Yes, Vicky?

MS. KAO: Hi. This is Victoria Kao, Officer of External Relations.

I have a question about pharmacists--excuse me--an awareness campaign for pharmacists. Again and again we've heard today it stressed that customized messages delivered correctly to targeted audiences is crucial to the success of any educational campaign, and I was just wondering, for the pharmacists, your presentations went very much in depth into the messages and the information that you need to hear from law enforcement officers, from regulators. I was wondering if you could touch a little bit on the mechanisms you think that would be successful in us delivering those messages to you?

And the second part of the question is, as was also stressed today, that it takes money to have a successful public education awareness campaign, that we at the FDA don't have that luxury, and I was wondering if there are mechanisms out there among your organizations that would step to the plate and help us in such a collaboration? How can we best hone the messages out there and to

continue to hone and focus these messages successfully with your help?

MR. GANS: I think we need to take a step back and have a very consistent long-term approach, a certain access point, 800 number, website, et cetera. All pharmacies that I know of have administration distribution computer systems, and there has to be a way to effectively penetrate those systems through the FDA, state boards of pharmacy, through the large chains, through hospitals, et cetera, to be able to get that message and be able to immediately access that for a pharmacist, and I think that should become sort of a requirement that the FDA could get that information into the system.

As far as--and then we have our own websites which could easily be used, and they're getting tapped all the time. I mean we have one website for the Pharmaceutical Technician Certification Board that gets over a million web hits a month from technicians, so they're looking for information all the time. So what you've got to do is get it standardized and get it out there and just continue to repeat it and make it easily accessible, and accessible the same way in

everybody's system. So that's how I would do it for pharmacists.

As far as the consumer is concerned, I don't know how you're going to communicate to consumers how they report information back. Most consumers are going to take the product back to the pharmacy that they got it from or to call that pharmacy, and since most counterfeiting does not occur in a hospital or a community pharmacy, they're going to get a positive result from that pharmacist talking them through it, and then going on some website somehow to pull down information if that product has been reported as a counterfeit. So that's how I think we're going to deal with it with consumers.

And the way to finance that is there's plenty of money out there to do direct consumer advertising, and one of the things that concerns me about our profession and industry is there's lots of great ads on anti-tobacco, there's lots of great ads on not driving and drinking. I think we've done a great job of penetrating people about driving when they've had too much to drink or had a drink. I think it's time that we took some of that money and began to tell the consumer about what

they needed to know about counterfeit drugs and that they do exist and where to buy them. So those messages could become part of, it seems to me, the requirement among these advertising programs. A lot of people making money off of drug ads. It seems to me they could put a little space into doing consumer-oriented ads at your behest.

MR. SCHECKELHOFF: I would agree that having a consistent message that can be shared with pharmacists would be helpful and something that they can, you know, grab onto and remember. I think working with the professional associations will allow you to get to a very high percentage of practicing pharmacists, and by using things like state boards of pharmacy newsletters, you'll get to every pharmacist who's licensed in those states. So I think those type of communication tools will be able to get the message out, but it's an ongoing thing that will need to happen over and over.

MR. TAYLOR: Jeff?

MR. SHUREN: Jeff Shuren, Office of Policy.

This is a question to the panel. We've had a lot of discussion today about the potential value of using anti-counterfeiting technologies,

and as you all know, if there's value to it, it requires not only adoption but actually use of those technologies by the various participants in the drug distribution system.

I want to get your sense of the role, if any, of the market, health care organizations, the states and the federal government in promoting or requiring the adoption of those technologies as well as the use of those technologies by various participants.

MR. MAYBERRY: Speaking from the packaging perspective, we're of the opinion that perhaps the greatest thing that could be done is a movement away from the current paradigm in the United States where drugs are dispensed in bulk from the manufacturer by and large. The bulk distribution, which is somewhat unique to the United States, operates all sorts of opportunities for introducing counterfeits into the system. Now, whether there ought to be regulatory requirements or whether industry ought to be encouraged to move away from bulk distribution and more into unit-of-use and unit dose distribution, I wouldn't want to speak to that subject with such a limited amount of time, but the bottom line is that the entire nation would

benefit if we moved from bulk and more to manufacturers' original packaging.

MR. GANS: There is an enormous amount of money being spent by pharmacies to repackage drugs. They're buying machines that can do so many prescriptions an hour to replace a pharmacist, and to us, if we were into the unit-of-use type of system, that's money that doesn't need to be spent. Plus the packaging I think gives us all kinds of advantages. So we have investments into these machines, 50, 100, $150,000. They easily return on investment because you eliminate a pharmacist's salary if you have enough volume. Why are we even doing that? Why don't we have standardized packaging in this country? It seems to me that if you have standardized packaging, that gives you a whole lot of other material to put anti-counterfeiting devices into it. I mean you look at this new $20 bill, one of the big jokes when you travel internationally is that people love to travel with American money and Canadian passports, but most foreigners don't like our money because it looks all the same, and every now and then they whip out a $100 bill and they mean to whip out a 20, but they both look the same to them.

Well, I think our drug products and our mass and our bulk is something that we're moving away from, and there was a big debate in our House of Delegates this year, where one delegate took on 500 people and turned all of their minds from moving away from us requiring unit-of-use to requiring unit-of-use. That's our policy today. So we would strongly encourage moving in that direction, and then having different things embedded in there to help us determine whether or not something was counterfeited.

MR. MAYBERRY: Including barcodes.

MR. TREALEAVEN: We would also support, as I had said in my comments, the use of unit-of-use or possibly unit dose, but the idea is, is to have a package that goes directly from the manufacturer intact all the way to either the pharmacist or occasionally the end user. So there isn't, as the other gentleman said, any type of repackaging.

