DEPARTMENT OF HEALTH AND HUMAN SERVICES

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FOOD AND DRUG ADMINISTRATION

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COUNTERFEIT DRUG TASK FORCE PUBLIC WORKSHOP/VENDOR DISPLAY

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THURSDAY,

FEBRUARY 9, 2006

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The workshop came was held at 9:00 a.m. in the Versailles Ballroom of the Holiday Inn Select Bethesda, 8120 Wisconsin Avenue, Bethesda, Maryland, Randall Lutter, Ph.D., and Margaret Glavin, Task Force Co-Chairs, presiding.

TASK FORCE MEMBERS PRESENT:

MARGARET GLAVIN, Co-Chair, Associate Commissioner for Regulatory Affairs

RANDALL LUTTER, Ph.D., Co-Chair, Associate Commissioner for Policy and Planning

DEBORAH AUTOR, Associate Director, Office of Compliance, CDER

ILISA BERNSTEIN, Pharm.D., J.D., Director of Pharmacy Affairs, Office of the Commissioner

WILLIAM McCONAGHA, Associate General Counsel, Office of General Counsel

STEVE NIEDELMAN, Deputy for Operations, Office of Regulatory Affairs

JEFFREY SHUREN, M.D., Assistant Commissioner for Policy, Office of the Commissioner

STEVEN SILVERMAN, Acting Director, Office of Compliance, Center for Drug Evaluation and Research

TONI STEFANO, Special Assistant, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research

TERRY VERMILLION, Director, Office of Criminal Investigations, Office of Regulatory Affairs

C O N T E N T S

P R O C E E D I N G S

(9:07 a.m.)

DR. LUTTER: Good morning, ladies and gentlemen. Please take your seats. Welcome to the second day of FDA's conference of the Anti-Counterfeit Drug Task Force.

I have the deep pleasure today of introducing our keynote speaker, Assistant Secretary for Health of the Department of Health and Human Services, Dr. John Agwunobi. He was recently appointed last month to his position and is known to many of you for his former work as Secretary of Health for the State of Florida.

Please join me in welcoming him to the podium.

(Applause.)

DR. AGWUNOBI: Thank you, Randy, for keeping that introduction short because I intend to keep my remarks short and to the point. I recognize as I look across this room that this is about business. There's a lot of you here to do work, and so I'm going to try and get you to that point in

today's agenda as quickly as I possibly can.

I served, prior to serving in this position, in Florida at the state level. As the Secretary for the Department of Health, I was given a unique opportunity, an opportunity to combat what we thought at the time was an escalation in the prevalence of drug counterfeiting and drug diversion.

Our team had long recognized that we needed to be able to trace and track the movement of drugs, pharmaceuticals, across our state from manufacturer to individual prescription. And we recognize that we needed a partnership, a strong partnership, with each individual organization, industry participant, and individual across that chain.

Combatting counterfeit drugs is a goal that Florida shares with every other state and with the FDA and, indeed, each and every one of you. I just had the pleasure of walking through the room across the hall where all of the technology displays are laid out, and I get the sense that a lot of work across this nation has already gone into this effort.

Today I wear a new hat as the Assistant Secretary for Health in the Department. I'm the chief public health advisor to the Secretary. I get to sit in on many meetings and participate in a lot of policy discussions.

I should probably caveat that the FDA isn't under my purview. I'm just an interested bystander, watching on, learning as many of you are, and offering comment where the opportunity arises.

When I was the Secretary of the Department of Health in Florida, I was charged with trying to make change happen. It wasn't enough for us to state what needed to occur. Many had done that before my arrival. It wasn't enough for us to simply have a policy or a rule or even a law.

Our job was to try and make it actually happen. My approach then, and I recognize from seeing you in the room that the FDA's approach today was to bring everyone together. It's tough to make good policy translate into real action if you don't involve all the participants, all the players, all the stakeholders, and all the constituents.

I hope here's that most important constituent represented in the room today, the consumer, the patient. I hope they're here listening and participating in the discussion. But I also recognize that there are many other important participants in this discussion, from manufacturer all the way through to that final retail dispenser.

The Florida law that passed took a fair amount of energy to get it passed and, quite frankly, took a little bit of energy to defend it between that date back then and today. We worked for a year with industry, both the technology, the wholesalers, the distributors, secondary wholesalers, and of course, manufacturers. We worked for almost a complete year sitting in rooms, my personal input, as we deliberated on what should go into that law. What should it look like? How would it best serve the entire continuum, the entire spectrum?

Consumers were in that room as well, and I think we came up with language that the very fact that it continues, that it's in place today, that July 1st of this year is their implementation date, I think

that's all a testament to the fact that we found a consensus position. We focused on safety, eliminating counterfeit drugs, eliminating drug diversion, and gathered all of the players around.

I think the fact that it's about to go into effect on July 1 is a testament to the fact that this kind of process is the right way to get it done. You know, we often talk about the role of government as it relates to regulation, as it relates to pushing quality, as it relates to assuring safety, and I believe one of the premier tasks of government should be to convene, convene stakeholders, listen. Listen to what stakeholders have to say.

It's important, I believe, that we recognize that many states are moving in this direction. Many states are following this model, bringing together participants and seeking their input.

As the FDA and all of you now look to the widespread use of track and trace technology by 2007, I applaud that. I think we should also recognize that there are other halls filled with some of you and some

of your counterparts in other states, and they're watching what's happening here today. They're watching because they, too, want to take that next big step doing what's right, assuring that we drive counterfeit drugs -- which isn't just about safety, it=s bad business -- and the drug diversion -- which isn't just about safety, it's also bad business -- out of the distribution system, out of the continuum that goes from wholesaler to consumer.

From my perspective, I think it's important that we state the obvious. This is about safety, primarily. My family and your family, I imagine, do the same thing. We walk into a pharmacy with their prescription. The prescription is filled and they take their medicine home, and they give it to their children. I have three kids, and one of them is on antibiotics as we speak.

At no point in that exchange, at no point in that process, do I ever question the safety of those drugs. But those of you in this room and myself, we know, I think, something that most consumers don't, which is that there are counterfeit

drugs out there. FDA has uncovered it more than once, as have state regulators.

There are people who would cut into legitimate businesses= profits and cut into the safety of my children's lives and yours by trying to distribute fake drugs and trying to redistribute drugs that shouldn't be redistributed. And we collectively, I believe, collectively owe it to those that we serve, whether it be through our businesses or through our officers, we owe it to my children and yours to do something about it.

Each day that we delay action is a day that another child, or thousands or millions in this country, your children and mine, that walk into that pharmacy and receive a drug that potentially could be counterfeit.

We have to act now. I'm encouraged by what I hear from the technology community. I'm encouraged by the fact that I see manufacturers and wholesalers, albeit a little slower than we had hoped, moving up and assuming their responsible position in this effort.

We all know the value of a secure Pedigree for all drugs. We all know it's the right thing to do. We recognize that it's a tough step, and I would urge all of you to redouble your efforts and join us as we try to move towards what I think is an absolutely necessary goal: the expanded track and trace of all of our drugs in the system.

It's good business, by the way. I was just telling my colleagues that it's entirely possible that one day we'll all wake up and we'll open the newspaper and splashed across the headline of that newspaper there will be a tragic event, the death of our friend or our family or our community member because they ingested something that they thought was a legitimate pharmaceutical, something that they got from a legitimate source, and they eventually found out through that tragic outcome that it was counterfeit and dangerous and toxic.

I think on that day, as CNN is running the story on its TV and you're reading it in your newspaper, there will be some companies that have the ability to stand and say, "Not in our system. Our

system is protected. Not in our chain, not in our manufacturer, not in our distributors, not in our pharmacies. We're protected. We took a step early on. We invested as early as we could."

And I think that brand will stand out in front of all the others. I think there will be an accounting on that day. I would urge you to join us and to offer us advice as to how we can help. How could we facilitate moving towards this goal? How can we expedite the expansion of track and trace technology to the extent that we desire and to the extent that I know you desire?

Thank you. I'm going to stop right there.

(Applause.)

MS. GLAVIN: Well, what a great way to start our second day. That was really an inspiring kickoff to this second day, and my job is to, as we're starting the second day, just do a brief summation of what happened yesterday, to bring us all back to the same page. So I'm going to do that very briefly.

We started with Dr. von Eschenbach challenging us, challenging us to move forward and

asking those of us who were in FDA for a report back in May on the pace of progress in this area and for our advice on the stay of the PDMA.

We then went on to a variety of presentations with terrific panel members who really stood up and shared their knowledge and experiences. We started with a keynote panel on building a more secure supply chain, answering the question of what it will take to effectively implement track and trace technology into the pharmacy supply, the pharmacological supply, by 2007, and learned from that panel discussion.

Well, first of all we learned that two wholesale distributors are now accredited, the first two accreditations, which demonstrates that accreditation programs can work, and so that was a great way to start off the panel.

We also learned that industry wants regulatory clarity with a focus initially on the end user dispensing point. And we heard about some efforts, DOD and some industry efforts with pilots, to begin to move this technology forward. In the DOD it

was not in the drug supply chain, but we did hear that they are moving in the direction of including the technology in the drug supply in the coming years.

We also heard from a panel on what is needed for widespread RFID implementation, what are the obstacles, what are the incentives that are needed.

And from that panel we heard that changes in the nature and complexity of the supply chain demand a state of the art technology and state of the art systems to protect that chain. But there are differences of opinion on the speed and scope of implementing such a system: what should the system include and how fast can we get there?

There are also differences of opinion on incremental phase-in. Should we do an incremental phase-in? If so, what should come first? How should it proceed? And is that a better way to go than waiting for a more comprehensive, encompassing approach? Should FDA set a more structured timetable?

The next panel talked about standards and data access issues where we learned that there is a

lot of agreement that the technology for RFID exists, but that successful implementation depends on the existence and use of effective management systems and very clearly defined roles. Who in the chain and where in the chain do various responsibilities lie?

We also learned from our last panel on privacy issues that issues of privacy are inherent in the use of this technology and a real agreement from the panel in response to questions from our committee that the public understanding and support of this technology is critical to its successful use in the pharmacy area, and that we need to build into the system as we design it and put it into place, we need to put those privacy concerns into that system from the very beginning, that it can't be an add-on at the end or we are risking facing public dislike of and opposition to this kind of a system.

So that was a lot of ground to cover in one day. I don't know about the rest of you, but I was whipped at the end of the day. I felt my head was spinning and that I had heard an awful lot of good information. It took me a while to sort it out, but

it was a good day. I think we have an equally good day planned this morning, starting this morning, and going through the afternoon.

I am delighted to see that we still have a full house. I know in the second days of meetings, the attendance tends to drop off, but it doesn't look like that happened very much here, and this morning I don't see any front row empty seats. So if you don't have a seat, I=m afraid that unless you come up over here by the wall, I don't have any to offer you.

Prior to our first panel, we thought it would be important to remind everyone of the issues related to PDMA. It's something we all work with and we've all been thinking about, but we thought it would be very helpful, and so we've asked Bill McConagha, our Associate General Counsel at FDA, to give us a brief overview of the relevant provisions of this Act and the history surrounding those provisions as a jumping off point for our later discussions on PDMA and how it needs to be implemented.

So, Bill.

MR. McCONAGHA: Good morning. It appears

I have the unenviable and, frankly, unfair task of following Dr. Agwunobi's very passionate remarks with an overview of a fairly wordy federal statute, and my sense is this is about as close as we're going to get today to an emotional roller coaster, but I ask you to bear with me.

(Laughter.)

MR. McCONAGHA: I'd like to begin, again, by thanking all of you for being here on behalf of the Task Force. We very much appreciate that you're all here after a long day yesterday, and certainly we are very appreciative of your interest in this very important subject matter.

During our discussion yesterday, there was quite a bit of reference to many terms of art related to PDMA. We heard terms like Pedigree and e-Pedigree and licensing and ADR kicked around, and for many of you, I would imagine most of you, those terms of art are very familiar. But as Maggie said, we also recognize that they may be a source of confusion for some, and so the hope this morning was that we take a moment to give you a brief overview of the relevant

provisions of the PDMA to help frame the issues for the discussion that will follow with the panels this morning and this afternoon.

PDMA is an acronym that stands for the Prescription Drug Marketing Act, which is a series of amendments to the Federal Food, Drug and Cosmetic Act that Congress passed into law in 1987 and President Reagan signed into law in 1988. The PDMA is a multi-faceted statute. It amended roughly half a dozen sections of the Federal Food Drug and Cosmetic Act, but collectively, the intent of Congress in passing these provisions was to insure that prescription drugs sold in the United States are safe and effective.

And to that end, Congress wanted to increase the safeguards to prevent the introduction and retail sale of substandard, ineffective or counterfeit drugs.

Now, as I say, the PDMA is a multi-faceted statute, and it certainly created a number of requirements with respect to the marketing and distribution of prescription drugs.

But for our purposes today, I'm going to

focus on just two of those provisions. The first is a federal requirement that any person who engages in the wholesale distribution of prescription drugs in interstate commerce needs to be licensed by a state in order to do so. This is shockingly enough called the state licensure requirement, and it's significant for two reasons. First, because it is a means of state and federal oversight of the wholesale distribution industry, and to that extent it is a quality check on the nature of the company's entities involved in distributing prescription drugs in the United States, but also because as we'll hear later today in some of the panels, many states, particularly Florida, Indiana, California, have been very active in strengthening these laws and in so doing changing the landscape for the wholesale distributors who operate within their state borders.

The second provision I want to talk about is a provision that requires certain wholesalers in certain instances to pass a statement of origin, also known as a Pedigree, that documents everywhere that a prescription drug has been during its movement through

the distribution chain.

I have on the screen here the language from the statute that lays out this provision, and what it says in a nutshell is that each person who is engaged in the wholesale distribution of prescription drugs and who is not the manufacturer or authorized distributor of record shall, prior to each wholesale distribution of that drug, pass along this Pedigree identifying each prior sale, purchase or trade of the prescription drug.

The flip side of that is that a wholesale distributor who is an authorized distributor of record need not pass a Pedigree, and so let me be clear. There is this duality for better or worse in the federal law. The only wholesalers that have to pass the Pedigree under this requirement are those who are not authorized distributors of record.

And as a shorthand, you will hear people refer to wholesalers who are authorized distributors of record as primary wholesalers. Those who are not authorized distributors of record are commonly called secondary wholesalers. And this concept of authorized

distributor of record is often referred to with the acronym ADR, and we heard that several times yesterday.

Obviously, an important issue for wholesalers is whether or not they are authorized distributors of record because, in effect, whether you are an ADR determines whether or not you are responsible for passing a Pedigree in any instance when distributing prescription drugs.

The Food, Drug, and Cosmetic Act defines an authorized distributor as a distributor with whom a manufacturer has established an Aongoing relationship.@

Now, in 1999, FDA promulgated a final rule in which it attempted to implement a number of these provisions in the PDMA, particularly related to the Pedigree requirement. And right away we discovered that among several, there were two particularly controversial provisions in this final rule.

The first is 21 CFR 203.3(u), which further defined ongoing relationship for purposes of this ADR definition to include a written agreement

between the manufacturer and the wholesaler. And the sum of that is it meant that merely having a history of sales or commercial transactions between a manufacturer and a wholesaler was not enough to confer status as an authorized distributor.

Under this rulemaking, under 203.3(u), there would need to be a written agreement in which the manufacturer designated the wholesale distributor as an authorized distributor for purposes of the Pedigree requirement.

The second provision in this rulemaking that I want to talk about is 203.50. It specified the fields of information to be included in a Pedigree, but more importantly, clarified that the information in the Pedigree documenting each prior sale had to be traceable back to the very first sale by the manufacturer.

Almost immediately after this rule was published, the FDA was inundated with concerns, which is a euphemism for complaints, filed by many of you, I think, related to the implications of the provisions I just cited. In particular, we heard concerns that

tightening the ADR definition with respect to 203.3(u) would drive wholesalers and secondary wholesalers out of business, drive up the cost of drugs, and adversely affect the public health.

We heard from members of Congress as well on this issue, and in light of the groundswell of concern on this, the agency elected to stay the effective date of certain provisions in the rule while it continued to consider the matter.

Then in October 2000, we held a public hearing in which we invited stakeholders, members of industry, and consumer groups to come in and talk about the significance of the rulemaking, its potential impact on the public health, and on the industry that distributes prescription drugs throughout the United States.