The other thing I would add in there would be--a possibility you could do is to mandate that there is at least one overt and one covert security feature in each package. Now, you wouldn't necessarily have to mandate the specific type that you put in. Perhaps you might offer a menu of

choices to the manufacturer, a menu of overt features that you might put in, and a menu of covert. But simply to say that you have to have at least one of each on the package, and then provide a means of educating the users of the product what those different features are, and then how actually they might use them, but the important point is, is that you mandate that there must be something like this in there and you have to have at least one of each unit.

MR. SCHECKELHOFF: As I mentioned in my comments, I think that you have to take into consideration, when it comes to technology, especially covert, is that virtually every pharmacy out there is very busy and has a high volume of products. So when you look at the monetary system where you have maybe four or five different bills that are used commonly, it's the awareness that people need to have of what those overt methods are is very limited, but when you have hundreds and even thousands of different products it's just not going to be practical and it would be a shame to spend that money and not have it to use, and our belief is that spending money on an electronic pedigree system would be money better spent.

MR. TAYLOR: Any more questions from the panel, task force?

We realize that lunchtime has come and gone and that we're a little behind. We were going to break for lunch now. However, members of Panel 4 were originally scheduled to go on before lunch, so if there are any members of Panel 4 that would like to go on before lunch, I invite you to do. If not, what I propose is that we have a 45-minute lunch, and then we come back and start Panel 4.

Yes, sir?

MR. BLAIR: Can I make a suggestion? As far as community awareness is pharmacists are licensed practitioners and continuing education is required. A great way to get to those practitioners is through mandatory CE on counterfeit would be one option that would be funded by drug companies or whomever. It would be very low cost. The second one is the unit-of-use packaging is--I've seen that work in the UK--by the way, I'm Jerry Blair with Cerna [ph] Corporation. The unit-of-use packaging they use in the UK is very beneficial in the fact that not only does it give you the ability to do counterfeit, but it also improves patient safety significantly, so by

getting that all the way to the patient.

MR. TAYLOR: Thank you.

It sounds like we're ready to go to lunch. People, please report back in 45 minutes, which is 1:30. There is obviously a restaurant upstairs. I'm not sure if they can service everyone, so there's some other restaurants in the area, next door to the hotel, Chatters and another place.

[Whereupon, at 12:45 p.m., there was a luncheon recess.]

A F T E R N O O N S E S S I O N

(1:35 p.m.)

MR. TAYLOR: It's about 1:35. If you recall, we ended with Panel 3, and so I want to welcome the members of Panel 4, and thank them for their indulgence in light of the fact that we had to continue after lunch. We're going to make a point of ensuring that everyone gets to speak this afternoon. However, we are going to ask that you keep to your allotted times in order to help move things. And Panel 6 in particular is one that has an enormous number of people.

I also want to remind you that even though we're committed to having everyone speak who is on the agenda, the vendors will need to be out of the room by 5 o'clock, so vendors just FYI, you're going to have to move out your wares.

The first speaker on Panel 4 is Alan Goldhammer from Pharmaceutical Research and Manufacturers of America.

MR. GOLDHAMMER: Thank you very much, John, and it's Alan Goldhammer. I'm Associate Vice President for Regulatory Affairs at PhRMA. We're pleased to be here to present today on what we think are some critical issues for patient safety.

I think that was a theme that you heard echoed throughout the morning, and certainly is one that we will keep to as well. I will try to go quickly over some of the points that were covered by earlier speakers, because I think there were some common themes that you heard, while saving time to amplify on those issues that PhRMA believes to be particularly important.

I think as everybody is agreed so far, there's no single approach or technological magic bullet to anti-counterfeiting, and PhRMA strongly believes that a systems approach is necessary that involves both technology approaches as well as improved regulations. And ultimately a closed distribution system is the system that best assures product authenticity. And as we will touch on in some of the latter slides, stiffer criminal penalties and improved regulatory approaches are definitely needed.

In order to assure product authenticity PhRMA member companies already--and I think this is a point that wasn't stressed earlier today--are employing both covert and overt approaches, both in terms of formulation development, as well as in packaging. Some of the covert approaches that

involve taggants or forensic analysis are particularly useful in assessing authenticity. However, they do not permit real time authentication, so if a pharmacist has questions when he opens the bottle, those technologies are not going to be useful in that setting.

In terms of overt approaches, companies are using special printing features. Tamper-evident packaging is being widely used. However, and the theme that we have heard constantly, is there is the need to rotate solutions, and in particular, probably on a 12-month horizon. So you're then faced with the question, what does the pharmacist see as these features start changing? Are they going to have to go back and look up and see, well, do I look for a color changing ink in this case or a new hologram here? It's still going to cause some problems at the workplace.

Track-and-trace was identified a little earlier. I think everybody believes that when this is fully employed it represents our best attempt to ensure authenticity. However, there are some major hurdles that need to be overcome. We will need to have serialized identification on all packaging units so that when the pharmacist dispenses they

can close out the database for that particular serial number. It can be done with barcode under existing technology, and I know that my good friend, John Roberts, will be on a later panel, and he'll talk about some of the work that the Uniform Code Council has done.

RFID technology has been mentioned. The Commissioner has mentioned it. I think a lot of folks are excited about it. Again, there's a lot of work that is going to need to be done.

The second bullet here, as I already noted, a need for an open standard, and then I think a critical issue here is the information technology infrastructure that is going to be needed to record each transaction.

And the ultimate final bullet her is the time and cost of implementation and a lot of question marks here. We don't know how long it's going to take to implement this down to a single packaging unit. I'm not talking about bulk packaging at either the case or pallet level which maybe can be done a little quicker, but that's not going to provide I think the security that we need to look at the whole chain.

We have heard from one of our

manufacturers that they distribute--and this is a worldwide figure--a billion package units per year. So even if you get the cost of RFID chips way, way down, this is still a lot of money on a yearly basis for a manufacturer to be investing.

The bottom line it--and I'll touch upon this a little bit later--is, well, there is a need for an interim paper pedigree requirement to track transactions.