Based on all that we heard and all of the materials that we received in the docket that we opened as part of that public hearing, FDA issued a report to Congress in 2001. We advised Congress of the dilemma, explained the situation, invited them to consider taking legislative action, and indicated that

while -- well, to give them time in order to make that decision, and to give us more time to evaluate the situation, we would extend the stay of certain provisions of that rulemaking until April 2004.

Now, let me be clear. Staying the effective date of 21 CFR 203.3(u) and 203.50 simply preserved the status quo as it existed before the final publication of the rule in 1999. The stays relate solely to the provisions in that final rule. They do not change the fact that there is still a Pedigree requirement in the Food, Drug and Cosmetic Act. The Pedigree requirement in the Act is still in effect, and wholesale distributors who are not authorized distributors of record are required by law to pass a Pedigree when they distribute prescription drugs.

We talked a little bit yesterday about the fact that in 2004, FDA issued its counterfeit report from the Task Force, its final report from the Counterfeit Task Force, and I won't go into great detail about that because I know most of you are familiar with it, and we certainly talked about it

some yesterday.

But obviously, a key feature of that report was the degree to which we cited the potentiality of electronic track and trace technology to potentially replace or obviate paper Pedigree. And so when we issued the final task force report and encouraged industry and ourselves to pursue the potentiality of electronic track and trace technology, we again delayed the effective date of 203.3(u) and 203.50 until December 2006.

And that bring us to today. Right now the agency is trying to decide whether to let the stay expire in December 2006 such that the rule and the provisions I spoke about a moment ago go into effect, whether to revise that rule, or whether to extend the stay, and if so, why.

That will be the subject of much of this discussion this morning and this afternoon, and one of the reasons that these are particularly provocative and timely questions is that so much has changed in the landscape related to the wholesale distribution of prescription drugs since 1999 when that final rule was

promulgated.

As I mentioned, the Counterfeit Task Force report talked about the potentiality of electronic technology as a replacement or an answer to the Pedigree problem. We talked about e-Pedigree, RFID, and even linear bar codes as a potential solution. And as we'll hear about from another panel later today, there has been quite a bit of activity on the state front, particularly California, Indiana, and Florida, in which the states have passed Pedigree laws that actually exceed the federal standards. And what we'll hear about is how industry has responded, how that has changed the expectations for both industry and government, and the challenges that that's posing for all stakeholders.

So with that, I thank you. I hope that this has given you some insight at least into the terminology that we'll be hearing about and help frame the issues. And with that, I look forward very much to the discussions of this morning and this afternoon.

Thank you.

(Applause.)

DR. LUTTER: Thank you very much for that informative presentation, which did not constitute the lowest point on the roller coaster.

(Laughter.)

DR. LUTTER: Our next panel is on Pedigree Pilots and PDMA Compliance. Would the speakers for that panel please come forward?

This panel consists of four presentations. We're aware of a number of pilot Pedigree projects by supply chain partners, and this panel will discuss the experience and lessons learned to date from these pilots.

The participants are Paul Chang of IBM, and then I'll introduce the others as we go through them.

So, Paul, you have ten minutes.

MR. CHANG: Okay. Thanks.

Good morning. One of the advantages of speaking on the second day is you know what worked and what didn't work on the first day. So last night I was frantically increasing the size of my fonts so that everyone could see back there. So I did my best

to squeeze all of the big words in there.

(Laughter.)

MR. CHANG: So I just have five key messages, and what I hope to share is not my opinion, not someone else's opinion, not IBM's view. It's actually some actual results from the pilot activities that we engaged in. And I think at this point, you know, we've heard a lot of viewpoints, opinions, but I think what FDA is looking for is just some numbers. So I'm hoping to provide some numbers that they can utilize to make some decisions.

So the first key message is that RFID technology is mature. It's reliable, and it's ready for a broader roll-out. Now, I want to couch that. I don't want to say it's ready for everyone to roll it out all at once, but I do think it's mature enough that most companies can begin to do pilot activities.

Implementation can be done in phases with minimal impact to your production. So keeping the production line going in the pharmaceutical environment is very important. So how can you install RFID equipment without impacting your current

business?

Elements of the system should be standards based, nothing proprietary. This is much too big of a problem, much too big of a market, for any one company to try to corner.

Pilot infrastructure should support additional capabilities beyond Pedigree. So while we're talking about Pedigree primarily here, I highlighted this term here, you can have a valid Pedigree of a counterfeit drug. So Pedigree isn't the single solution. What you have to have is product authentication that goes with the Pedigree. I'll explain that a little later.

And then data. A fifth point is data could be managed and easily shared with trading partners, and I think there are a couple of alternatives, and I hope to share those two alternatives with you.

So, the pilot scope. The client is a large, global pharmaceutical manufacturer, and in fact, the client is GlaxoSmithKline. Rob and Bruce are sitting there.

What we did was we tagged one NDC, one product, one production line, one packaging plant, and one DC, a very limited scope pilot, but this is the kind of pilot where if you had to roll it out to broader sites, you know exactly what it takes to do. You know exactly how to replicate this pilot onto multiple lines and multiple sites.

The technology we use, again, I don't sell, or IBM, we don't sell tags or readers so we have no preference here. We just use what we thought was the best technology available when we made these decisions, just like, you know, Tom said from Pfizer. So for item and case level tagging, we used precommissioned RFID tags because it was just easier to unload the burden to the label converters, to apply the tags, write the numbers for us, test it, and then ship it to us.

We used non-NDC serialized scheme because of the privacy concern. We hope that this could be all sorted out in subsequent pilot activities with trading partners to know whether NDC is actually valuable or necessary to do processes at the

wholesalers and the retailers, but again, until you do a pilot activity, you don't quite know, right? It's just people think they need it, but have they really looked at it? Have they played with it?

So what we're encouraging is, let's do an industry pilot and start to figure out do you really need this, and perhaps prove some reasons why you need the NDC. Because obviously the privacy concern is a big concern, and we just don't want any person with a handheld reader reading what you have in your bag.

Frequencies. Item level, we used HF, which is technology that has been around for I think over ten years. It's globally accepted, and at case level we used UHF, and in this case we used the EPCglobal Gen. 1.

From a hardware perspective, we used a combination of fixed antennas and handheld readers, HF and UHF at the packaging line, UHF at the pallet association, UHF at the reading of the DC receiving. So when you're receiving, you just scan the UHF tag, and that tag will tell you what items you have inside.

HF and UHF DC shipping because when you're

doing unit shipping you need to know which EPC numbers are in the tote that you're shipping out, and we had HF and UHF readers at the rework stations.

What have we learned? Tag quality: better than 99 percent yield when we were receiving these integrated tags from the converters. Read reliability: better than 99 percent read reliability on randomly packed, randomly oriented bottles inside using HF tunnel reader.

Now, I will qualify this by saying the product was a solid or a dose on a bottle. There was no metal and there was no liquid. But, again, our goal wasn't to make our life difficult. This wasn't a technology challenge. We wanted to see what it takes to implement a full solution.

Read reliability. Ninety-nine percent read reliability on simulated cases on the UHF tags.

Chip UID. So we had a couple of comments about this. I just threw this in last night. So chip UID, why is RFID more secure than bar code? Because it's easy to print bar codes. So counterfeiters have the same equipment that you all have. They can scan

and print 2D bar codes and apply to a counterfeit drug. Very simple.

With RFID, with a chip UID, even if the EPC number says 1234 and a counterfeiter can buy some tags that look just like your tags and they can write 1234. What they cannot do, at least for now, is they can't replicate the chip UID, which is unique in itself in the world. So the original tag will have a chip UID that says ABCD. The counterfeiter will purchase a tag that probably says EFGH. Then you're going to know that this is not the authentic tag used by the manufacturer.

So in general, my comments about the bar code versus RFID, bar code is cheap to print but expensive to read all the way down the supply chain. RFID is expensive to write, but it's cheap to read down the supply chain.

Phased implementation approach. So those chevrons are a little small, so I'm not going to go into detail. What we did was we took it in phases. Phase one was packaging plant with manufacturing, execution system integration. Phase two was DC

receiving. Phase three was DC shipping with WMS integration.

Standard phase components. What you see here is EPCIS as EPCglobal=s EPCIS standards body has defined to date. So what we have is we have the readers at the bottom pushing data up to I'll call RFID middleware; we call it premises server. That pushes additional filter data up to the EPCIS repository which manages the data, and EPCIS repository also interacts with, you know, operator console and generates a report. Discovery service sends data to e-Pedigree applications, and it integrates with MES and WMS systems.

Pilot use cases or capabilities as some like to call it, e-Pedigree product authentication, targeted recall, diversion tracking, charge-back, shipment verification, product movement capture, inventory visibility, expiration management, and labor savings.

Now, why did I highlight numbers six through ten? It=s because those are the only items or the only benefits that the retail industry -- Wal-

Mart, the CPG companies -- they are only getting benefit from six to ten. Yet they chose to move forward with broad RFID implementation because they see the value. They don't have the same problems that this industry has. No one is counterfeiting paper towels. They don't have that issue.

(Laughter.)

MR. CHANG: You don't need a Pedigree for that.

Product authentication, targeted recall, diversion tracking, charge-back resolution, those problems just do not exist in the retail environment, yet the retailers saw value and decided to move forward.

So my point is, for pharmaceutical industry, not only can you capture all of the value that the retailers can capture, you can actually capture additional value, numbers one through five.

Distributed architecture. So this might be a little bit of a new concept here, so bear with me. So how we see distributed architecture is we think there's no database in this world that's going

to be large enough to manage all of the data. So what we've done is we've architected the databases so that people can manage their own data and share that data with your trading partners as necessary.

So what we have here is, for example, e-Pedigree. e-Pedigree can be passed to downstream trading partners, which is a PUSH model, and when I think Florida and the PDMA laws went into effect, which was late '80s, well, when you were thinking about paper, well, there's no other way but to really hand the paper off to your next trading partner.

But we think there's an alternative, and the alternative is Pedigree can be also downloaded on demand to the local EPCIS or the trading partner. So this is the PULL model.

So when you go to a website, that's completely a PULL model. No one dumps you all of the contents of their website onto your browser. You just go to that website and you download what you want. And so this model says with this electronic data capture, you can actually pull and download all of the data elements of a Pedigree.

I have an asterisk under distributed architecture because I wanted to talk a bit about the discovery service. A discovery service is basically a thin central database where authorities can go and look to see what transactions have occurred.

So I'm being pulled off, so I'm going to just run through this.

Challenges. There are still challenges with data sharing, adoption schedule, validation, technology enhancements, and different form factors. So I=ll briefly mention that.

But at the end, I still think this is a win-win-win proposition. I think the industry can win because of all the benefits. Regulatory agencies can win because I think they provide a safe and secure supply chain. And at the end of the day, it's you and I and our kids and your parents who win because we can be sure that we're taking drugs that are authentic and that are produced by the companies that we trust.

Thank you.

(Applause.)

DR. LUTTER: Our next presentation is by

Andrew Dubner of 3M.

You have ten minutes.

MR. DUBNER: Well, good morning. This morning, I plan to share with you some of our thoughts and experiences related to securing the pharmaceutical supply chain.

I want to start with this, and I understand there was some discussion yesterday related to this. Our opinion is that tracking can be a security solution as long as there is 100 percent compliance. But if there are gaps in compliance, then the validity of the chain of custody becomes suspect.

So what do you do to get on the path to this e-Pedigree that may require 100 percent compliance? Well, for over 30 years, 3M has provided tracking and security solutions to our customers. Routinely we face the question: so how do I know that people are going to do this? How do I know that if I implement this system, people are going to do what they are required to do to make sure that the product is secure or that it's being tracked or what have you?

Obviously, there needs to be some

incentive for people to comply, and typically that incentive winds up being something that's in addition to security or tracking. It may be security and productivity or tracking and efficiency, those kinds of things.

So I think in order for the industry to comply with PDMA, the industry needs to experiment, and the industry needs to find those "ands," those things that are in addition to the security and tracking.

So in thinking about the pharmaceutical supply chain, ideally one could go right to the contents, right to the pharmaceutical itself, and authenticate that that molecule or that compound is what you expect it to be. But in today's supply chain and with today's technology, that's really not practical and not possible for all of the drugs that are out there, the range of products that are out there.

So the best one can do is to elevate confidence in elements that surround that product. So asking yourself the question, is the packaging

authentic? Is the packaging intact? Has it been tampered with? And do I trust the people who have handled this product before me; do I have a supply chain history that I trust?

If you can elevate confidence in those three areas, then your confidence that the contents are genuine, which is what we're after here, after all, are increased.

So how do you implement a solution? Well, we interpret the problem as one of patient safety. Our hypothesis is, if you have item level authentication that bridges the ends of the supply chain, you'll have an immediate impact on addressing the problem. We focus on how do we elevate that confidence that the product is genuine and we focused on delivering some compelling business results, that incentive that I talked about earlier.

Now, I imagine there are lots of ways to solve this problem, and I'm just going to talk to you about one, one that we're implementing today. Authenticated RFID is a platform to authenticate and to identify in order to secure and to track. It

allows you to start with a basic capability, which I'll describe in a moment, and then to turn on or activate additional features as infrastructure expands.

The basic capability is authentication. You do not require a connection to the network in real time. You can authenticate using a unique encrypted digital signature that's on the RFID tag. It uses that unique number that Paul talked about a moment ago, and it also provides a mechanism for authenticating at the dispensing sites.

That mechanism can be manufacturer-specific, meaning that each manufacturer can have their unique digital signature, but on the flip side, it provides an automatic way for the dispenser to authenticate all manufacturers' products without having to have 20 different devices to authenticate.

That basic capability grows to e-Pedigree as the infrastructure, the network infrastructure, expands. The unique identifier required for e-Pedigree is already there. It's part of the RFID tag. So as more readers are deployed, you can create a

Pedigree just like you would with an EPC license plate kind of tag.

Now, the intelligent tag in this model provides additional capability. It allows you to write event markers to the tag and to ultimately create a more secure Pedigree. So the platform has stages, has phases. Authentication is the basic capability. We're looking at authentication between the relevant points in the supply chain, the manufacturer and the dispenser.

It enables e-Pedigree consistent with all of the standards that are being adopted today, and it provides flexibility, flexibility to find those business reasons to comply, those incentives to want to do what you're asked to do. It's a platform also for additional security features, whether they're electronic security features or physical security features, to create a layered approach, a multi-layered security approach, and it allows people to realize that little triangle in the bottom corner, that triple A rating: I'm confident that the packaging is authentic, that the packaging is intact, and that I

trust everyone who has had the product before me.

We are currently working with a major manufacturer to implement this model, this security solution, for one of their products that's on this list of susceptible products. Our goal is to increase confidence that the product that's being dispensed is genuine.

We are tagging at the manufacturer and establishing authenticity at that point and then validating authenticity at dispensers. Both the manufacturer and the dispenser have identified business justification for implementation. They have strong incentives to do this, and they found them by experimenting.

The flexibility and the simplicity of the platform approach enabled them to do that, and I think it was an enabler for them to get started.

And those are my comments. Thank you very much.

(Applause.)

DR. LUTTER: Thank you very much.

Our next presentation combines two

speakers, I believe. Only one. Paul Fowler from McKesson.

I have you down for ten minutes. Thank you.

MR. FOWLER: I'd like to thank you for the opportunity today and congratulate the FDA on 100 years of service to the nation.

McKesson just recently celebrated our 175th year of health care service to the nation, and the subtle perspective on that, when we were founded, Andrew Jackson was in the White House and Beethoven was the pop list.

Health care is a balancing act, and I'm going to talk a little bit about how technology is going to help balance that act. Every health care community, every government, has to balance quality, access to that health care and cost. As cost goes up, access goes down. Quality has to go up, access has to go up, and cost has to go down.

As a health care technologist, this is the formula that will make this technology proliferate through the chain naturally. If we can make sure that

quality of our health care goes up, broad access to health care goes up and cost goes down, those are the technical pieces that go through the chain naturally.

Our nation obviously requires a secure medical supply chain, but we also require cost effective health care and access for all of our citizens. It goes without saying.

The quality of the medical supply chain includes not only safe and secure products, but a safe distribution chain. So as we're implementing these rules, I would particularly ask the panel to look at Florida and watch for distribution disruptions in the chain that may be caused by this law.