I'd like to now turn to some of what we call the regulatory issues here, and there are four principal ones here: finalizing the PDM pedigree requirement, strengthening licensing requirements for wholesalers, addressing repackaging requirements, and increase penalties and enforcement activities for counterfeiting. And again, some of these we've already heard from from previous speakers.

PhRMA feels very strongly, and I think we stated so at the Part 15 hearing, John, that you chaired, I think it was back in 2000. So we're almost three years now, that the pedigree requirement should be implement. We realize it's been stayed. However, drug pedigrees do serve two very important purposes. They prevent introduction

of counterfeits into the supply chain and they facilitate the recall of counterfeit products.

PhRMA believes--and I think if one goes back and reviews the congressional record on this that the final rule is an accurate reflection of congressional intent and will help prevent counterfeits from entering the drug supply.

In terms of the pedigree what has changed since the law was passed? We're already heard there have been an increased number of FDA counterfeit investigations. We know that there's an increased sophistication of counterfeiters. Even sophisticated holograms can be replicated within six or seven months time. There are increased health risks to the public if they get a counterfeit product, and one only need turn to the Florida Grand Jury report, which took an extensive look at what was going on in the state of Florida in terms of counterfeiting, and their conclusion was that there's a strong need for a pedigree requirement to deter counterfeiters, and here is some language from the grand jury report, and I would also note that PhRMA was very active in the discussions that went on in the state of Florida to strengthen their state regulations.

The options to strengthen the effectiveness of the pedigree is to have a universal pedigree that requires all wholesale distributors to pass pedigrees along including authorized distributors, so this would address one of the issues that a speaker raised earlier, and secondly, to require pedigrees to be passed to all customers including retail pharmacies. And then verification to require purchasers to verify the authenticity of pedigrees.

In terms of wholesale licensing--and again we heard a significant amount of this earlier this morning--this is done at the state level. We have 50 states so there are 50 different sets of requirements, and in some cases enforcement may be lax. Again, this was extensively dealt with by the Florida Grand Jury, and there were significant problems there which have been corrected with the stronger state regulatory approach. And it may be perhaps that federal standards for wholesaler licensing need to be strengthened.

PhRMA believes very strongly that there need to be efforts to deal with repackaging. Recent counterfeiting investigations have involved such operations, and there are two key points here.

Repackaging poses a risk to product quality because the repackager may not use the container closure system that is in the original NDA and which was studied exhaustively by the manufacturer, so it could present some issues with regard to product deterioration. And secondly, if we are going to move to implementing some types of anti-counterfeiting technologies on packaging, the simple act of repackaging will negate anything that the manufacturer might have done in that regard.

So PhRMA believes strongly the FDA should reassess policies regarding repackaging in light of this threat, and if the Agency decides to move in the direction of requiring anti-counterfeiting technologies to be included in packaging, that repackagers should be subject to the same requirements, that is, whatever the packaging technologies that are decided on as the original manufacturer.

In terms of increased penalties and enforcement, this was discussed by the first panel. We also believe that it would be useful to take a long, hard look at the criminal and civil penalties for counterfeiting and strengthen those. Again, this was noted, that the penalty for drug

counterfeiting is three years, and as we say in the third bullet here, there is significantly greater criminal penalties for distributing elicit drugs than there is for the counterfeiting of legal drugs, which actually put patients' health at risk.

The penalties for counterfeiting a pharmaceutical should be commensurate with the significant public health threat posed by the counterfeit drugs, and sufficient to deter counterfeiting activities, particularly those that are carried out by organized crime.

In conclusion, PhRMA believes that all the stakeholders need to have a primary focus on patient safety. We're working on the task force that HDMA has convened to look at electronic track-and-trace simply because we believe that this represent probably the best approach, but we have a number of trading partners, the distributors, the pharmacies, and then ultimately the patient, that we all need to keep part of this as we move forward, so that patient safety is not compromised.

I thank you for the opportunity to present today.

[Applause.]

MR. KUBIC: Good afternoon. My name is

Tom Kubic. I'm the Executive Director of the Pharmaceutical Security Institute, and I'm pleased to join my colleagues in discussing an issue of growing importance to all Americans. I also want to join my colleagues in thanking the FDA for hosting this hearing. As you look at your anti-counterfeiting initiative, it's clear to me that there is much work to be done.

Because of the limited time I'd like to focus my comments on four areas that I believe are critical to a successful anti-counterfeiting effort, those being the opportunities and limits of technology. I'd like to discuss some best business practices currently being employed by the manufacturers, talk a little bit about the improved or the need to improve information sharing, and then close with a discussion about some recommendations for an improved and enhanced FDA effort at international investigations.

In late 2001, in order to strengthen their response to the growing threat of counterfeiting, 16 research-based pharmaceutical manufacturers came together to establish the current PSI. The goal of PSI is to support its members in their efforts to ensure the distribution of pharmaceuticals that are

safe and effective. PSI's mission is to collect, analyze and disseminate information about counterfeiting, theft, as well as diversion of medicines. This information is then shared with the appropriate authorities here in the United States and in other countries throughout the world.

Echoing some of the earlier comments about the global nature of counterfeiting, in fact, in the 2002 PSI situation report, we did find counterfeiting as having been identified in 32 countries. For the first three-quarters of the fiscal year 2003 that number has risen to 36 countries and I think that this trend is entirely likely to continue as the well organized counterfeiting groups expand and develop further their illegal operations.

The increasing number of investigations undertaken by FDA is just one indicator of the success of counterfeiting organizations and these are just the instances that we currently know about and have been able to identify. Counterfeit, mislabeled, diluted, expired and contaminated drugs have entered the American pharmaceutical system because in part the market is such an irresistible lucrative target to these organizations, and also

in part because of the dispersed distribution system.