Those are the kind of things that we absolutely want to avoid as we move through this technology change.

Process redesign and automation is absolutely required for this. We do not believe that paper is the solution. We do not believe that paper can be actively managed in our environment. If you look at McKesson alone, McKesson will end up doing -- if every individual item on our Rx chain is

serialized, we will end up doing 35 million reads every night. Every night. That's just for McKesson.

Improving quality and affordable cost requires policy and technology redesign across government and trading agencies. I greatly appreciate the efforts of MIT and I greatly appreciate the efforts of other academic organizations. I greatly appreciate all of the vendors who are putting lots of energy and time here. But we believe that this problem will only be solved by the trading partners working more closely together across the industry to drive strong pilots that will discover facts and data that we can help write good technology, good business policies, and more importantly, good regulations.

We believe that focused pilots will help us balance our investment. Companies like McKesson spend an average of $150 million a year in technology. It's not that we are underspending in technology, it's that we're hesitant to invest in technology if there are no standards, if we can't guarantee that we're going to have at least some return on that investment over a long period of time.

So that means, you know, we have to understand where the balanced investment. This is here, I think, Accenture was out in front of the industry, recognizing that pulling industry partners together and redesigning processes person to person is probably the best way to approach this problem.

So they started in 2004 with the Jumpstart I, brought many industry partners together to prove the business value of RFID: where is the business value, safe and secure supply chain, but also returns management operational efficiencies. We have to pay for this technology somewhere.

In Jumpstart II, Accenture and a broad set of partners began to look at the serious issues relative to this, many of which have been discussed here at the forum here in the last two days, and model costs for the industry and full adoption of RFID.

At McKesson, for instance, we anticipate, depending on the cost of the technology at the time, that we'll spend about $40 million investing in RFID technology to implement our network. Again, not a massive number to a company our size, but a reasonable

size investment that we want to make sure we're going to get a return on and at least secure the safety of the supply chain as we anticipate.

So for that, McKesson is sponsoring another pilot this year, which is really an attempt to go much broader than what Paul and other folks have talked about. We're getting together with the GSKs of the world and the Rite-Aids of the world and the Wal-Marts of the world, and we're trying to bind together partner pairs that are going to go across the chain. It=s very similar to what we're doing with Pfizer on the Viagra pilot where we are taking in their product, we are doing authentication currently as we stand here, and we're making sure that some of our partner pairs, some of our customers, are able to do the same thing so that we can work out ahead of time where the industry issues will be.

We'll be kicking this off. We're going to have a large meeting in Chicago where over 40 members, many of which are sitting in this room today, will be discussing how we're going to go forward with this effort. And again, I honestly believe that not only

are just the companies the trading partners, but quite honestly, physically, most of the people in this room who I have seen over the last year and a half at meetings just like this are going to be the ones who solve this problem.

So how are we going to move forward? From the standpoint we believe we need real world pilots to answer a lot of the questions. As Paul said, we do have a lot of facts and data on the table. The GSK example, for instance, the 99 percent reads, what Paul might have failed to say was that that was at a 60 percent line rate compared to their normal production. If you do that same pilot at 100 percent, you're not going to get 99 percent reads. So that's an important fact that we need to keep in mind.

We have to be able to keep up with the current speed of distribution. I don't believe that we all have a full consciousness of how massive the U.S. health care system is. Again, 35 million reads a night is what McKesson would have to do at a single item level.

We have to accelerate industry standards.

I think it has been said here quite a bit. The technology companies out there have to know what they're designing. Companies like McKesson have to understand what the standards are, and we cannot tolerate any situation where we don't have interoperable systems. So standards will create an opportunity for all of our systems to go together.

I mean, obviously, if we're investing $150 million a year, we have massive amounts of infrastructure that are already established in our company. Technology innovation and, again, interoperability is absolute.

We believe that, and I think I've seen it the last couple of days, we have to collaborate more closely. The industry groups and trade groups that are here, I think, have very different views. I think you've heard very different views from some of them. We have to get together. The constituency of those groups has to get together to guide those groups to be closer aligned to get this accomplished.

And finally, we need the support of the FDA. We encourage and we appreciate the opportunity

of these last two days. We think more of that activity has to occur. We certainly have been participating very heavily in the Florida environment, and we do believe that it has to be nationwide. We can't pound these issues out state by state.

Thank you.

(Applause.)

DR. LUTTER: Thank you very much.

Our next speaker is Peter Spellman from SupplyScape.

And, Peter, are you sharing your time?

MR. SPELLMAN: I think I get ten, but I probably won't use all of them.

Okay. I'm here to talk about a set of e-Pedigree pilots that we've been involved in. There were two of note that we're going to talk about. One is the Drug Security Network, which was an initiative founded in the wake of the February 2004 FDA press conference. And Mike Celentano and Rob Kashmer will talk about the Purdue and H.D. Smith RFID Pedigree pilot.

So the Drug Security Network was actually

a rather comprehensive look at how we can achieve electronic Pedigree that would comply with existing and evolving regulations in the context of RFID, without RFID, across manufacturers, wholesalers, pharmacies, through a set of other operational processes, kitting, repacking, et cetera.

What we did is we looked at the entirety of the Pedigree problem as deeply as we could with these trading partners and came up with what we would have a supply chain-wide consensus with all of us, around issues around serialization, Pedigree, and then conversations around data sharing and security in the value stream tracks.

The interesting thing about having such a broad group work at these problems at such a deep level is you get a lot of very spirited discussions, and you get a lot of very interesting and diverse perspectives.

In terms of running the project, Cap Gemini provided the facilities in Cambridge, Massachusetts, as well as program management. The trading partners were, in fact, two major

manufacturers, and one of the primary larger three wholesalers, also including repack and pharmacy operations as part of their purview. And then there were a large set of technology providers providing technology as well as software and services.

So the deliverables were, first, what are the Pedigree use cases. And then on those use cases, what are the additional capabilities, either for increased supply chain security, for other operations like recalls, returns, repacks, diversion detection, counterfeit detection? A wide swath of use cases.

Then there was the lab itself. This was much more than a paper exercise. What we were doing is we were going to deploy technology in the lab and we were going to move Pedigrees from partner to partner and understand that and really prove that out. Another major deliverable that came to the forefront was what will the serialization scheme be.

At this time in 2004, it was still very much in question, and so we needed to get from the manufacturers and other participants what kind of serialization scheme could actually work.

Obviously, the Pedigree format itself, the existing Pedigree format that we're working through EPCglobal, a lot of it is derived from this work, and then extensive discussions on data sharing.

This is something you can't possibly read.

(Laughter.)

MR. SPELLMAN: But if you could, you would see that this is one of several screens of its ilk that basically document the use cases for Pedigree from the perspectives of the different trading partners. It just goes to show that sort of the depth to which we examine this problem from the perspective of each trading partner for all of the different operations they have. So it's within picking, shipping, receiving, all of it, and how those use cases work and all the exceptions.

This is basically a layout of the lab. There were four stations, four primary stations, the two manufacturers basically initiating products and Pedigrees, moving them through the distributor and then out through the pharmacy. We also accounted for third party returns processing.

So what came out of this was effectively each participant participated in coming up with the process and technology participation in generating any Pedigree process, so creating, tracking, sharing, archiving, digital signature. The participants were, as we said, manufacturers, wholesaler, repack, pharmacy operations. And then what it also did is it gave us a baseline for how we could do electronic Pedigree, effectively, what do the records look like? How do you integrate with public key infrastructure so that you have self-authenticating Pedigrees? Electronic authentication? And then the Pedigree exchange itself.

And then how do you do this with serialized and non-serialized items? Because in the time frame of the existing laws and regulations, not everything will be serialized. Not everything will have RFID. And so it was more like how can we solve this problem.

And so what we achieved as part of the Drug Security Network is effectively integrating e-Pedigree and operational processes, also identifying

counterfeit, recalls, diversions, all sorts of things as part of the Pedigree process.

And then we piloted real world technology. So what we did is we came up with an approach for serialized and non-serialized, an approach for RFID in today's bar code, defined serialization scheme, a Pedigree format that will expand and work with all of the different states. That's also the baseline of the existing standard. And then finally a common electronic certification and authentication framework.

Mike.

DR. LUTTER: Thank you very much.

Our next speaker is Mike Celentano from PurduePharma.

MR. CELENTANO: And Rob Kashmer, also. We'll co-present.

Okay. I'll introduce myself. Again, Mike Celentano from PurduePharma. I'm the Director of Supply Chain and RFID Systems. I'll be up here co-presenting with my colleague Robert Kashmer from H.D. Smith. We'll talk a little bit about our joint pilot together in the realm of electronic Pedigree.

And first of all, I think on behalf of both of us, we want to thank the FDA for allowing us to come up and talk a little bit today about this pilot.

Before I move on, I think a key point I want to make right now is to highlight the fact that this is a production pilot. And we talk about a number of pilots, and I think we talk about them sometimes with generalization. We've talked about them yesterday in that format, but I kind of echo Paul Fowler's recent comments in that production pilots are where the rubber hits the road and where we need to be going to really start to get some key learning moving in our industry.

So we're happy to be here today talking about -- can you guys hear me okay? Is that better?

PARTICIPANTS: Yes.

MR. CELENTANO: Thank you. Sorry.

-- talking to you in that capacity.

So as we move into this, just a little background to kind of let you know how we got started in embarking on this RFID-based e-Pedigree pilot.

From Purdue's perspective, I'll give you a quick briefing. We've been involved in the RFID technology area now for about two years. We started in January of 2004 on our RFID tagging initiative. It's an item level initiative.

By November of 2004, we had actually manufactured and produced our first batch of item level tagged, RFID tagged, OxyContin. In the following month of that same year, we actually shipped our first batch of RFID tagged OxyContin.

I should note, to date, first of all, that's kind of talking with 2004. The bulk of our work in 2005 has really been leveraging that basis to move into an electronic Pedigree proof of concept.

Just a couple of closing points there. I noted it was interesting the other day that Ron Moser from Wal-Mart cited the fact that they've now scanned over 230,000 pallets. Ironically, we've now scanned, tagged, and data collected over 230,000 individual bottles.

And at this time I'll just quickly turn this over to Rob to give a little brief background on

H.D. Smith's background here.

MR. KASHMER: Thank you. H.D. Smith is committed to the support of the PDMA through our RFID and our e-Pedigree initiatives. Our focus is on patient safety through the integrity and authentication of the product.

We also focused on usable technology. We wanted to make sure that we could build on the technology, using a building block approach, and we also focused on our integration of our systems.

As you can see in our time line, we demonstrate that expanded capabilities. We started our funding in November of 2003. We targeted the bottle level tagging because we felt that was going to be the challenge, not necessarily the case or the pallet level. We also wanted to continue through to retail pharmacy, and we did that in August of 2004.

This was the pilot background. We've also continued through integration of our CSOS application, and our first order was an RFID order.

We also support multiple frequencies today, and again, that=s same bottles or different

frequencies in the same tote, as well as obviously our integration into our e-Pedigree.

MR. CELENTANO: Okay. So that's a little bit of pilot background. So obviously the framework for starting into a foray on electronic Pedigree, what I want to make sure is clear here, we talked about how we=ve tagged and shipped product. We also started from day one collecting the tag data from every bottle we=ve shipped. So we started to build a localized database with some key contextual beyond the EPC code itself, that being the lot number of the product and the delivery number of the product.

We felt it was important at that time to at least have some context around that RFID data, and that has started to build the basis for us to move to electronic Pedigree, which at the time we really weren't thinking a lot about.

So just a quick graphic here. I won't spend a lot of time on it, but basically two things happen in our operation at Purdue. We apply the RFID inlay to the label. The label is applied to the bottle in a pretty conventional fashion on an RFID

enabled packing line, and we end up with an RFID labeled individual bottle.

Those bottles are then packed further down the line into cases of 48. That entire 48 count package is then moved through an RFID tunnel where all 48 tags are read, typically in the range of three to four seconds, and that information is data collected for the first time.

There are two subsequent data collection points internally in our operation, one at the time we check the product into the vault. This is C-II product, our controlled substances. So when we check it into the vault, we read and time stamp it again. And then upon delivery, we also read and time stamp it again.

So we=ve started to model some track and trace functionality within our own four walls.

I don't know if many of you can see this, but this is an actual image of our labels on the applicator with the RFID tags embedded, just to give you some visual of what that looks like, and hopefully you can see the inlays embedded to the tags.

One other quick visual. I just referenced the fact that the case is actually moved through an RFID tunnel. That's what you're basically seeing there, and it takes about, again, a three to four second time frame to move through that tunnel. All 48 tags are read, and at that time they're data collected.

So now kind of moving into the electronic Pedigree pilot, that gives you some background in how we get started. Again, a very busy slide. I don't expect you to read it, but the point is that this is the schematic that largely drove our effort into e-Pedigree. What we tried to do here is really outline the process flow and the data flow that results in our current operation and how we would go after that data to start pulling together an electronic Pedigree to try to take our effort to the next level. And this was a collaborative process with some of our partners who we'll talk about shortly.

So really I think a key take-away from this slide is we hear a lot about drowning in data and so much data and where do I store it. And in this

simple operation, we're storing the EPC numbers with very little information, but with those two pieces of information I mentioned, lot number and delivery number, we're able at the time of shipment to then reach back into our core ERP system, our core system that runs our business, and pull out all the other contextual information that's relevant for a Pedigree.

For instance, from the lot number we can pull the expiration date, things of that nature. We can also go back and pull the NDC number and all those other data elements. And from the delivery, we know all of the information about the destination shipping address for that customer. So we could effectively assemble, certify, and send the Pedigree. At that point, we are actually passing that out to a SupplyScape application.

Guiding principles, and I think this is very important. These are really the principles that governed our electronic Pedigree pilot.

Number one, first and foremost, these are in no particular order other than they kind of immediately spell out the acronym "PRIME" which helps

me remember them. And we can all use another acronym.

In any case, the first is production environment. So an important note here is that these are with live orders, live shipments, and live systems, that it would be RFID based, item level serialized, manufacturer initiated, and done on an electronic Pedigree platform. So, again, those are the guiding principles going into the pilot.

And a short list, bullet points, really, of what each company, Purdue and H.D. Smith would do in this process. Purdue will -- well, first of all, let me, I guess, neatly put the scope around the effort so I can give perspective there.

The scope was to create, certify and electronically transmit item level Pedigrees for RFID tagged OxiContin shipped from the PurduePharma manufacturing plant in Wilson, North Carolina, to the H.D. Smith Distribution Center in Springfield, Illinois.

So, again, to put it in perspective, which I think is very important, and I think Rob and I feel a deep sense of obligation to do when we talk about

this pilot, this was a one plant to one distribution center operation. So in this process, Purdue will tag the product, initiate the Pedigrees, certify the Pedigrees, transmit the Pedigrees, and ship the product. And I'll let you run down the H.D. Smith side.

MR. KASHMER: And H.D. Smith carried it from that point. We received and authenticated those Pedigrees, received the product, matched the Pedigrees to the product, and obviously certified that receipt.

I think one of the most important points here as well is that we spent a lot of time in determining if there was a problem and reporting it on an exception basis. Again, we just wanted to make sure that we could see any issues through this Pedigree, and that was in a test. In the production environment, obviously, there were no issues.

MR. CELENTANO: Okay. This is, again, just another graphic that I think illustrates or is attempting to illustrate scope. So this is a slide we borrowed from our SupplyScape friends that you may have seen before, and it just illustrates a typical

supply chain movement of product from manufacturer to wholesaler, potentially to chain drug warehouse and then on to pharmacy.

To be clear, the scope of this pilot was really the first node, and that, I think, we felt was the primary proof of concept area that we wanted to focus on. I think the concept of then replicating that to downstream nodes, I don't want to oversimplify that, but I think that, you know, the focus was just getting that first node in place.

And then just a couple of pilot facts and figures. The RFID tags that we did use were Matrics/Symbol Class 0 UHF tags at the item level. We were not tagging at the case level at all at this time. So we, kind of differently than the other pilots you've heard about, we are using UHF right now at the item level and consider the fact that we were early adopters in doing this, you know, a couple of years ago, that was the direction we started out in.

The Pedigree messaging format that we use is an XML based format. We are using SupplyScape Pedigree software running on a hosted Unysis platform

for this pilot, and we actually transmitted 192 item level electronic Pedigrees from Purdue to H.D. Smith over a 60-day pilot window and a planned observation window. So the pilot had an opening and closing phase to it, and it was really more, again, about proof of concept.

And then lastly, I think I'll just let Rob make a point here.

MR. KASHMER: We felt very strong about this pilot, and in having those feelings, we have licensed the SupplyScape software as our full enterprise nationwide Pedigree solution, and our implementation will begin in April of 2006.

MR. CELENTANO: And just some last key conclusions, I think, from our pilot. Again, I think Rob and I both feel a deep sense of responsibility to this community to make sure we put the pilot in perspective and do the best job we can there. And I think we've kind of distilled that down to a couple of key take-aways.

One, I think we echo some of the earlier sentiment you've heard up here from some of the other

presenters that the fundamental building blocks for an RFID based, serialized, point-to-point electronic Pedigree model exists today, and I think our study has shown us that. But then I guess the tempering statement there is to understand the impact and capabilities and expanded supply chain distribution scenarios, i.e., larger volumes, multi-tiered packaging levels, additional supply chain nodes, additional testing in a broader supply chain environment or environments would be very beneficial.

And I think just one other point I think I'd like to make there. I do think that those pilots are underway and the opportunities to do that will be there. I think one thing that struck me was in listening to the Pfizer and then also the GSK approach coming up, in a lot of ways they're very much a study in contrast in terms of we're using UHF tags right now at the item versus HF. We are embedding the NDC code and the other pilots were not. Ours has taken something of an electronic Pedigree bent versus an authentication bent. We're using pre-encoded tags. I think at least one of the other folks was writing to

the tag.

So I think that's actually a good thing for the industry in setting up some real opportunities to try to find out about some best practices to the earlier points there to see what does happen in each environment using different opportunities in the retail pharmacy and so forth. So I'm actually encouraged by that.

MR. KASHMER: And our final comment is, as you can tell, that this solution is complex, but it is attainable. H.D. Smith believes additional pilots need to occur with more volume.

We have entered into that agreement with SupplyScape, and one of the next pieces that we will do in our next phase will be to go ahead and implement a Phase 2, which will be from our facilities to retail pharmacy, as well as work to comply with the Florida Pedigree legislation.

And I wanted to also say that we're a proud and active member of HDMA, and we support all the comments by both John Gray yesterday, as well as Lisa Clowers. I think this was a very important step

today and appreciate the FDA providing this forum.

DR. LUTTER: Thank you very much for these enlightening and informative comments.

(Applause.)

DR. LUTTER: I'd like to introduce a new member of our panel from FDA today. My colleague Steve Niedelman has joined us, and he is Deputy for Operations in the Office of Regulatory Affairs.

So I think what we'll do is proceed with questions from the FDA Task Force to the members of the panel. Our goal would be to try and finish slightly before 11. We have the next panel beginning at 11, but we will need a little bit of time to be sure we have adequate telecommunications facilities for a presentation by somebody who's not in this room, and that might give us a reason to schedule a break at that time.

So let me offer one personal perspective on this. The phrase "the rubber meets the road" in describing these pilots was used, and I think that's very apt. It's always useful to have empirical evidence and data about the effectiveness of a new

technology in a new environment, particularly if it's being used to address something important such as a legal requirement, as was alluded to earlier by Bill McConagha.

I haven't heard a lot of discussion here about cost, and I think that's partly because there's a presumption that those would change radically if the scale increased substantially, and that's maybe something that can be explored, but instead there's a focus on technical feasibility at this point.

So I've learned a lot. I'm appreciative of that, and with that maybe I'll turn it over to questions that people may have. Deborah.

MS. AUTOR: Thanks, Randy.

For those of you who are actually trying RFID and have done these pilot programs, I'd be interested in hearing from you what you think are the biggest barriers at this point to widespread implementation of RFID.

DR. BERNSTEIN: Can I add another addition onto that, if that's okay? And e-Pedigree, as well.

DR. LUTTER: Maybe we need just a few

volunteers for that.

(Laughter.)

MR. HINTLIAN: I'll start the dialogue on that particular point. There are actually lots of barriers, and I think one of the things that a lot of these pilots recognized was that despite those barriers, you needed to take that first step and launch into some kind of effort to field test these capabilities, to understand the art of the possible, to get a grounding in what the real challenges would be rather than just read them off of the White Paper.

One of the challenges that I=ll start with that hasn't really been talked up a lot here is just the notion of skills and training and changed management because a lot of what you're talking about requires different kinds of processes, different business activities, different trading partner relationships, contractual relationships, and different skills inside the enterprise, whether it's the distribution facility, whether it's the water management activities. These are practices and skills that in many cases did not exist before. You had to

implement some of these types of Pedigree and authentication processes, and that was something that Jumpstart tackled.

There were fingers on keyboards. There were operators in warehouses that needed to be trained, and that's something that was a great learning in terms of the anticipated challenges.

DR. LUTTER: Thank you.

Other perspectives on the question of what are major obstacles to more widespread adoption?

MR. FOWLER: You know, I think the question about e-Pedigree, e-Pedigree rolled out nationwide at a lot and expiration date level is practical. It's similar to what the Florida law states, and I think the barrier to that would be having some kind of nationwide approach to executing it nationwide.

At the item level, I think there are still significant issues with understanding the volume. If you look at the volumes that we're talking about here on nonauthentication, 150 items, 200 items. I mean, McKesson processes six million items every night in

Rx. So we really haven't done the size scale.

I do want to make one correction, though. My good friend Rob Cole assures me that they did get and achieve reasonable reads at full speed for their line. So I did not want to disparage in any way the great work that GSK and other members have done in trying to move forward this RFID technology because we support fully and support GSK in many ways.

But it still is at the volumes. We need higher volume pilots, and that's why we really, specifically, Pfizer and their move to move significant numbers of tags through the U.S. health care supply chain with Viagra is giving McKesson an opportunity to do large scale pilots to understand the real impact to the large scale on RFID and individual items.

DR. LUTTER: Thank you.

MR. SPELLMAN: To Paul's earlier point on electronic Pedigree, I think he's right. At scale, electronic Pedigree from the information system's perspective is absolutely achievable today at scale, and I think the question comes in what the operational

implications would be.

But from an IT perspective, even at six million items, you could certainly do it technologically from an IT perspective.

DR. LUTTER: Thank you.

Other questions? Jeff.

DR. SHUREN: I seem to be sitting in the most inconvenient seat for speaking. This question is for Mike Celentano and Rob Kashmer.

I was sort of struck that in terms of the information that's being put in the RFID tag, that it was lot number and delivery number. Yesterday we heard from the retailers that their big concern is that they have the NDC number, or at least have access to that, and there isn't going to be return on investment for them unless they do.

On the flip side, we've heard that if the NDC number is put in there, there may be security and privacy concerns. You've mentioned that by putting the lot number you can actually link back to the NDC number. Is putting in the lot number and not the NDC number, but a link to it, a way of getting around

this? That a retailer could link to your database, get that NDC number as it comes through, but it isn't traveling in the RFID and it could not then be scanned on the product itself?

MR. CELENTANO: Okay. Can you hear me okay?

DR. SHUREN: Yes.

MR. CELENTANO: Okay. First of all, I have to correct the statement, just to be clear. We did not mean to indicate that we're putting the delivery or the lot number on the RFID tag. What we're doing is, when we scan and data collect the tag, I guess I can see now in retrospect how that may have been unclear.

We are only putting the EPC number on the tag right now, and it does contain the NDC code, and that is all that's on the tag. And when we collect that information, we collect it along with the contextual data that I mentioned, the lot number, for instance. The way we have our line set up, we're able to input the lot number and essentially read that lot number into the database where we collect our EPC

codes when that line is producing that particular lot number.

So that's how we add the data to our database, not to our tag. Similarly, when we scan the tags on the outbound delivery, that's the time that we add the delivery information. That's also captured in that local database. So then I'm able to pull from that database that other contextual information for the Pedigree, just to be clear.

So the only thing on the tag right now is the EPC code containing the NDC.

DR. LUTTER: Toni, you had a question?

MS. STIFANO: Yes. This is to the panel as a whole. Has there been any thought or any plans to do any studies with regard to repackaging?

MR. FOWLER: With respect to?

MS. STIFANO: With respect to your tagging something, shipping it off and then it's repackaged. So it's taken out.

MR. FOWLER: Right. McKesson actually has a couple of repackaging operations as part of our global enterprise, and we are investigating how those,

both on a Pedigree perspective and on an RFID perspective, would be managed.

I think you've heard the panel also. I think you heard the consumer side say that bar code will be the standard at least for a short time in our hospital communities. It may be a long time in our hospital communities for unit dose, patient, safety. Certainly we understand that as a distributor and as a repacker, but we're trying to do some pilots.

We haven't scheduled any yet, but we certainly have those operations and are in the strategy phases.

DR. LUTTER: Any other respondents on the packaging question?

(No response.)

DR. LUTTER: Maggie, another question, please?

MS. GLAVIN: This is for anyone on the panel who would like to comment. We had an ongoing or recurring discussion yesterday about the importance of keeping focused in our minds the difference between authentication and e-Pedigree, and so I wondered which

of those drove or was the major driver in your pilots, and did you find conflicts between the imperatives of e-Pedigree and authentication?

Michael, are you willing to take it on?

MR. CELENTANO: Sure. First off, I should say I guess the question really is, did we have a particular bias, I think, toward the question of authentication versus pedigree in terms of how we approached our pilot and why? And I think I can say that when we chose to approach the Pedigree capability, I think some of the inputs that drove our interest in that I will say, at least speaking for myself, were coming from our direction and work with EPCglobal at the time where as an action group we've identified electronic Pedigree as a first capability, using RFID as enabling technology. So that's what started some of our early work there.

My participation with that group, I felt that if we could potentially do something as a company who was well positioned to maybe take a leading edge there in collaboration with our partners, it might be helpful as a reference model. So that's really what

drove our interest again.

I think it was following the leadership of the EPCglobal bag.

MR. CHANG: And I think our focus was based on FDA's suggestion of having a two-pronged approach of track and trace, which is Pedigree, and also the authentication. So you know, as a consumer, you know, do I want to take a potentially counterfeit drug that has a valid Pedigree or do I take an authentic drug, but I don't know the history of that drug?

So it's a tough question, and so what we've done is we wanted to put the infrastructure in place that can manage both the authentication and the track and trace capability.

MR. SPELLMAN: Yes. I mean, our position is that they are complementary technologies. One secures the transactional history and the chain of custody, and the other speaks to the validity of the product and really together they tighten things down very effectively.

MR. HINTLIAN: I would just add from a

Jumpstart perspective, actually, three years ago this month was when we sort of launched that whole program, long before this dialogue was popular, and the principle objectives of it were to move outside of the enterprise. So you could look at the application of technologies within an enterprise, within a distribution facility for the purposes of operational improvement or track and trace within the company's own supply chain, but we thought that it would be worth testing the value of this kind of technology across trading partners.

And so amongst dozens of areas where you could imagine applying a tag and seeing how you can get value, three areas popped out. One was safe and secure supply chain. It was reverse logistics and operational enhancements, again, across the supply chain.

It was just a few months after that, so the summer of 2003, when the Anti-Counterfeiting Task Force was officially launched that suddenly what came into focus was the safe and secure supply chain. They were all interrelated. Nothing was mutually exclusive

in terms of what we were looking at, but it provided that laser focus on what it is that the group would focus on in terms of a cross-supply chain effort.

MR. CELENTANO: I think also maybe another perspective on that, I do think the authentication piece of it, at least in some respects, has a focus for the group from EPCglobal I think came in a little bit later than the capability focus and started to get more attention. But I think also from the onset we envisioned this to be a manufacturer initiated Pedigree, and unless we're producing our own counterfeited product, that would seem --

(Laughter.)

MR. CELENTANO: So I think in that sense if we're using the Pedigree in the way we envisioned it, it would be kind of difficult to introduce that.

MR. DUBNER: In our case, our partner on this, their product is on that susceptible list. Their main driver was authentication. They wanted to make sure that what they did to elevate confidence that it was genuine was consistent with e-Pedigree and those kinds of things, but their initial driver was

authentication.

DR. LUTTER: Another question? Ilisa Bernstein.

DR. BERNSTEIN: You've all talked about the pilots that you've done, and several of you said that the pilots are a great tool for getting lessons learned and moving forward, and I'm just wondering -- and encourage additional pilots -- at what point do you move beyond the pilot stage and feel that you've had enough lessons learned to take this more widespread?

Based on your experience, was there enough that you got out of it that you could say, "Yes, we were really close," or, "No, we need to do a lot more"?

If you could share any insight there, that would be helpful.

MR. FOWLER: You know, I think from McKesson's perspective, our goal in this on track program is to identify the pieces and parts of the supply chain that make sense to serialize first. We have medical specialty businesses. We have cold chain

businesses. We have a lot of supply partners with us who are looking at this program.

Our goal is really to find out where does it make most sense to proliferate this technology first, and that's going to be based on value and security in the supply chain, quality of the particular product. Certainly in addition to assuring Pedigree in part of the cold chain it will save product. I mean, there are products that expire on the way. We need to know that they're heat protected on the way to their customer and not sitting on the back dock.

So we're looking at those kind of technology areas, and we'll know when we will implement. I think this will be most rationally implemented from an RFID perspective in those areas where it makes most sense.

I would tell you I was talking, again, to Paul from IBM. They're doing a lot of work in the medical device area because keeping up with a four or five thousand dollar device is very critical, but we have four and five thousand dollar vials of drugs that

keeping up with that is probably where we're going to start with the RFID effort.

MR. HINTLIAN: Just to build on that, I think in some sense you could say that all of the chapters for pilots have been written, and the term pilot is almost a misnomer going forward because it's all about how do you commercialize these capabilities. A lot of the pilot programs are characterized by very isolated supply chains, very sort of sanitized approaches to making sure that you can eliminate all of the variables so that you can get the kinds of learnings that have been obtained, and now it's about making it real.

And the notion of pilots, again, being something that you start, you stop, you study the results of I think has sort of concluded. Now it's all about can firms now start to develop and deploy capabilities and do so in a commercially safe environment in that they can collaborate, understanding that it's not perfect, that there's still a sense of you don't know what you don't know, and that you can continue to develop the learnings,

but the difference here is that these are now commercial capabilities, not just something that is going to be started and stopped. They will evolve and develop over time as technology matures, as business practices mature, as laws become better understood, et cetera.

So I would offer up that clarification.

DR. LUTTER: Can I ask a follow-up on that? You had earlier said that the big obstacles at this point pertain to development of skills, training, and just change management within the production facilities themselves, and can you talk a little bit more about if the pilots are behind us, the chapters are written, so to speak, and the next stage is a much broader scale implementation that really doesn't deserve the name of pilot, what is the timing to complete the necessary training and skills and development and change within the organizations, and if that's the obstacle going back to the main theme of this conference, what could we do or others do to help facilitate the necessary skill development training and change management?

MR. HINTLIAN: I think my co-panelists could also comment on this. I don't know that I can give a good answer in terms of timing, but I would suggest that in terms of the successful path forward on skill development and change management, I think the key thing here is inclusiveness of those who will be involved in the process as it becomes a commercial capability.

So as you're developing, as you're transitioning from a pilot activity to a commercial capability, the actual user community that's going to be involved with those activities, whether it's the folks in the warehouse, whether it's order management, whether it's the regulatory capabilities and so forth, they all need to be included as part of that process, not as something that's brought in after a technology has been implemented.

MR. KASHMER: We at H.D. Smith also believe that we need to share the expense throughout the entire supply chain, and we're in the middle of the supply chain, and we need to react to our business partners and their changes. So this is an evolving

process with introduction of new frequencies. We in the middle have to be able to read all frequencies as the items are just put into a tote.

And, again, "pilot" is not a good term because our RFID initiative has continued to expand. It has not just started and stopped, and so I think that also is very important. Our Pedigree solution did, and now it's starting again, and it will be deployed.

MR. DUBNER: I think that "pilot" isn't exactly the right term to use, but I think that transition that you asked about, Ilisa, has a lot to do with business case, and I think that there's still experimentation going on.

Jamie, I think, is correct. Perhaps the chapters have been written. They may not have been read, and sometimes reading isn't enough. Sometimes you've got to get out there and do it. So I think there's still some work to be done.