I was also pleased to see the FDA's interim report clearly stated that there are limits to each and every technological fix. There simply is no single technological solution to counterfeiting. Criminal organizations and their associates will continue to adapt to any new anti-counterfeiting solution that is proposed. They'll continue to copy overt markings. They'll continue to refill vials. They'll continue to over label packages, and they will continue to seek coconspirators who will accept counterfeit packages irrespective of the lack of appropriate packaging or pedigrees.

However, the use of technology, when combined with stricter enforcement of the counterfeiting laws, as well as stricter penalties, can form the basis for a comprehensive approach to help deter counterfeiters. PSI members have and will continue their efforts to incorporate the latest in appropriate anti-counterfeiting technologies in both their packages and their products.

For example, in September of 2003, 100

percent of the PSI members responding to our survey stated that they are actively studying the issue of new technologies for packaging. In the past year alone, over 59 percent had introduced new packaging security devices, and over 92 percent were planning on introducing new packaging security devices in the next 12 months.

While it's good to note that the members are continuing to improve package security features, they also fully understand the nature and the ingenuity of the counterfeiters. In a most telling statistic, over 72 percent of our members reported that based on their previous experience and investigations with the counterfeiters, individual packaging security devices did not and could not have prevented the particular problem.

I wanted to mention briefly two best business practices currently employed by our members. Each one of the members has a standing internal cross-disciplinary committee which is comprised and brings together personnel from the security department, quality assurance, quality controlled units, as well as the legal department and product packaging experts. Whenever there is a counterfeiting incident which has occurred or is

suspected, as weaknesses are identified, suggestions for improvement are promptly developed.

Secondly, each PSI member has dedicated personnel responding to the problem of counterfeiting. On a daily basis these experts work closely with law enforcement and health care authorities throughout the world by monitoring and quickly investigating any complaint by a patient, pharmacist, physician, that a drug may be counterfeit. They monitor and return packages of medicines as well as suspicious packages that are on the market to ascertain possible signs of tampering. They then provide critical information on their products and efficiently assist law enforcement whenever requested to do so.

The investigation and prosecution of suspected drug counterfeiters, whether in the U.S. or abroad, is significantly improved by the timely exchange of information. Prompt information exchanges allows for the efficient allocation of enforcement and investigative resources, and ideally, the seizure of counterfeit products before they enter the supply chain.

From the manufacturer's perspective we need to know the specifics of the counterfeiters'

modus operandi. With this information we can strengthen those weaknesses that are exploited.

PSI also agrees with the FDA's call for American stakeholders to work with foreign stakeholders to better coordinate their anti-counterfeiting efforts. In fact, every PSI member has pursued anti-counterfeiting initiatives around the world, as security staffs frequently interact with their counterparts in a support of law enforcement efforts.

PSI has staff permanently assigned abroad and works closely with Interpol's Intellectual Property Action Group. But there is a need to reinvigorate the U.S. Government's effort at the identification and dismantling of these criminal organizations that have targeted the United States' markets. Since these organizations are in fact internationally based they are outside of the reach oft times of the FDA. Without a presence in key manufacturing countries the investigative components of FDA is in a constant defensive and reactive posture. To improve their effectiveness, PSI believes that FDA should take immediate steps to establish an investigative presence in key foreign source countries. Only through the full-

time posting of agents from the Office of Criminal Investigations to counterfeit pharmaceutical source countries will the financial structure, the transportation route, the distribution points of these organizations be fully identified.

In closing, PSI believes that the FDA's multi-pronged approach to addressing the criminal problem of pharmaceutical counterfeiting, as outlined in the task force report, is comprehensive and well-reasoned, but additional improvements can be made in the three areas I mentioned.

Firstly, substantial information sharing should be put forth as one of your priority efforts. A high-level commitment from all the stakeholders with regularly scheduled information exchange is needed to advance this initiative. Secondly, we also join, as some of the other speakers have mentioned, in the need for more aggressive enforcement of anti-counterfeiting laws and tougher criminal penalties against counterfeiters and lastly, it's our belief that the FDA should assign more investigative resources abroad in these key foreign source countries where the counterfeiting organizations exist. In these regions the U.S. leadership and support is

immediately needed.

Thank you.

[Applause.]

MR. DEMPSEY: Good afternoon. My name is John Dempsey and I'm Executive of Trade Relations and Brand Security for Ortho Biotech. Ortho Biotech is Johnson & Johnson's biotechnology company.

Some of the folks here in the room, Tom McGinnis, Jim Cohen, and a few back in the audience, have seen bits and pieces of this presentation, but I wanted to go over and provide to you the experience that we had as a company when we first discovered counterfeit drug in the marketplace, and the format will be what it was like, what happened and what it's like now. So we'll give you some firsthand experience of what we did and the security measures that we decided to implement on the teamwork that occurred between Ortho Biotech and the FDA and the Office of Criminal Investigation, and what drove all of us, J&J, Ortho Biotech, OCI and FDA, in reaching the solution that we reached, and also talk a little bit about what we see as short-term solutions and then long-term solutions in terms of some of the

new and exciting technologies that are out there in the marketplace that have been mentioned previously.

On or about May 20th we received a phone call that was probably one of the worst phone calls I ever received in my career, and that was to let us know that FDA had found some product in a distribution warehouse in Grapevine, Texas that was of a suspicious nature. We believe that the initial investigation a Medicaid fraud investigation, but that because the product--there was no paperwork associated with it, this caused FDA and OCI to suspect that there might be something more to this case than just Medicaid fraud, and in fact, the product was sent out to Amgen to be analyzed. There were 1,004 vials that were analyzed. And just to be clear on this, Amgen manufactures PROCRIT for Ortho Biotech, and we market it in the United States for all non-dialysis usage.

It was in fact confirmed that the 1,004 vials that had been discovered were in fact 2,000-unit product that had been relabeled as 40,000-unit product. We immediately had a conference call with the FDA to discuss and identify our next steps, and

that was a very large team that consisted of FDA, Amgen and J&J along with Ortho Biotech.