DR. LUTTER: We have questions from the panel. Bill McConagha.

MR. McCONAGHA: Shifting gears slightly,

this is directed at Mr. Fowler. You made reference in your remarks to the Florida state law and then also said that things could not be hammered out on a state-by-state basis. I just want to make sure I understand your thoughts here more precisely.

Is it your view that state laws, like Florida's, somehow frustrate implementation of widespread RFID? And if so, how?

MR. FOWLER: Well, I would say two things. One, they will frustrate implementation of RFID because, for instance, many of the people in the room have literally stopped what they're doing in RFID to comply with the Florida law in a paper in e-Pedigree form. Many of the companies you see in the room across the hall stopped what they were doing to develop e-Pedigree solutions that met the Florida law.

I mean, Peter and I were quite honestly in Florida a lot together, as were many people in this room.

Secondly, I would tell you that we are concerned that implementation of one part of the country -- you know, the commerce strength of the

United States of America is that we gathered together early to make commerce free across all of the states. So when you take a state like Florida and you make different laws for different products, now we have challenges of a major distributor that we can't just pick up any item in California and ship it to Florida. So there will be disruptions in the supply chain.

Emergency supplies, the state has certainly taken care of things like disasters and items like that, but on a more practical basis, the supply chain to the U.S. is a very critical supply chain, and we move product; all of our distributors more product worldwide or country-wide every day, and when one state isolates itself in that supply chain, they will cause some problems in getting supplies there.

MR. NIEDELMAN: So as a follow-up, what you were referring to in your presentation about potential disruptions in Florida is responsive to the 50-state distinction.

MR. FOWLER: Yes.

MR. NIEDELMAN: Your requirement

distinction.

MR. FOWLER: Yes, I mean, almost all of the major distributors are making arrangements right now. To the earlier question, when will we start training, I have three technologists dedicated in my E-commerce group right now to e-Pedigree because we will be complying with Florida laws with all folks, and that same platform, which is a Cyclone platform in our case, will be used nationwide for our Pedigree solution, and it will be adaptable to RFID at the appropriate time.

So we are, you know, essentially in the process to Jamie's point.

DR. LUTTER: Does anyone on the panel have contrary views that the state initiatives have helped promote adoption of RFID or Pedigree technologies?

MR. SPELLMAN: I mean, clearly having a catalyst, something to spur people to move I think is definitely causing forward progress. I think Paul's point is a good one. I think if you have 50 flavors of how you handle something like Pedigree, I think that will be very problematic for the supply chain.

DR. LUTTER: Other questions from the panel?

DR. SHUREN: I want to follow up on a point that Jim Hintlian had mentioned, which is that there's a need for greater inclusion as we start to move forward and either have, if you will, expanded pilots or out in commercial use. And Paul Fowler had mentioned that there's a need for more collaboration than we have seen so far.

Are there any barriers that you've encountered that would lead to or prohibit this greater collaboration? If so, could you elaborate on what those are?

MR. HINTLIAN: I'm start, and Paul is going to also build on these remarks, but I think as you look at any new kind of capability deployment there are several common denominators, things that everybody needs to do and do well so that you have the kind of cross-supply chain interoperability for processes and technologies and so forth, things that are not going to differentiate anybody competitively, not going to compromise strategic imperatives or trade

secrets or things of that nature.

And I think the early part of these pilots all sort of recognize that those weren't going to be issues. I think as you start to get into greater levels of collaborative programs and so forth, you will need to depart from that large group type of effort around collaboration because I think at that point there will be concerns around compromising strategic positions or trade secrets and things of that nature.

So I think in that sense from a cross-supply chain view you'll start to see some of those concerns amongst the participants, but still within any particular enterprise there will still remain the increased need for broader participation across all the different functional groups within a company.

MR. FOWLER: I would say that I have seen a tremendous over the last three or four years improvement in the collaboration, not only folks like Purdue, GSK, the leaders, Pfizer. The leaders in this area have really pulled together, and the McKessons and Cardinal, AmeriSource, Bergens, the large

distributors, we are actually working more closely together than we ever have for this problem of solving these kind of electronic commerce problems.

From our customer base, certainly the ones who are the most leading are the Wegmans, the Wal-Marts of the world, the Targets, the Rite-Aids, but those names are very large names. They have very large technology organizations, and they have very large infrastructures themselves, usually on the consumer product goods side, that have exposure to RFID technology.

What you don't see here represented very strongly are the acute care facilities. You know, large hospitals don't have exposure to the consumer package good side. So they don't have RFID on their lips. They don't have large technology organizations that are dedicated to infrastructures. They're dedicated to medical analyzers and those kind of things.

Those are the areas where we make the most impact in the health care chain probably, particularly from a long-term patient safety perspective. Those

are the areas that they just don't have a focus. They don't have the capability to focus at this point.

DR. LUTTER: Thank you very much.

Please join me in thanking this panel for this very enlightening presentation.

(Applause.)

DR. LUTTER: We'll meet again at 11:10 in this room to talk about state efforts.

(Whereupon, the foregoing matter went off the record at 10:55 a.m. and went back on the record at 11:15 a.m.)

MS. GLAVIN: Welcome back to our second morning session. This panel is on state efforts with respect to RFID.

As you all know, many states have moved to implement stronger wholesaler and Pedigree laws to further protect the drug supply chain. We are very fortunate today to have representatives from three states that have taken the lead in these efforts: Indiana, Florida, and California.

Our three state representatives are Donna Wall, from the Indiana Board of Pharmacy; Judi Nurse,

from the California Board of Pharmacy, and Judi will be joining us by phone; and John Taylor, from the Florida Department of Health.

So I know they have some very interesting information to share with us, and so, Donna, if you would start out.

DR. WALL: Good morning, everyone. My name is Donna Wall, and my real life paying job is that I am a critical care clinical pharmacist at the Indiana University Medical Center in Indianapolis, Indiana, and my full-time barely paying job is that of serving as a board member on the Indiana State Board of Pharmacy. Currently, I am serving as its president.

Last year, May 11th, 2005, our governor, Mitch Daniels, signed into law the new wholesaler drug distribution laws. Why, people ask, did Indiana pass such a law?

It actually came from a patient, a patient who went into their pharmacy and asked the pharmacists, "How do I know this is real?"

And the pharmacist said, "Well, let me

check." Well, the pharmacist happened to be State Senator Marvin Riegsecker. Senator Riegsecker called through the various line of where the product he thought had been, and he finally wound up with a repackager.

He asked the repackager the question that the patient had asked him, and the repackager said, "Trust me." That was not the answer that the senator wanted. Thus, we have our law.

Indiana's new wholesale drug distributor law actually consists of four main parts, of which the task force may see as very similar or actually comes from your report of 2004. We've increased the penalties for counterfeiting drugs. We have rigorous licensing requirements, including mandatory accreditation for all wholesalers. We have determined a normal chain of distribution, and we're requiring Pedigrees for all drugs that come from outside of that normal chain of distribution.

To give it a little bit more detail, in the counterfeiting penalties, it is now or what we have put into place in the criminal section of the law

is a new legend drug deception statute. The statute now gives anywhere from a felony D to a felony A penalties, up to 20 years in prison or a minimal of 20 years in prison if it is a felony A, if you are caught counterfeiting and a patient dies.

Effective licensing requirements. We are now requiring the following things to be a part of the licensing: the criminal background checks, surety bonds, due diligence for cause authentication, and a mandatory on-site inspection of all facilities that are going to ship into the state.

Along with that, I mentioned we are going to have a mandatory national accreditation. The statute says that it can be a VAWD accreditation, and VAWD is the Verified-Accredited Wholesaler Distributor program that Carmen Catizone spoke about yesterday.

The law also says "or another board approved accreditation," of which we have none at this point.

What we have felt is that the accreditation will insure compliance with relevant state and federal laws no matter where this wholesaler

is located.

The biggest point that or why the state really bought into it, this last line which is with the accreditation program there is negligible physical and operational impact upon the state, and when we all look at our state's budgets, we know how important that is. If they had to pick up the cost of this program, it wouldn't happen.

The normal chain of distribution. The normal chain of distribution is a bridge between the no Pedigree to the all Pedigree. So eventually this is going to go away.

We defined six different areas of normal chain of distribution. The last two on the list you see we included in ADR to an ADR transfer. That came out of our summer meeting. This is just one ADR to ADR. It's not ADR to ADR to ADR to ADR, to keep on down the line, and we wanted to make that very clear.

But, again, when you look at the normal chain of distribution, it is all just an interim bridge between getting all Pedigrees. The Pedigree laws that were passed, there's two phases to it.

Phase 1 is that by July 1st of this year any product that is outside of that normal chain of distribution must generate a Pedigree.

The second part of it is the part that we will be looking to this task force recommendations, is that the legislature wants the Board to prepare a report defining whether we can do a track and trace system, and this report has to be in by January 1 of '07.

We also must conduct a viability study and talk with the FDA, which is why we're really excited to be here listening to this presentation and look forward to your report.

The basic time line of the Indiana laws we had, the law was passed in May of last year. In June we had a stakeholders meeting, where we listened to everyone's concerns. We sat in a group and we hammered out things that we needed to put into regulation and things we needed to take back and change.

The current implementation, as of now any new wholesale distributors who are coming to the State

of Indiana must be VAWD accredited, period. I put 6/30 and I realize this should say after 6/30, in reality 7/1, Pedigrees will be required for all products that go outside of the normal chain of distribution.

As of 9/30/06 of this year, that's the end of our renewal cycle for all wholesalers. All wholesalers who want to do business within the state must be accredited, and then I mentioned that we will need to have a study and information back to the state legislature by January of next year. What are we going to do with the Pedigrees?

What are the issues that we faced when we worked with all the various stakeholders? What did they express frustration or concern about?

When we looked at the wholesalers, their concerns were thinks about the surety bonds, the authorized distributors. What was in the Pedigrees? Could invoices count as Pedigrees?

There was concerns of the normal chain versus the drug susceptibility list. They wanted the inclusion of the ADR to ADR transaction, and there was

a concern about the accreditation process from the aspect of they were afraid that the confidentiality of the information that they were going to share would not be kept confidential. We have put things into place, along with the accreditation agency, that they will be kept confidential.

The drug manufacturer is the issues. We had a request or it was requested that the drug manufacturers give full exemption from the Pedigrees. They felt that this was a very duplicative effort between the state Boards of Pharmacy and the FDA.

There was also a large discussion about the normal chain of distribution versus the drug susceptibility list. Manufacturers wanted all products included because they felt that the drug susceptibility lists were only products that had been counterfeited and that the state boards could not react quickly enough to respond to any compromised products. They also in the Pedigrees wanted included both lot numbers and content.

The chain drugstore warehouses. This entity was a new one to come into play because they

have their own enigma that we didn't quite fit into any category. So we had to create a new category. They weren't really considered ADRs. They weren't really in the first couple of versions of the normal chain of distribution, but now that we included them in.

Lastly, there was a criminal history background checks for personnel. There were concerns about that.

There was an entity called a third party logistics providers. In Indiana, that's UPS. Basically these are the folks who take possession of the product from the manufacturers, but never take possession of drug title. There was a concern about do these folks need to be licensed, and they also had a concern that they did not want to designate a representative at each site.

Indiana pharmacists. We need to include the pharmacists within this process. They are very supportive, but their biggest concern was about authentication requirements at the pharmacies level.

And lastly, our board. We felt the bottom

line was no accreditation, no go with this legislation, and we feel very strongly that we need to work with everyone to secure the entire distribution chain.

Which takes us to the present, which is Senate Bill 202. It's called Pharmacy Matters. It's just basically a clean-up bill for the Indiana State Board of Pharmacy, and we do have a couple of issues on the wholesale drug distributors within that. Basically they don't change the law. They are just a little clean-up things within it.

We had a senate Health Committee meeting on January the 25th of this year, and I am very pleased to say that we did have supporting testimony at that hearing from HDMA, Indiana Retail Council, Indiana Hospital Association, Cardinal Health, and Indiana Pharmacists Association.

That bill has since passed the Indiana senate with a vote of 49 to one, and it is now on to the House of Representatives, which we hope to pass it.

I mentioned in the beginning that I was a

clinical pharmacist because I need to relate one last story to everyone before I leave, and that was in 2002 my hospital, Indiana University Hospital, received the counterfeit Epogen, and it went out to patient care areas, but by the professionalism and by the efficiency of our staff, we got it back before any doses were given to patients, but it got that close.

And that changed how most of us who work in that facility look at this process. Where we used to look at a patient who may be failing therapy and you think, "Well, is it because they weren't compliant or is it because this is disease progression?" we've now added to our thought process, "Is it real?"

And most people, if you've never been faced with that, aren't adding it to their thought processes, and I think that they need to.

The Indiana Board of Pharmacy is made up of six pharmacists. All have practiced. All do face-to-face with our patients. One just retired. It is very important to us as pharmacists and as trying to be protectors of the public to be able to look these patients in the face and say, "Yes, answer the

question that the senator received, and that is, yes, you have received a real drug."

Thank you.

(Applause.)

MS. GLAVIN: Thank you very much.

Our next presenter is Judi Nurse from the California Board of Pharmacy, and I'm going to let our technicians get her on for us.

Judi, we have your slides up. Are you ready to start?

DR. NURSE (via telephone): Yes, I am.

Good morning. On behalf of the California State Board of Pharmacy, I would like to thank you for the opportunity to participate in today's panel discussion. I apologize for not being present today. It seems that out of state travel is a foreign concept to the State of California.

(Laughter.)

DR. NURSE: Are we there?

MS. GLAVIN: Yes. Hold on just a second and we'll try and get the hum out.

Okay. Go ahead.

DR. NURSE: I have been asked to provide a brief overview on the California Pedigree installation. So here we go with that, to Slide 2.

In 2004, our Pedigrees legislation passed. The purpose of the legislation was to reduce counterfeits in the prescription drug supply chain in California, and to reduce the diversion market in California.

In January of '05, some of the sections of the new statutes were implemented. Those sections were not the Pedigree portion of the legislation, but the restrictions on wholesale sales by pharmacies and also the requirement for licensure of out of state wholesale distributors.

Then in January of '06, we implemented a surety bond requirement for wholesale distributors, both licensed in California and out of state distributors, and then coming in January of '07, the wholesale Pedigree legislation is due to implement. In January of '08, the Pedigree legislation would be implemented at the pharmacy level.

Now, moving on to Slide 3, however, we

have written into our statute a provision of the California Board of Pharmacy can delay implementation of the wholesale Pedigree, and the California legislature has the ability to delay the implementation of the pharmacy provisions. The wholesale could be delayed until January of '08 and the pharmacy until January of '09.

Moving on to the specifics of the Pedigree, Slide 4 indicates the actual definition in California of the Pedigree. I won't go over that. The key element here is that it's electronic and that we do not mandate the technology.

(Pause for interference noise.)

DR. NURSE: I apologize.

We don't really intend to. Our goal is not to micro manage this technology, but to allow the best technology or combination of technologies to evolve. We realize there's a delicate balance between letting technology evolve and things being so out of control that a system won't work.

With that in mind, we are putting together a work group, and the first meeting of that work group

will be March 13th in the afternoon at one. Anyone with any interest in this process we would encourage to attend and participate in that meeting.

Our legislation was designed with the concept that the manufacturer would create the pedigree. Allowing the Pedigree to start at the wholesaler allows the potential for diversion before you even get the Pedigree started.

We also are not currently looking at the normal distribution chain concept.

Moving on to Slide 5, the electronic Pedigree requirements, this slide outlines what our Pedigree actually requires, and I think most of us are pretty familiar with that.

Number one is the prescription drug information. That's pretty easily understood. We don't include the NDC code, but we don't have any objection to the NDC code being part of the Pedigree as long as the information that we need is on the Pedigree.

Transaction source information, that's the information around the current transaction. The

ownership information is the previous ownership information of the drug history, and the certification is somewhat similar to what we talked about certification yesterday.

Now, Slide 6 through 9 talk about those issues in more detail, but I' not going to talk to that at this time.

Slide 10 through 13 talk about the detail of the rest of our legislation package dealing with counterfeiting and dealing with reduction in gray market diversion in California. I also will not discuss those details.

If we could go on to Slide 14, it talks about implementation challenges, and emerging technology is obviously a challenge and has been a challenge. I realize how very difficult it is for the industry and that everyone is making Herculean efforts and very expensive efforts to try and make this work, and we're very appreciative of everyone's efforts.

It's equally difficult for us to try and write legislation or regulations when you don't have the technology right in front of you. So that is a

challenge.

Industry is a challenge, and I say this kind of kiddingly. You know, just like regulators drive industry crazy, there's give and take there.

(Laughter.)

DR. NURSE: I don't want to sound like an advertisement for our work group, but just to let you all know that at that work group on March 13th, Patricia Harris will be putting on the agenda the issue of extending the implementation of the wholesale requirements until January of '08. So if there are people planning to attend to or requesting an extension, it's important that you provide the board with some plan for implementation and assurance that the compliance date of January '08 can be met in some fashion.

Anyone with pilot programs or anything like that is really asked to come forward.

Other challenges, of course, once we figure out exactly what we're doing, the next challenge is always education.

As I move on to Slide 15, I need to

indicate that at this point what I have to say is my own opinion and not the official opinion of the California Board of Pharmacy.

Lessons learned they asked that I discuss. This is some of the process of implementing. It's somewhat difficult to know at this point exactly what the lessons are. There are a couple of things we do know.

We do know that we don't want 50 states with 50 Pedigree standards, and we don't want every manufacturer to have their own format of the Pedigree. We need something standard.

We also need state Pedigree systems that we communicate within each, you know, back and forth with each other.

And I think it has been discussed repeatedly in the last two days that all of these systems, all need to be able to communicate with each other. That doesn't mean that everyone has access to everything, but everyone needs to have the ability to read all of this information.

I would like to indicate how the SBA could

complement our efforts, and I kind of consider this to be my wish list, and again, this is not official opinion of the Board of Pharmacy. I have five items.

One, each state develop and implement electronic Pedigree systems for prescription drugs. We don't want to spend all of this money and effort at all levels of industry to have some states become, you know, a haven because they are not Pedigree states, where drugs travel through that state in order to have the Pedigree basically cleansed.

Secondly, mandatory enforcement of state Pedigree requirements needs to remain with the state. The FDA can't possibly investigate on their own all of these pedigree violations.

Third, mandate that the manufacturer only create the Pedigree for prescription drugs entering commerce in the United States. We have been able to see how the technology can be worked around to a certain extent, I don't know that you want that technology spread all the way through the supply chain.

So having the tagging and the creation of

the Pedigree needs to rest with the manufacturer.

Next, a special clearing house. Now, we're not married to the concept of a special clearing house versus decentralized. So my slide is not really accurate, but just the concept as we discussed it yesterday, that entire area needs to be dealt with, and it needs to be dealt with in a comprehensive way, not the way that just the individual states would attempt to deal with it.

Next is, as I said, mandated compatibility between the Pedigrees and the systems that the individual states would utilize. Again, having everyone be able to read everyone else's data, not necessarily have access to it, but the ability to read it.

In conclusion, we at the state need federal standards now, not later, and the states need your support, the FDA support, now to assist us in moving this issue to completion. There is a very important health safety issue, probably one of the most important that the industry and consumers have faced in years, and we really need your help.

We're on the front line trying to protect the health and safety of the consumer, just as you all are, and we're trying to do this because there have been long delays at the federal level, and so we very much now need your support and your standards now.

So I thank you very much for inviting us to participate, and that concludes my remarks.

MS. GLAVIN: Thank you very much.

(Applause.)

MS. GLAVIN: And Judi will stay with us through the question period.

So right now we're going to move on to John Taylor of the Florida Department of Health.

MR. TAYLOR: Good morning. My name is John Taylor. I'm a drug inspector for the Florida Department of Health. I've been in that position for three years, and I previously served as the Executive Director of the Florida Board of Pharmacy for 13 years before that.

On behalf of the Florida Department of Health, thank you for this opportunity to summarize the Florida efforts to combat drug counterfeiting.

Responses usually begin with stimuli, and the Florida response to threats to the integrity of our prescription drug supply is no different. Many practitioners and even some of us in other aspects of regulation assume that prescription drugs travel from the manufacturer to a wholesaler and then to a pharmacy or practitioner.

In 2002 and before, better informed individuals were seeing drug products travel through multiple primary and secondary wholesalers. While there may be nothing wrong with this when taken at face value, these multiple and sometimes difficult to track transactions provided an opportunity for unscrupulous individuals to insert a counterfeit drug product into our drug supply chain.

This did, indeed, occur in Florida and most likely in other states. Department agents broke a high profile case that helped expose the threat, but the exposure also showed some glaring weaknesses in our regulation of prescription drug wholesalers.

A statewide grand jury report was very direct in its criticism, but also quite helpful in

recommendations for improvement.

In the spring of 2003, the legislature amended the Florida Drug and Cosmetic Act. This was a massive rewrite of many sections of the law regulating the wholesale distribution of prescription drugs. I think it is fair to say that it was challenging. Dr. Agwunobi gave you a few comments this morning about that.

But in the end the stakeholders came to agreement on many issues, and Governor Bush signed the bill into law. Some of the highlights include phased implementation. The amendments also provided for nearly immediate Pedigree paper requirements for a specified list of problematic drugs. This gave statutory authority to a regulation the department had been developing.

The bill also provided a definition for authorized distributor of record, although the definition was quite complex. The amendments provided for Pedigree papers for all prescription drugs by July 1st, 2006. Probably not as well known, the amendments strengthened other provisions of the act as well.

The bar was significantly raised with new requirements for those wanting to become permitted or remain permitted as in state or out of state prescription drug wholesalers. I think it is important to note that permits were not grandfathered in with these new enhanced requirements. In fact, the existing two-year renewals were shortened to one year to expose all permits to these new regulations sooner.

A surety bond the department holds during and for a time after permit relinquishment was increased from $200 to $100,000.

The amendments also required each establishment to designate a management person responsible to the state for the permit. These individuals are called certified designated representatives or CDRs in our law.

These individuals are required to pass a rigorous examination on their responsibilities under the act. The phase-in for this part of the act was concluded in August of 2005. An early high failure rate has changed to a much better passing rate as individuals gained a better understanding of what was

expected of them as CDRs. A better understanding of the requirements of the act may help an establishment prevent the unwitting introduction of a counterfeit product into their inventory. These requirements apply to out-of-state prescription drug wholesalers that are licensed with us, as well as in-state wholesalers.

The amendments to the act also provided disincentives to those that would recklessly put their greed above the public expectation for a safe drug supply. As you can see, our amended act includes new and significant criminal penalties. The failure to deliver or acquire Pedigree papers where required may be a third degree felony.

The knowing delivery of contraband drugs may be a second degree felony and the knowing delivery of a contraband drug that leads to great body harm may be a first degree felony.

Of course, the most significant and most discussed provisions of the amendments are Pedigree paper requirements. As I mentioned earlier, the amendments provided for a three-year phase-in for

Pedigree papers. The legislature gave the department the authority to require pedigree papers immediately for a select group of products that a broad based advisory committee felt had the highest potential for product integrity issues.

This is our specified drug list, and it currently includes 34 products. The advisory committee is administratively housed within the Department of Health, and its members are appointed by the Secretary of Health.

Pedigrees were also required for transactions between wholesalers where the supplier wholesaler was not an authorized distributor of record. The problem with this practice, known as the status quo, was that an ADR buying from a wholesaler that is not an ADR and then reshipping to its customers was not required to supply the Pedigree that it had received to their new customers. This effectively washed the Pedigree.

The pre-July 2006 section does not require that a Pedigree be supplied to a pharmacy or a practitioner. Beginning July 1st, 2006, a Pedigree

starting with the first wholesaler and including each wholesale transaction must be supplied to the end user pharmacy or practitioner for all human drugs, human prescription drugs.

Prescription drug manufacturers are not required to supply the Pedigree document when selling their products, but the first wholesaler will prepare the initial Pedigree, including the information on their transaction with the manufacturer. The ex-authentication requirements may require the most resources of wholesalers. Each wholesaler party to a transaction must authenticate each prior transaction on the pedigree before accepting the product into inventory.

The proliferation of fraudulent Pedigrees renders a Pedigree almost useless unless it has been authenticated. Department rules list several acceptable methods of authenticating Pedigrees. These methods include receipt of a copy of original invoice or packing slip for the transaction, the telephone communication with the seller, an E-mail communication with the seller or a verifying E-mail communication

with the seller, and also verification through a secure Web-based system.

Pharmacies and practitioners are not required to authenticate the Pedigrees that they receive, and that's under the 2006 requirement.

Clearly, the desire to supply authentic products has led some wholesalers to shun the secondary market and to buy only from the manufacturer. Our requirements may have hastened those actions.

Some pharmacy chains now require products purchased directly from the manufacturer. As I stated earlier, some of the more naive among us thought that was happening in the first place.

The message that I would like to leave with you is that our amendments have tried to approach the threat to drug product integrity from three directions. We want to make sure those doing business in Florida are knowledgeable and accountable. We want to make sure that there are appropriate penalties in place to discourage unlawful behavior, and we want Pedigreed papers to help increase confidence that

wholesalers, regulators, and consumers have in our prescription drug integrity.

The prescription drug wholesaling climate in Florida has certainly changed in the last three years. We've gone from about 500 in-state prescription drug wholesalers to about 200 prescription drug wholesalers, but that is still a large number when you consider the number of pharmacies and practitioners in our state. And also, we haven't noticed disruptions in our drug supply.

I think that time will tell that the leaders, such as Dr. Agwunobi, have made wise and appropriate decisions as we move forward with these amendments to our drug law.

Thank you.

(Applause.)

MS. GLAVIN: Thank you very much.

For the task force members, I remind you that Judi Nurse is still with us by phone. So if you have questions that you want to target to her, please feel free to do so.

Bill.

MR. McCONAGHA: I was actually going to target this to Ms. Wall, if that's okay.

MS. GLAVIN: That's absolutely fine.

MR. McCONAGHA: Thank you for your presentation.

You discussed how under the new Indiana law the pedigrees would be required for drugs that are outside the normal chain of distribution. Could you just please define for me how you define a normal chain of distribution and explain the rationale behind drawing that distinction as a regulatory matter.

DR. WALL: The normal chain of distribution really came from the thought of how should a drug really travel through the drug system. I guess John said it best when he was talking about how we all assume that it goes from the manufacturer, wholesaler, to the pharmacy and why does it need a lot of other detours.

What we did was we sat down with all the various stakeholders and we looked at what were the most important parts, and that was basically the manufacturer. I think most complicated was the

manufacturer to the logistics provider, to the ADR, to the chain drug store down to the pharmacy or to the hospital or to the patient, whichever way it goes.

But we wanted to basically straighten out a lot of detours that drugs would have to take. It's like why not give them the most direct path, and that's the basic thought process behind the normal chain of distribution.

But, again, this is what we consider as a bridge method until we can get the pure Pedigrees, and that's what we really want.

MR. McCONAGHA: If I can follow up on that, I understand that with both you and Mr. Taylor, that both of your laws defined authorized distributor of record or ADR, and albeit as Mr. Taylor described it in Florida, certainly it was kind of an interim provision until there's a universal Pedigree requirement.

How did you go about defining ADR? And what feedback, if any, did you get from the secondary wholesaler community on the significance of that definition?

MR. TAYLOR: Although I did not play a role in it, I believe I can summarize that. As Dr. Agwunobi mentioned this morning, many stakeholders were brought into the process. There was a wholesale advisory committee prior to the enactment of the law that brought these folks in, and they played a role. As I said, it's a complex definition, but it's because all of those types of issues were considered.

DR. WALL: And basically we looked at NABP's model regs. at that point, which I believe had defined the ADR, and as we also sat down in discussions and we looked at what is it -- at what point do you push somebody over the edge that you really say that they are an ADR or they have an exclusive contract. So that's why we put in a little bit about pricing into it, but most of it is based on the model regs. and the follow-up from Florida's legislation.

MS. GLAVIN: Randy is reminding me that he and I made an agreement during the break that we would revert to the United Nations protocol, which in this case means if you have a question you want to ask or

if you're on the panel and you want to respond to one of the questions, if you would turn your name tag vertically rather than horizontally, it means that I don't miss people and I can keep track of how many people we have.

(Laughter.)

MS. GLAVIN: Well, Judi is going to have to just holler over the phone sine I can't see her placard. I'm sure she is sitting with a name placard in front of her though.

Having said that, Randy, you were the first one to do it. So you get the next question.

DR. LUTTER: Thank you.

This question is for Judi Nurse. Can you hear me?

DR. NURSE: Yes.

DR. LUTTER: You said that you supported a mandate that each state develop and implement an electronic Pedigree for prescription drugs. You also said that you do not want 50 states with 50 Pedigree standards, presumably 50 different Pedigree standards.

Thus, I think either, to interpret your

statements, either you believe there should be federal standards, in other words, unique federal standards adopted by all 50 states, or there should be a federal standard that the federal government itself mandates.

And my question is whether the latter would be -- wouldn't the former be significantly more complicated because it's a two-step action where we would mandate standards, actually identify standards and then mandate that the states all adopt the same standard so as to avoid the problem of the different states having multiple standards?

Thank you.

DR. NURSE: I don't know if I have the answer to your question, I apologize. Federal standards? We don't want 50 different standards, and my meaning is that I don't want it to become so federal that the states can't regulate it.

What was an issue with the original PDMA is that some of the provisions were federal provisions which meant that a lot of the enforcement had to be done by federal agencies, and it was difficult for states to do any enforcement, and we just need enough

authority left with the states so that we can do our own Pedigree enforcement.

The FDA can't possibly investigate every Pedigree violation, and what currently happens is that the FDA can only take on very large investigations, and they tend to be very long to investigate and adjudicate.

Like I said, the system just needs to be devised so that the states can regulate their Pedigrees within their states.

Does that make any sense at all?

DR. LUTTER: So your key point is that the enforcement responsibilities should continue to reside to a substantial degree with the states, but that the standard setting should be predominantly federal?

DR. NURSE: Well, I would prefer one standard that everyone can work towards. That would be my preference. Obviously all of the stakeholders need to have input to that standard, but I think everyone has spoken, I think, for the last two days saying we need one standard here, not 50 standards.

And all I'm saying is we want to retain

some enforcement capabilities.

DR. LUTTER: Thank you.

MS. GLAVIN: Okay. I'm going to do Steve and then Deb and then Terry. So Steve.

MR. NIEDELMAN: Thank you, Maggie.

And this question is for Donna Wall. Again, thank you for your presentation.

You indicated as you were going through your process in Indiana that various confidentiality issues had arisen and you dealt with them. What were they and how did you deal with them?

DR. WALL: The biggest confidentiality was that the various wholesalers or those who were going through the accreditation process would have proprietary information leaked or it would become public knowledge. That was not ever the purpose behind this. So we worked with NABP, and it is within their agreement with us and also the agreement that they signed or the wholesaler signs with them that they will keep that information confidential. It is not to ever come out of the process. It's mostly proprietary and financial.

MR. NIEDELMAN: Thank you.

MS. GLAVIN: Deb.

MS. AUTOR: Thanks, Maggie.

This question is for Mr. Taylor and Ms. Wall, and the question is Ms. Nurse addressed, I think, pretty extensively the role that she would like to see for FDA here with respect to Pedigree requirements, and I think you heard that, but she talked about, as we said, federal standards while retaining state enforcement.

Do you agree with that or, if not, what role do you see for FDA in Pedigree issues at this point? What would you like to see FDA do, if anything?

MR. TAYLOR: I am not a policy maker in Florida, and so I'm not really prepared to address that. Certainly somebody had to take a first step, and I think our state has done that, and we're moving forward. We'd like to see, you know, uniform requirements obviously across the country, but I'm really not in a position to say what the state would like FDA to do at this point.

MS. AUTOR: Thank you.

DR. WALL: I agree with Judi and her comments. I think that we do need a standard set, and I would like to see you guys put down a date. Just give us a date. Let's start the process and lets move it forward to take care of the patients, and then work with the states. Work together with both of us so that we can work on the enforcement piece and make sure that we don't have anything falling through the cracks.

MS. AUTOR: Thank you.

MS. GLAVIN: Terry.

MR. VERMILLION: Yes, I'd certainly like to applaud all of your states' efforts, and I must admit from my office, the Office of Criminal Investigations, I'm very envious.