On the 30th an internal core team was established. And I give this information to you because if there are other pharmaceutical companies out in the audience, I think this is important. The process that we went through is one that you might benefit from and might be able to implement yourself.

But our internal core team was a small team, and it consisted of myself, trade relations and brand security, communications, our medical department and our legal counsel. That core team also consisted of a representative from the FDA, and that was Jim Cohen. I just want to take an opportunity to recognize and acknowledge the work that Jim Cohen did as we worked through this very, very difficult process that involved phone calls late into the evening, work on the weekends, and without Jim's team and the work that he did, we could not have successfully addressed this issue in the marketplace.

On the 31st we produced to FDA our timeline, and communicated to them what the month of June would look like.

Now, just to give you some of the things that we were up against at this point in time, number one, anything that we did we would have to do in conjunction with Amgen. We were not the manufacturer of the product, so in order to do anything and implement any security features in the packaging we would have to present a case to Amgen and then present a case to the FDA that would allow us to pull the product out of our current inventory and redress that product with the anti-counterfeiting technology features built into it.

Keep in mind that we also were not approved at that point in time in New Jersey, none of our sites were approved to redress product, and because of speculative buying that occurred in the previous year, we had about $1.2 billion worth of product in inventory.

J&J had also decided that none of that product would go out into the marketplace until it had some type of anti-counterfeiting technology built into the packaging.

So there was a number of issues that we had to deal with, and we decided that, very simply, that we would be guided by our credo, and FDA, ourselves, we all knew what was of utmost

importance was customer safety and satisfaction for the patients that we service.

So it became very easy for us, after we identified that this product was out in the market, the process that we had to follow.

So we did, from June 1st until June 22nd, we had continuous proactive communications. We sent out over 400,000 different letters, two separate "dear doctor" to the health care providers letting them know what we had discovered. We had discovered two separate lots of counterfeit product that had been labeled as PROCRIT, both of which had been 2,000 unit relabeled as 40,000 unit. Our redress was a cross-functional team that consisted of packaging, quality, manufacturing, engineering, operations, shipping, legal and trade relations. And I think that hats off to this team and what they accomplished.

In order to build a case, working with the counsel of FDA to allow us to go in to create a manufacturing line to take product out of inventory, to unpackage it, and then to redress it, and to be able to present that case to FDA and have FDA approve it, obviously we couldn't have done it without their great cooperation, insight and

counsel. So, hats off to the team.

We decided during the process that our platform, our basic platform in the initial development of our brand security program would be security ink, and we were going to go with carton closure seals.

From the 1st until the 22nd we had daily meetings, conference calls with the FDA to let them know how the plan was progressing, and to let them know when we thought the redress would be completed.

I have to chuckle when I look at that, it's one bullet point, because trust me, it wasn't one bullet point from June 1st to June 22nd.

On the 22nd the redress activities actually began on the first lot of our 40,000 unit product, and on July 1st that first lot was shipped out of our Franklin Distribution Center with the carton closure seals and the security features built into it.

On August 29th the complete $1.2 billion worth of product had been completely redressed.

So when we look at different types of brand security plans, I think from our standpoint, obviously people have already spoken about overt

features, covert features, we also added some features that are both covert and then become overt in some of the adhesive seals that we have on our product.

This is what a carton closure seal looks like. We have a color-shifting ink similar to what was used with the U.S. Treasury Department on the $20 bills. We go from a green to a gray. We also have covert features that are built into the security inks, which I won't go into detail about, but I can tell you that our district managers can go to an end user's office, to a hospital pharmacy, to a wholesaler, or to a hospital and authenticate product at the end user's place of business. And that's the covert feature.

I'll also say that there's been some conversation about how sophisticated the counterfeiters are, and they are very sophisticated. One of the covert features that becomes overt on our carton closure seal is that when you remove the seal initially we had a pattern on the adhesive where it would say "Void," and it would say "OBPLP" when you removed the seal, and we felt very comfortable that that was another feature that we built in that would be difficult to

replicate. Well, nine months we had put the seals on the cartons, fortunately, through an informant, FDA and OCI conducted a sting operation, and this was the product that we found. And the counterfeiters had reproduced a very unsophisticated version of the carton closure seal. They didn't have the adhesive indicator on the back, but they did attempt to reproduce the seal. So that addresses one of the issues.

When you talk about a security program, it has to be fluid, it can't be static. It has to have many features that are both overt and covert, and certainly complacency is the greatest threat that you'll face. For us, we had the carton closure seals, we had the security ink, we had the covert features that were built into those carton closure seals. We then took all of our caps and foil wraps and we color-coded them to the specific strength of our product. On our foil wraps we built in covert features that identify the strength and the name of the product.

And this is an example of the different colors in the caps and the foil wraps that are used on our vials. For those that are unfamiliar with PROCRIT the vial is about this big, so about an

inch high.

In addition we now have covert features, actually overt and covert features that are built into the individual unit vial so that they also can be authenticated at the end user level by our district managers.

Key learnings. Complacency will kill you. You've got to have a comprehensive security program and you've got to have many components and many layers. Neither the program nor the threat is static. If you sit still, you can be guaranteed that counterfeiters are not sitting still, and that they're looking for a way that they can counterfeit your product and make money.

Communications have to be transparent from the very beginning. I urge anyone who's in the pharmaceutical industry that if you discover this, be as transparent as you can. Let everybody know. Call the FDA, enlist them as your partner. Set up your websites. Link your websites to the FDA's website. Over communicate as much as you can. We had eight different mailings, 200,000 mailings for each time that we sent out. We had, I believe, the first mailing Jim probably had six or seven pages and it included color photos that showed the

difference between authentic versus counterfeit product. On our website we have the authentic versus counterfeit product pictures also, and that can be seen at www.procrit.com.