I was curious, Mr. Taylor. When you were talking about the selection of your phase-in of drugs to require a Pedigree, I believe you said there were 34 currently on the books. Were there 34 when you started out? Have you added on?

And secondly, do you have the ability to

rapidly add another one on if a drug emerges as a drug that comes on your radar for a counterfeit?

MR. TAYLOR: I believe that there were 29 drugs on the first list that was adopted into rule, and they have been added in ones and twos and threes to the point that we're at 34 now.

Also, I believe there is produced -- and that goes through a committee process, and there are set criteria for the selection, parameters for the selection for a drug to be added, but I do believe there is the opportunity for the state's Attorney General to make a recommendation for an emergency addition to the drug, sir.

MR. VERMILLION: And one other thing. I address this to all three of you. After you're enhanced your criminal penalties for these different violations, now that you've had time to actually exercise these penalties, do you have a process? Is there a periodic process to go back to the folks that are using those penalties and find out is it working; do they need adjustment; do they need some enhancement modification?

DR. WALL: All I can speak to from the Indiana perspective is we're so new in this process we haven't gotten that far. We've had a couple of questions bounce back and forth, but I don't have that process down in place, but we will work on that.

MR. TAYLOR: I'm not sure whether the criminal penalties have been applied to date in our state, but certainly the Attorney General in our state is a stakeholder and involved in it. In fact, the Attorney General has a representative here at this meeting following the discussions here today.

MS. GLAVIN: Judi Nurse, would you answer that question also if you could, please?

DR. NURSE: Yes, I would agree. We're just implementing and we haven't gotten to that point either.

MR. VERMILLION: Thank you.

MS. GLAVIN: Bill, did you have another question?

MR. McCONAGHA: Thank you, Maggie.

I actually have a couple, but I'll begin with one. I would just address this to all of you,

and maybe Ms. Nurse can answer first because she's on the phone and then I can hear from you, and actually I think Ms. Nurse covered this in her presentation, but I'd be interested in hearing a bit more.

I've heard from all three of you now that there's an interest in having some federal leadership in setting standards, and that begs the question exactly what kind of standards you think ought to be set.

It seems to me there are any number of variables in this equation. You know, issues like what's the definition of an ADR, who's required to pass a Pedigree, what fields of information should be on that Pedigree, whether there should be a universal Pedigree requirement.

And when you speak of a desire for federal standards, exactly what are you seeking there? And on the flip side, where would you, for lack of a better term, prefer the government not to intervene?

DR. NURSE: Okay. Let's see. I think I listed, you know, my preferences just in terms of mandating a Pedigree by each state, and definitely a

list of standard Pedigree requirements. As I said, the area that I'm most concerned is that we can retain an enforcement capability, and we are very interested in the manufacturer generating the Pedigree. And that would be, you know, a national standard.

And, again, mandating or guiding how all of this data is cared for and assessed and privacy regarding the data and also mandating that all of the data be usable between all of the parties. In other words, if we have every state with a pedigree system, then that all needs to be, you know, usable between states. The only way this system works is if all states are participating and if all of the data is usable, you know, by everyone else.

MR. McCONAGHA: Just to follow up on that, I take it -- and correct me if I'm wrong -- that the state would still like to retain the prerogative to be able to define exactly who has to pass a Pedigree in any given situation, be it a universal requirement or some such other requirement."

DR. NURSE: Well, I think at this point we start out with that, and we probably would want to

retain that, but at some point in the future if things were, you know, to develop so that this was such an integrated system that something like that could be looked at, that might be something for the future.

MR. McCONAGHA: Okay. Thank you.

Do either of you have thoughts on this issue?

DR. WALL: When I look at the standards, I agree with Judi. I think we do need the one Pedigree, and I think that that is something as we've just seen in the conversation in the last few days that people have different visions of when that should happen, but I think that the FDA should take the leadership role. It should set that standard so that we all know what we need to go to.

I think that there are things that can be done in the meantime. There are various other parts to this counterfeit process, and one of them that I want to throw back is the VAWD accreditation. When you look at it, one of the pieces is we want to make sure that we've got the right people who are playing, who are taking care of the drugs within our country.

If the FDA were to endorse it like they have the VIPPS system and said this is the standards that we think that wholesalers should operate by, I think that that would make a difference and you could do that in a very short period of time.

But for general standards and for transported drugs across the states, we've got to have the consistency among them just for any point of information and to be able to get the drugs across.

MR. TAYLOR: I think the area where we're most likely to diverge is in the area of authorized distributors of record. Obviously, our leaders have determined that that system doesn't work very well, and in fact, it won't be in place in our state in July.

There are problems that have been mentioned several times this morning with that type of thing, and so that's obviously a place where we may be different than the rest.

MS. GLAVIN: I think I have -- is this a follow-up?

DR. BERNSTEIN: It is a follow-up.

MS. GLAVIN: It's a little bit of a cheat, but we'll let you do it.

DR. BERNSTEIN: Is that all right? Okay. Thanks.

It's kind of a two-part question, but one, for your states are the Pedigree requirements mandated or defined by you?

And in addition, yesterday we heard from the e-Pedigree standards group that they've come up with a format and are looking at specific standards to include. Have you looked at that? And do those match up with Pedigree requirements that you all have in your states?

DR. WALL: I haven't looked at their standards. When we did this, it was last June, and basically all of the stakeholders sat in a room and we talked about which way we needed to go. So it is under regulation. We have some flexibility to change what is actually within the Pedigree, which it is really done that way on purpose so that we can see what kind of national standards come through and what is the best way to track and trace that drug.

MR. TAYLOR: Does your question relate to the form or the format of the Pedigree itself?

DR. BERNSTEIN: No, the specific information in the Pedigree.

MR. TAYLOR: Our statute does give a specific list of elements that are required in it.

MS. GLAVIN: Okay. We have time for two more questions. So Deb and then Jeff.

MS. AUTOR: Okay. Well, I'm going to cheat a little bit because mine is a two-part question, but I think it's short, and this is addressed to all of the panelists.

First of all, does your Pedigree law at all affect active pharmaceutical ingredients?

And secondly, given that repackaging operations have been identified at times as a source for entry of counterfeit drugs into the drug distribution scheme, does your state law address this in any way?

MR. TAYLOR: Our state does require that a repackager basically follow the same requirements as a wholesaler.

DR. WALL: Our follows the Florida rule, is that they are considered wholesalers. And I forgot your first question.

MS. AUTOR: It had to do with APIs, active pharmaceutical ingredients.

DR. WALL: All the law states is in drugs.

MS. AUTOR: So that if a repackager, once they entered a drug into the distribution scheme could give a Pedigree from that point to the point of consumption, and that would comply with the law even though the drug itself could be a counterfeit with a valid Pedigree; is that right?

DR. WALL: I'm confused. Yes, I guess they could. If a counterfeiter is making the drug and they sell it to the repackager, and you would be starting right there with the Pedigree, you could get a falsified Pedigree.

MS. AUTOR: Okay.

MR. TAYLOR: I'm not sure how we handle APIs to be honest with you. I'd have to check.

MS. AUTOR: Okay. Ms. Nurse, any comments on this?

DR. NURSE: Within our system, if I understand the question correctly, you're asking about repackaging, and in our system the Pedigree would need to go to the original manufacturer. So go back to the original manufacturer so when a repackager does their repackaging, the Pedigree, yes, they have to generate a Pedigree because they might be changing NDC numbers or they might be changing vital information, but that needs to be linked back to the manufacturer. We don't start a new Pedigree at the repackager level.

And in the State of California, repackagers are actually not regulated by our agency, but by our Department of Health Services.

And then the second part of your question was about entry of counterfeits into the system. I could barely hear the question.

MS. AUTOR: The second part was about active pharmaceutical ingredients, whether your law affects those at all, just APIs or active ingredients used to make finished pharmaceuticals. I think the answer is no, but I just wanted to check on that.

DR. NURSE: Oh, no.

MS. AUTOR: Thank you.

MS. GLAVIN: Okay. Jeff.

DR. SHUREN: Thank you.

First, I just want to echo Terry's sentiments and really applaud all of you and your states for taking the threat of counterfeit drugs very seriously. I, again, do applaud you.

What I want to explore a little bit is who actually falls under Pedigree. Who is required to actually pass Pedigree and who is required to authenticate?

And the three states actually do it a little bit differently. So, for example, in Florida there's no ADR. It's all wholesalers, but on the flip side, manufacturers and retailers are sort of excluded. You don't have the bookend approach and certainly retailers aren't required to authenticate.

We heard from California that it's very important that it be the manufacturer who creates a Pedigree. So I'd like to hear from all of you regarding your systems just kind of why you put in the systems you did in terms of who's required to pass

Pedigree, who's required to authenticate.

And then if you want to speak either on the record or personally whether you would kind of agree with that approach or would see it a little bit differently.

MR. TAYLOR: Well, again, our law on July 1st includes every wholesaler for the Pedigree. The manufacturer specifically by the statute is not required to supply that, but the first wholesaler is required, and then it goes all the way to the pharmacy or practitioner.

The difference at the end is those individuals are not required to authenticate the Pedigree, but each --

DR. SHUREN: Oh, no, I understand the requirements. I'm just trying to better understand why that particular scheme was adopted, why the manufacturer not included to actually create the Pedigree, why the pharmacy not required to authenticate.

MR. TAYLOR: Well, I can't answer those. I'm not sure. I wasn't involved in those discussions,

sir.

DR. WALL: The process was actually created by all of the stakeholders, and it was called compromise. It was the best thing that we could do at the time to get it passed and to try to get a start on this process, and this was what we wound up with. And it's basically Pedigree would start with the wholesaler or exempt from the Pedigree would be the manufacturer, the ADR to a chain drug store, to a pharmacy or the third party logistics provider.

But in all honesty, it was the compromise. Is it the ideal system? No, it's not the ideal system. The ideal system will be a Pedigree from start to the end of the process so that anyone along that line knows where it has come from, who has had it, and where it has been.

MR. TAYLOR: If I could just add a little bit to mine, you heard Dr. Agwunobi this morning talk about bringing the stakeholders in, and obviously those were factors that shape what the law ended up being.

DR. SHUREN: Judi, are you still there?

DR. NURSE: Yes, I am. I can barely hear. So I apologize if I have not responded appropriately.

We have the Pedigree starting with the manufacturer because we feel that that's sort of the beginning of the process, and if we go in to look at a Pedigree, if a wholesaler says to you, "I'm the first wholesaler and I'm generating the Pedigree," then the first thing we have to do would be investigate that and go back to the manufacturer.

So if we have the Pedigree starting with the manufacturer, that seems like the most appropriate starting point. Who has to pass a Pedigree is whenever ownership changes of the product, and so a manufacturer would create the Pedigree. It would then be passed to a wholesaler and then passed to various wholesalers until it passes to the pharmacy or a prescriber or what we would term to the prescriber or a pharmacy.

We have certification, and the entity that -- I would use the term loosely -- the entity that's selling the product in a particular transaction is the one that has to certify the document.

Also, when it gets to the pharmacy level, if pharmacies return drugs or if pharmacies were to wholesale drugs, then that would be a step on the Pedigree also.

MS. GLAVIN: All right. I want to thank this panel for their good presentations and good answers to the probing questions. Thank you.

(Applause.)

MS. GLAVIN: I have a couple of small announcements. One, we will reconvene at 1:30.

DR. NURSE: Thank you very much for your help.

MS. GLAVIN: Thank you.

Secondly, if you plan to speak at the open mic, you must be registered to do so. You must sign up to do so at the registration desk, and we will be closing that sign-up at 12:30. So if you plan to speak at the open mic between now and 12:30, you need to get your name on that list.

Thank you.

(Whereupon, at 12:17 p.m., the meeting was recessed for lunch, to reconvene at 1:30 p.m.)

AFTERNOON SESSION

(1:34 p.m.)

DR. LUTTER: Good afternoon. I'm very pleased to begin the final organized panel on the second day of our conference. This one is entitled "PDMA in 2007 and Beyond."

The stay of certain provisions of the 1999 rule expires in December of 2006. In the coming months, FDA will determine what the future is of that stay and the PDMA provisions.

The following panel will discuss where they see PDMA and the safety and security of the drug supply chain in 2007 and beyond. Our first speaker is Scott Melville of HDMA.

MR. MELVILLE: Thank you, Randy.

And let me add my appreciation to the FDA task force for conducting this meeting. I will join the chorus of other speakers who thanked you for it. I think it has been a very enlightening two days for everyone.

Many of us live, eat, and breathe this issue day in and day out, and as much as we like to

think we know things and understand everything, we certainly don't. We're learning all the time in forums such as this, giving an opportunity for everyone involved in this very important issue to learn from each other.

Good afternoon. I am Scott Melville. I'm the Senior Vice President of Government Affairs at HDMA, the Healthcare Distribution Management Association.

We represent, as I think has been previously mentioned by John Gray, our president, and Lisa Clowers, our Senior Vice President, we represent the nation's primary health care distributors, the full service health care distributors. And on any given day, our members will deliver roughly seven million prescription drug products to about 142,000 dispensing locations in all 50 states and U.S. territories.

The nation's pharmaceutical distribution system provides a ready, reliable source of medications for patients when they need them most in times of sickness and in need. And HDMA members

provide this function with really little public recognition or visibility, and they do so at great savings to the health care system.

There's no greater concern among our members than the security of the prescription drug supply chain. In the nearly two decades since Congress first enacted PDMA, major changes to the pharmaceutical supply chain have taken place. Yet the threat of counterfeit drugs remains.

Manufacturers, distributors, and pharmacies must remain vigilant in their effort to address this increasingly sophisticated criminal threat and must continually implement new systems and processes to defeat it.

HDMA and its member companies have been at the forefront of the nation's efforts to address the threat of counterfeit drugs, and as John Gray said, there's no single solution to this threat. Rather, we view it really as a threefold strategy.

One, certainly and really the purpose of this meeting here today, in part, strict regulation and enforcement. We absolutely support that. It's

critical.

Number two, the other purpose of this meeting, adoption of new technologies, absolutely essential.

And three, adoption of best business practices and processes.

Now, let's talk a little bit about the PDMA and HDMA's position on the PDMA. First, I want to say that HDMA supports implementation of the 1999 final PDMA rule in tandem with necessary revisions to reflect the 2006 marketplace. We believe improvements and clarifications can be made to insure the continued safe and effective and efficient distribution of prescription drugs to all consumers.

This could be achieved either through clarifications to the rules itself or through other administrative action.

Second, HDMA recognizes that FDA and state authorities must faithfully implement the law as established by the governing PDMA statute. While we believe the PDMA statute was a necessary and effective first step for Congress to take in the 1980s, current

circumstances in our opinion require a fresh look.

In particular, HDMA is calling for the law to be amended to provide for uniform federal licensing of pharmaceutical distributors.

With regard to the final PDMA rule, since the enactment of the law and the promulgation of the final rule, the marketplace has gone through a tremendous change. There's been an explosion of new biotechnology products, new generic products, new companies, new manufacturers.

Simultaneously there's been a revolution in health care delivery. There are more and more sites of medicine and dispensing and patient care that are serviced by our members on any given day. As I mentioned earlier, about 142,000 sites.

These changes have made the distribution system significantly more complex and require regulatory precision to maintain a continued efficient flow of necessary products to these facilities and the patients who depend upon them.

HDMA believes PDMA's rule should be enhanced to address the realities of today's complex

health care system, and let me emphasize first something really that quite frankly I don't believe has been emphasized enough either at this hearing or in previous discussions on this matter, but we believe that first and foremost the single most effective and immediate step that regulators and states can take to address the threat of counterfeit drugs is to insure that there are uniform, tough licensing standards applied to manufacturers, distributors and pharmacies. It's essential to insure that criminals never receive a license to handle pharmaceutical products in the first place.

Unfortunately, we know that there were situations earlier in this decade where that happened, and so we are very supportive of stronger, stricter licensing. HDMA recommends strengthening FDA minimum standards for the licensure of distributors to incorporate many of the elements that are included in HDMA's model state legislation and which have been adopted by many states, such as Indiana, Florida, and California.

We commend those three states for moving

forward in this area and for enacting tougher standards for licensing. These include, as it was mentioned this morning, mandatory criminal checks, financial background checks, a physical inspection prior to the issuance of a distribution license.

This may surprise people, but that isn't always done or hasn't always been done, and we know for a fact that that's an essential requirement if you want to tighten up the supply chain.