The effectiveness of any security program rests on your weakest link. You constantly have to do your threat and vulnerability assessments. Meticulous management of the supply chain is paramount.

And I have to say two things that we did. In three of the eight communications that we sent out, we told our direct distributors--those are those customers that we sell our product directly to--that if they're caught with product purchased from a source other than Ortho Biotech, they would lose their direct account status with us. And in an industry where 2 percent, 30 days is very important to generate revenues, that had some impact.

A second piece of that communication was we solicited and asked all of our customers that utilize PROCRIT to let us know if they ever receive mailings or faxes from a source other than Ortho Biotech to purchase PROCRIT, and I'm happy to say that on a number of occasions we did receive phone

calls to that effect. We were able to pass those on to FDA and OCI and successful investigations occurred. I'm unhappy to say that the frequency of those phone calls was very, very small.

So I think there's an issue there that we all need to take a look at in terms of responsibility and accountability. The reason that counterfeit drug gets into the marketplace is because someone's willing to buy it, and if flyers are out there suggesting that product can be purchased at a price that's below market price, then there's probably something wrong with the product.

The cost and benefits are not always quantifiable. It's difficult to put a dollar and cents figure on them, but at the end of the day, what's most important is patient safety, and cost is not an issue when that's taken into consideration.

And this is our icon on our website. Thanks very much.

[Applause.]

MR. THERIAULT: Good afternoon. My name is John Theriault.

Since 1996 when I joined Pfizer as Vice

President of Global Security a significant portion of my time has been devoted to developing and implementing a robust anti-counterfeiting program. The basis for that program lies not only in Pfizer's desire to maintain public confidence in the Pfizer name and the integrity of our products, but also to safeguard public health and safety. So I would like to thank the FDA for this opportunity to express Pfizer's views on the FDA's anti-counterfeiting initiative, and the importance of that initiative in ensuring the integrity of the U.S. pharmaceutical supply.

My comments today are going to focus on two related areas, how the FDA and the pharmaceutical industry can work together most effectively to protect that supply, and our recent experience with counterfeit Lipitor as a case study in the effective management of a threat to that supply.

Lipitor is the largest-selling pharmaceutical product in the world. As many of you may know, a substantial amount of counterfeit Lipitor was recently discovered in the U.S. distribution system. Investigation into the sourcing and distribution of the counterfeit

Lipitor disclosed a large-scale international operation involving as many as 16 companies in nine countries. It was in fact a very sophisticated well-organized international criminal enterprise.

The counterfeits were apparently manufactured in Brazil or Argentina. They were introduced into the U.S. by repackagers who commingled the product with authentic product and distributed it to pharmacies throughout the United States via the secondary wholesale network. At the end of the day over 18 million tablets had to be recalled.

The original Lipitor case came to our attention as a result of consumer complaints that were received and investigated by Pfizer. The number of complaints, fewer than 20, represent only a tiny fraction of those who take Lipitor on a daily basis. And an examination of this photograph, if you can see it, may explain why there were so few complaints. Visually the counterfeit tablets on the left are virtually impossible for a consumer to differentiate from the authentic tablets on the right.

As this case developed Pfizer and the FDA were in almost daily contact. While the primary

contacts were between Pfizer's Global Security Unit and the FDA's Office of Criminal Investigations, there was also frequent contact between Pfizer and FDA laboratories. As Pfizer received sample from those consumers who had filed complaints, the samples were tested and found to be counterfeit. We not only shared with the FDA our test results, but also provided them with samples necessary for them to conduct their own analyses. Our security unit also coordinated the verification of lot numbers, expiration dates and distribution of the lot numbers that were called into question.

For its part the FDA worked closely with Pfizer to ensure that once a recall was issued, the public would be promptly informed of the nature and extent of the recall. The FDA issued talk papers that not only informed the public of the recalls but also reassured those taking Lipitor that it was only the tablets repackaged by a certain company that were subject to recall.

Also when it became clear that a recall was imminent the FDA provided Pfizer with notice, thereby permitting us to put in place our own plan of action to inform and reassure our customers. The steps that we took included the issuance of a

press release, posting and updating information on our Lipitor website, preparing a detailed Q&A to provide accurate and consistent information to the media, health care professionals and patients, and an informational fax that was sent to pharmacists throughout the country.

To ensure the success of the FDA's anti-counterfeiting initiative we feel that attention must be given to three particular areas: government and industry cooperation in preventing the introduction of counterfeits into the U.S. pharmaceutical supply; prompt and coordinated reaction to counterfeits that are discovered; and strong remedies against those responsible for counterfeit activities.

Regarding prevention. We agree that packaging should be developed to permit counterfeits to be more readily identified. To accomplish this goal the FDA should provide flexible guidelines for implementation by the industry. But technology alone is not the answer. It should be viewed as one important part of a multi-layered solution.

Those involved in the distribution channels for pharmaceuticals must also be made

active participants in ensuring the integrity of the supply. They must improve business practices to authenticate and track products, and stricter penalties must be imposed upon those willing to jeopardize public health and safety by engaging in reckless business practices that facilitate counterfeiting.

To ensure the success of these measures there must be a greater commitment of resources, not only by the FDA but by state regulators as well. Current regulations must be strictly enforced. Wholesalers and repackagers should be regularly inspected to determine their compliance with existing laws and regulations. The industry must also be alert for signs of counterfeiting through enhanced product surveillance and close monitoring of distribution channels.

I can't over-emphasize the importance of open and frequent communications between the FDA and the industry. In the event of a serious counterfeiting threat these communications can be facilitated by designating points of contact and establishing briefing schedules. In order to facilitate its investigations the FDA requires information concerning our products, our packaging

and our anti-counterfeiting technologies. Given the proprietary nature of that information, however, it's necessary to have in place a system to ensure the confidentiality of that information.

We also believe that a more efficient method to inform and educate the public must be developed and implemented. Key components of any system should include a coordinated FDA industry process for disseminating information concerning recalls. Examples of such solutions could include the use of Internet websites and the mass faxing of information to pharmacists as proved so successful in Pfizer's management of the Lipitor recall.

Finally, Pfizer remains committed to aggressively addressing the counterfeiting problem. We will maintain our proactive surveillance of the market through consumer relationships and global security to identify and investigate possible sources of counterfeit Pfizer products. We will seek to forge a strong partnership with the FDA and other enforcement agencies. A training program recently held for a joint task force from the FDA OCI, the FBI and local police is a first step in forging a strong partnership with the FDA to ensure that the pharmaceuticals dispensed to U.S.

residents are authentic, safe and efficacious.

Again, thank you for the opportunity to comment on this very important FDA initiative. Thank you.

[Applause.]

MR. TAYLOR: Any questions for the task force?

MR. McCONAGHA: I've got a very quick question, if I may, for Mr. Goldhammer.

MR. TAYLOR: Bill, just before you go on, just in case there are people who--

MR. McCONAGHA: I'll identify myself. Bill McConagha with FDA's Office of Chief Counsel.

Mr. Goldhammer, I have a quick question for you. Does your organizational membership have a view with respect to unit-of-use packaging?

MR. GOLDHAMMER: We don't have a firm view yet. It has been discussed and there are some potential drawbacks to it. Mention was made earlier about the use of blister packs as one approach. There are a couple of key points to be noted about that. (A), it is widely used in Europe, and there also large numbers of blister packs have been counterfeited in Europe, so it's not a panacea in that respect.

Also, in the United States we have the Poison Prevention Act regulations that have to be complied with, so every blister pack has to be evaluated for each drug. You can't just say, "We've got a blister pack and we're going to use this for our whole line." It's got to be evaluated on a drug-by-drug basis.

And the final point is, for drugs that have multiple dosing regimens, you really run into a problem. Take the example of antibiotics where you have a 7, 10, 14, 21-day dosing regiment. How do you blister pack those? It's going to be complicated and pharmacists may end up having to carry multiple inventories.

MR. McCONAGHA: Thank you.

MR. TAYLOR: Any other questions?

MS. BERNSTEIN: Yes. Ilisa Bernstein from the Office of Policy.

I have a question for Mr. Kubic. In the survey that you did, did you by any chance survey and ask people what they think about in terms of when they're going to institute anti-counterfeiting technologies, what kind of factors they consider? Because if you recall, in the report we had a question about that, so I was wondering if you can

comment on that at all?

MR. KUBIC: The survey that was conducted by PSI did not go into the detail in terms of what types, and we did ask within the next 12 months who was interested or who had a work in progress that looked as if in 12 months they would have something new online, and that was the basis for that number.

MS. BERNSTEIN: And in fact, if anyone else wants to comment on that, that would be--

MR. DEMPSEY: John Dempsey. In terms of other companies, I think the thought is, after hearing what we had to present and what my fellow peer at Pfizer had to present, if you're a pharmaceutical company and you're not looking at implementing some type of brand security program now, you might want to reconsider that.

MR. TAYLOR: Yes, Terry?

MR. VERMILLON: Yes. I'm Terry Vermillon. I'm Director of the Office of Criminal Investigations.

Mr. Dempsey, I was just wondering, in the injectable market, I wonder if the industry has started looking at any kind of technology that would preclude the reuse of vials, so it would be a single use vial, where after it was used it could n

longer be reused?

MR. DEMPSEY: I think from our perspective there's a number of different technologies that we're looking at both in vials. We also have examples of products that are out there that are delivered in a syringe. From our perspective I wouldn't want to comment on what we're looking at or what we're thinking about doing, but certainly the technology is evolving and the technology hopefully will be there.

When we look at what's out in the future and I didn't comment about this in my presentation, but many folks here today did talk about radio frequency identification tags, and I think from the standpoint of the future and what the future holds I think there's two things that RFID provides us as an industry and to the customers that we serve. One is the anti-counterfeiting technology that we can afford. It's very difficult to duplicate. We can authenticate product at the end user level. But then the secondary piece that that provides the industry on the supply chain side are supply chain efficiencies in terms of inventory management, reverse logistics, data collection.

Whether or not FDA gets to the point where

they mandate a program going down that path, the only thing that I would say is we had barcodes out now for 20 years--40 years. And when have they become fully implemented in the pharmaceutical industry? So I think there's an opportunity for all of us to come together and look at this new evolving technology and make a decision that this is that this is the direction that we want to go, and certainly if the masses come to the table, then the cost of the technology will be insignificant.

MR. TAYLOR: Any other questions?

[No response.]

MR. TAYLOR: Okay. I want to thank the fourth panel very much.

[Applause.]

MR. TAYLOR: And I would like to ask the fifth panel to please come down to the table.

The first presentation will be by John Roberts and John Terwilliger from Uniform Council Code.

MR. TERWILLIGER: Good afternoon. My name is John Terwilliger. I'm the Vice President of Market Development at the Uniform Code Council. I would like to thank the FDA for this opportunity to talk about drug counterfeiting.

Counterfeit drugs are harmful to patients and costly to the health care industry. It is an issue that the Uniform Code Council or the UCC takes very seriously.

I would like to provide you with some information about the UCC and highlight some of the global tools we have available that can help fight counterfeiting today and in the future.

For 30 years the Uniform Code Council is a recognized world leader in standardizing bar coding in electronic commerce that enables unique and accurate identification to the global supply chain. We are a neutral, not-for-profit global standards organization. Our mission is focused on working with users to develop open multi-industry, technology neutral standards that improve the way business is conducted around the world.

Our solutions have brought tremendous benefits to businesses and consumers alike. Our organization is best known for the development of the ubiquitous universal product code, or UPC, which we commercially introduced in 1974. The UPC has had a dramatic impact on business and has been recognized as one of the most important innovations in the history of commerce.

As use of the UPC grew, Uniform Code Council expanded this technology to address other business processes. Today the UCC provides a complete suite of physical identification electronic commerce standards that can be used in any industry to identify items, including all levels of packaging, logistics units such as pallets and other shipping containers, assets and also locations.

While my presentation will be focused on UCC tools that are currently available to address any counterfeiting, I want to note that UCC has launched a new entity named EPC Global. This new organization will lead the worldwide commercialization of the breakthrough electronic product code or EPC that has been researched and developed at the MIT Auto-ID Center. EPC technology will be complementary to our existing standards and provide greater ability to combat counterfeit drugs.

While the UPC was originally developed for the U.S. grocery industry, its dramatic success quickly generated interest from other industries both here and around the world. The technology behind the UPC became the basis of the global

EAN/UCC system, a system of open, multi-industry supply chain standards. The following information demonstrates the global strength of the EAN/UCC system.

Our global standards are used by over 1 million members worldwide, and these would be primarily companies, distributors, et cetera, and other organizations. They are used by 23 major industries including health care to conduct business efficiently in 141 nations. These standards are at work in the hospital setting, pharmacies, health care manufacturers, distributors and stores for over-the-counter health care products today.

Our system is well established, provides a global user base and offers a broad range of integrated solutions to facilitate accurate, unique item identification. These are the same reasons the FDA, in March 2003, incorporated the standards of the EAN/UCC system into its proposed standard to reduce medication errors and save patient lives.

As I mentioned, the EAN/UCC system provides tools that can combat counterfeiting of drugs. For logistics we offer the SSCC or the serial shipping container code that uniquely

identifies logistics for like pallets, containers and mixed cases as they move from point to point in the global supply chain. For applications that require identification of a case, intermediate pack or a unit-of-use, companies can utilize the global trade item number or GTIN with a serial number. GTIN plus serial number ensures global unique identification of that specific item anywhere in the supply chain. These tools are already in use and available today.

Implementation can be expedited quickly leveraging existing systems and infrastructure. Most importantly, the industry can begin addressing and combating counterfeit drugs now.

The first layer to combat counterfeiting for the health care industry is to continue to identify items with the global trade item number which carries the national drug code. The global trade item number is a unique identifier for trade items, as I mentioned before, used in 141 nations around the world. GTIN is the de facto identification standard for pharmaceutical items worldwide.

Most barcodes that are used in the marketplace only carry the GTIN. However, there is

often a need to provide other information specific to a particular item or set of items. Application identifiers allow companies to include secondary information about their product. Application identifiers are another important tool in the EAN/UCC system to combat counterfeiting. Over 100 different application identifiers are available to provide additional information such as lot numbers, serial numbers and expiration dates.

The GTIN combined with a serial number and a lot number can identify all packages from individual units-of-use to cases with precision. The GTIN, serial number and/or lot number can be bar coded now with available commercial equipment.

The UCC has worked with the health care industry to develop small barcode size for end of use packages, and this is an example on the screen. The result of this collaboration is reduced space symbology or RSS, a globally recognized standard. RSS symbols can be printed, scanned and verified, using readily available commercial equipment. RSS is currently implemented by the pharmaceutical industry's largest and best known companies. It is being used today.

The use of reduced space symbology on

small units-of-use items is having a positive and significant impact on global health care, enables accurate and complete identification of pharmaceutical products right down to the lowest unit-of-use to reduce medication errors. By improving product identification, product safety and traceability will be enhanced and inventories will be better managed.

I would like to discuss how our standards ensure the accurate movement of shipments between trading partners, such as between the manufacturer and the distributor and between the distributor and the health care institution. The second layer to combat counterfeiting is the SSCC, as I mentioned before. The SSCC is an individual license plate for logistics units and it is the global unique identifier of logistics, and it can be used throughout the entire shipping process between all points.

When a logistics unit is broken up, the SSCC is discarded. If a company receives a shipment of products that is without a valid and accurate SSCCs, the questionable shipment can be immediately quarantined and investigated.

This slide displays a label on a logistics

unit. The SSCC is the large barcode at the bottom. The SSCC is in wide commercial use.

Let me give two well-known retain examples. Federated Department Stores, which includes Macy's and Bloomingdale's, has successfully used the SSCC since 1994. The SSCC moves merchandise into stores more quickly and cost efficiently and reduces shrinkage. Federated receives and routes 50 million cartons annually. The use of the SSCC in tandem with EDI, 856 advance ship notice, electronic data interchange, has increased efficiency, reduced cost and increased accuracy while providing excellent track-and-trace capabilities.

As mentioned earlier, there are a number of retail products that are widely counterfeited, mainly that would include designer clothing, luggage, leather goods, and also fragrances, so it is a major issue in that industry also.

Sears is a second example of the commercial use of the SSCC. Every year 35 million packages from over 1,000 vendors are moved through a 870 plus store system, or approximately 5,000 cartons per hour in seven distribution centers here in North America. The SSCC has brought efficiency

and effectiveness in moving this vast quantity of diverse products.

In conclusion, Uniform Code Council offers several recommendations to this panel. The health care industry should fully adopt and implement the global standards of the EAN/UCC system. Our solutions will help reduce medication errors in their equally powerful enabling unique identification that can combat counterfeiting. Full adoption of these standards will build upon the FDA's proposed rule to reduce medication errors and save lives by incorporating these standards.

The health care industry needs to build an integrated anti-counterfeiting infrastructure. We have the barcode solutions and they are available today. The industry will need to build databases and communication links that support the expanded efforts of physically identifying products in those logistics units.

The UCC is the organization behind the commercializing UPC technologies as I mentioned before. EAN/UCC data structures will be mapped into the UPC.

Ms. Dicki Lulay, the next speaker and the President of EPCglobal U.S., will provide