We also believe that regulation must recognize -- I mentioned tougher criminal penalties as well, and that's certainly a key element of our state model bill and something we strongly support.

Regulation must also recognize, however, new manufacturing and distribution models. Increasingly products are being manufactured, delivered and dispensed in ways that were not contemplated or widely adopted at the time of PDMA enactment. These include greater outsourcing of manufacturing by products; use of third party logistics providers, three PLs; higher manufacturer minimum order standards that might impact smaller

distributors who don't do the volume; use of an exclusive or semi-exclusive distributor to provide product on behalf of a manufacturer necessitating some trade between distributors; drop-shipping of products from the manufacturer to the pharmacy customer. Though the distributor owns the product technically they may never physically take possession of that product.

And more recently widespread adoption of inventory management agreements between manufacturers and distributors that reduce the amount of the inventory in the supply chain and create a virtual "just in time" inventory.

A recent example illustrates this problem. A large manufacturer recently notified many distributors, many of whom are members, but wouldn't sell to them because they didn't purchase enough product to meet the manufacturer's annual product sales buying requirements. As a result, those distributors, many of whom have distributed this company's products for many years, will now have to buy that company's products from another distributor

or risk not meeting their customer needs.

Just a real world example of something that happened just in the last week or two that is obviously something that I think FDA and state regulatory authorities need to keep in mind as they regulate in this area.

Any implementation of the PDMA final rule must address these current and emerging pharmaceutical supply chain realities. As we've just illustrated, a manufacturer designated authorized distributor of record for nearly or can be an ADR for nearly all of the manufacturer's products or all of the manufacturer's products, but that can change. Again, that's why we think it's very imperative to be careful and understanding the definition of an ADR and the intent of ADR, quite frankly, when Congress passed it in 1988.

As far as the Pedigree requirements, and this was something that was discussed, I think, in the last panel, certainly there are issues as to who is an ADR, and tied to that is when then should a Pedigree be required to be passed and what should be the

elements within that Pedigree.

We've had a lot of talk over the last couple of days about, you know, what are the effective elements to include and can it be produced in an e-Pedigree. Obviously this industry is strongly supportive of serialization of product; that until you get to serialization you will never know for sure where a particular product unit has been, and that is certainly the goal, the goal that we strongly support.

Basing tracking on a lot number can be instructive, particularly in recall purposes, but certainly will not tell you where that particular lot has been, given that there are many units, identical lot numbers.

And transaction history, this has been a big issue, I know, in the past, being able to tie a Pedigree back to the manufacturer, and I wish I had a simple answer for you for this. There is not a simple answer for this, but what I think we hope is that with an electronic Pedigree certainly and RFID primarily, that that can be done very easily electronically and effectively. So that's certainly the goal, and why

HDMA supports moving in that direction.

Finally, the second message we'd like to deliver is that while we hope FDA is willing to consider some of these recommendations to strengthen and clarify the final rule, we also believe the time has come to revise the PDMA statute. We believe that in an era of increasingly sophisticated domestic and international threats to the nation's prescription drug supply, HDMA believes the current state-by-state licensing structure simply cannot provide the consistent and uniform regulation of pharmaceutical distribution necessary to further secure the supply chain.

I think it's something we've heard throughout the day and even from the states themselves who have asked for uniformity here and whether it's a license or it's simply federal uniform standards, we certainly want to discuss this with all of the stakeholders and encourage uniformity across the supply chain.

So in conclusion, HDMA commends the Food and Drug Administration for conducting this public

workshop. We appreciate the opportunity to provide our perspective, and we look forward to answering any questions during the Q&A session.

Thank you.

(Applause.)

DR. LUTTER: Thank you very much.

Our next speaker is Kevin Nicholson from the National Association of Chain Drug Stores.

MR. NICHOLSON: Thank you.

Good afternoon, and thank you for inviting me to speak today about the PDMA and reducing the chance that counterfeit products could enter the pharmaceutical supply chain.

I'm Kevin Nicholson, Vice President of Pharmacy Regulatory Affairs for the National Association of Chain Drug Stores.

I'm going to start out by saying that NACDS and our members are deeply concerned about insuring that our patients receive safe and effective medication. We are working diligently to reduce the possibility that one of our patients would possibly receive a counterfeit product.

NACDS, for those of you who aren't familiar with us, we represent the nation's leading retail chain pharmacies and suppliers. Our members operate more than 35,000 pharmacies, employ 108,000 pharmacists, fill more than 2.3 billion prescriptions annually. Also, our members include suppliers of products and services to the chain pharmacy industry.

From the discussions yesterday and today, I think we all agree that there is no magic bullet to address the counterfeit drug problem and that we need a phased in approach. We need affordable solutions that will work and that won't unnecessarily disrupt the delivery of medication to patients.

I won't spend too much time going over the background of the PDMA, as Mr. McConagha provided that for us earlier today, and in the interest of time I won't go into any of that, but I just would like to point out that we would like to ask the FDA to take another look at the ADR designation. We believe this designation is often arbitrary and unfair in that chain drug warehouses are not considered ADRs because they can't meet the criteria that are developed with

wholesale distributors in mind.

For example, a manufacturer can make a wholesaler an ADR for specific products and not full lines. This is not manageable for a chain drug warehouse. We often can't meet the volume requirements to satisfy these requirements.

In many cases chain drug warehouses purchase and receive manufacturer products through a traditional wholesaler to leverage efficiencies and distribution networks. These purchasing arrangements are entered into with the full knowledge of the manufacturer and sometimes at the manufacturer's direction.

The manufacturer is aware that the chain drug warehouse will be distributing the product. We would like to point out that patients -- and I won't spend too much time on this slide either. I believe I have ten minutes. Is that the -- thank you.

I won't spend too much time on this slide, but I just want to point out that patients are far more likely to experience counterfeit products through the illegitimate sources rather than through the

legitimate supply chain, such as foreign pharmacies and Internet sites that engage in drug diversion.

So we would encourage FDA to address counterfeit drugs from these sources as they do constitute a vast majority of the counterfeit drug incidence.

NACDS is asking FDA to continue the stay of the Pedigree requirements of the PDMA. I believe we all agree that paper Pedigrees are unworkable, that their costs would be astronomical, and they would be logistically impossible.

With respect to electronic Pedigrees, we all understand from the discussions that we've heard earlier today and yesterday that electronic Pedigrees don't necessarily equal RFID, that you don't necessarily need RFID to have electronic Pedigree.

However, we believe that requiring any other technology besides RFID really would just be a distraction from the goal of eventually moving to an RFID system across the entire supply chain.

However, unfortunately, RFID technology will not be implemented across the entire supply chain

for many, many years to come. Yesterday we heard some estimates of between three and ten years with three years being for perhaps implementation for susceptible products and ten years being, you know, as an estimate for across the entire supply chain.

As for retail pharmacies, we have our own unique challenges to implementing RFID, the greatest of which is related to financial resources. Especially many of our smaller members are being challenged by the current cuts to Medicaid, one of which was just signed by President Bush this morning. I forget the name of the act now, but the act to significantly cut Medicaid spending over the next five years.

In addition, the Congress' proposed budget for 2007 is proposing additional cuts to federal reimbursement, federal upper limits for the reimbursement for prescription drugs.

In addition, many of our members are challenged in implementing the requirements for Medicare Part D and are concerned about being reimbursed for services provided under Medicare Part

D.

And additionally, too, many of our members have, you know, very restrictive contracts with managed care and with PBMs, which basically means that the end result is that retail pharmacies have a very tight profit margin of about one to two percent. This doesn't really allow for a lot of extra capital to be expended into new technology projects. So this is something that we are challenged with in implementing RFID technology.

In fact, we question whether pharmacies, besides the benefits from addressing counterfeit drugs, we're not sure that pharmacies would reap the benefits of RFID from an operational point of view. We believe it would be unrealistic and redundant to require pedigree authentication at the pharmacy level. In the State of Florida they're not requiring pharmacies to actually authenticate the Pedigrees they receive.

We would like pharmacies to be able to rely on the authentication being performed higher in the supply chain, whether that be at the chain

pharmacy warehouse or by the supplying wholesaler.

Despite challenges with the Pedigrees, there are changes in the supply chain that have greatly reduced the possibility that counterfeit drugs would enter the supply chain. All members of the supply chain -- I jumped ahead of myself -- all members of the supply chain have taken the initiatives to reduce the chance of counterfeit drugs entering into the supply chain, pharmacies, wholesalers, manufacturers.

Many pharmacies are scrutinizing their suppliers. Many of the wholesalers have announced that they no longer will trade within the secondary wholesale market. Manufacturers have introduced authentication technologies for their products and are limiting the amount of their products in the supply chain to reduce the chance of arbitrage.

In the states there has been much activity to tighten the licensing requirements for wholesale distributors, and we believe that the state activity has gone very far in reducing the questionable entities in the supply chain.

Some of the state provisions we see include the concept that is supported by many different members, including NACDS, is the concept of the normal distribution channel. This concept in addition to NACDS, this concept has been adopted or embraced by NABP, by PhRMA, and basically the concept that we support with Pedigrees, such as in Indiana, Pedigrees should not be required within the normal distribution channel. The reason for this is that these entities in the normal distribution channel are trusted entities.

In addition, some of our members are requiring that their wholesalers provide a statement on their invoice indicating that the product was purchased directly from the manufacturer so that the chain pharmacy or the chain pharmacy warehouse can be assured that the product is not more than one transaction away from the manufacturer.

This is a diagram of what the normal distribution chain looks like, and the strike throughs are where you see that Pedigrees are not transmitted or not passed.

And I also would like to point out that there is some similarity between this and the current process where under the PDMA where manufacturers are not required to pass Pedigrees. Your primary wholesalers who are your ADRs are not required to pass Pedigrees, and then chain pharmacy warehouses would not be required to pass a Pedigree to the extent that they are not engaging in wholesale distribution, that they are engaging just in intercompany transfers.

This slide just provides a -- I won't go through the whole slide, but this is a definition of normal distribution channel that we would support.

So as I begin to wrap up my presentation, we ask FDA to continue the stay on the Pedigree requirements of the PDMA. However, if the FDA decides not to continue the stay, we would ask FDA to consider the concept of the normal distribution channel and only require Pedigrees outside the normal distribution channel, and additionally we ask FDA to also consider the concept of the one forward, one back, which is a concept that NACDS had recommended to FDA a number of years ago.

However, we would ask that the one forward, one back concept apply to distributions outside the normal distribution channel. Basically how that would work is that when a Pedigree is received -- I mean when a prescription drug is received, the Pedigree comes with it, and then when that drug is passed to the next person in the supply chain, the Pedigree goes with that. But basically you don't have any transactions besides those on that Pedigree.

So if you do need to research the full Pedigree, you simply assemble the different links in the supply chain.

Additionally, we would ask FDA to consider requiring Pedigrees for only products that are particularly susceptible to counterfeiting, and we would ask that this list be maintained by FDA. Another option is to require Pedigrees only for brand name drugs as generic drugs are less likely to be counterfeited.

I just have this slide to reiterate that chain drug distribution centers should only be

considered wholesalers to the extent that they engage in wholesale distribution.

Finally, we believe that appropriate roles for the DEA would include working with the states to attempt to harmonize the disparate state Pedigree requirements. Pfizer and PhRMA have been introducing Pedigree legislation in states across the country, and despite the best intentions, the legislation always ends up different from what we had anticipated. Just that's the nature of the legislative process.

Also we believe it's key for FDA to remain active in the standards development process to help drive the industry towards standard Pedigree elements and universal technology standards.

Thank you.

(Applause.)

DR. LUTTER: Thank you.

Our next speaker is Eleni Anagnostiadis.

MS. ANAGNOSTIADIS: Thank you so much, Randy.

My name is Eleni Anagnostiadis, and I'm Professional Affairs Director for the National

Association of Boards of Pharmacy.

And just one quick housekeeping issue. I know that the task force has been very polite over the past couple of days in addressing people by their last name, and I know my last name is difficult. So feel free to just call me Eleni.

(Laughter.)

MS. ANAGNOSTIADIS: Just as everyone else has mentioned, we want to thank the FDA and the task force for inviting us to participate here today.

Our membership are the Boards of Pharmacy in the United States, and their mission is really to implement rules and regulations for the protection of the public health. So we are not here to represent pharmacy. We are here to represent the consumer, the patient, all of all who are also patients and consumers.

Today I'd like to talk about the collaborative efforts at NABP and FDA have had over the past many years, especially in addressing counterfeit drugs. And I'm also going to talk about some of the state legislative and regulatory

activities.

We've been very pleased to work closely with the FDA for many years on this issue. A couple of years ago when you guys had the task force in 2003, we ran and moved forward with all of the recommendations that you had asked us to, and so a lot of the things that are in this presentation, and I just don't want to be redundant, the FDA is supportive of those actions.

And I'm here to pledge again to you today if there are other recommendations that come forward to the Boards of Pharmacy that we can assist you with in moving forward, we are happy to play that role.

This morning they talked a little about the PDMA. I think the only thing that I'd like to mention regarding this slide is that the states do have the authority to license wholesale distributors, and the majority of the states, in about 42 states, give or take, it falls under the purview of the Boards of Pharmacy.

There are seven or eight states in which it falls under the purview of another public health

agency.

NABP's commission to revise the model rules was accelerated by the FDA's counterfeit drug task force, in addition to recent counterfeit events. In October 2003, NABP convened a task force on counterfeit drugs and wholesale distributors and subsequently, in February 2004, the model rules for the licensure of wholesale distributors and the national list of susceptible drug products were released and fully endorsed by the FDA.

In response to various state activity in 2004, the model rules were rerevised and released again in 2005. That task force had input from industry stakeholders, state, federal and governmental agencies. Many of those entities are in this room here today. So we really did our best to get all stakeholders involved in the process incoming up with the new model rules.

It was done in a concerted effort over a course of four months. We knew the importance of this particular activity, and again, the ultimate goal was to obtain uniformity among the states.

One of the concepts in the model rules, and I'm only going to talk about the Pedigree issue, since that's really what we're here to discuss today, that created probably the most discussion -- I don't want to say "controversy" -- but the most discussion over time was the Pedigree requirement, and I'm not going to get into the details, but we talked about ADRs, and we have the national list of susceptible products as part of the Pedigree requirement.

As Carmen mentioned yesterday, the ADR status and the national susceptible list are kind of going away just because they haven't -- in some states the ADR had been adopted, but it looks as if most states are starting to adopt the normal distribution chain, and it's very interesting because I heard many times over the course of the last two days about phasing in the Pedigree requirements with the drugs that are most likely to be counterfeit.

NABP, along with the task force, did create the National Drug Advisory Coalition a couple of years ago, and we did develop a list which currently have 32 drugs on it. I will say that NABP

stopped that committee under the direction of our Executive Committee in December, and the reason was that nobody was adopting the national list.

So it's very interesting to see how things come full circle, but that was out there in the beginning and nobody wanted to adopt it. We got rid of it, and it appears now that there there's interest to move in that direction again.

In addition, there were discussions that there were inconsistencies regarding electronic Pedigrees and what are the data elements that surround that.

So we convened a task force in January of 2005, and really the primary objective of that task force was to gain consensus from the state Boards of Pharmacy and the other regulatory agencies as to what components or data elements are they looking for in the particular Pedigrees.

The three recommendations that came out of that committee were, first, electronic Pedigree records record all transactions and distributions of a product beginning with the manufacturer until final

sale and distribution of the pharmacy.

The second recommendation had to do with an implementation of electronic Pedigrees by December of 2007, and it talked about the specified data elements of electronic Pedigrees. We have been involved in the EPCglobal work group, as well as many of the other entities and organizations here today, and we have shared the data elements with that particular group, and it doesn't appear that we're really that far off in what those data elements look like.

What I'd like to spend a few minutes on is regarding the date. I know there's been a lot of discussion. What should the date look like? And this had a lot of discussion within the task force meeting when we addressed this issue, and the state boards felt very, very strongly that if they didn't draw a line in the sand to give the industry a goal to obtain a certain level of electronic Pedigrees passing through that it would never happen.

If you keep saying, okay, it can't happen before 2010, well, that doesn't mean it's going to be

2050 before it happens.

So our members feel very strongly that there is a date. Now, the December 2000 date was the date that the task force recommended, but that's a very strong message that came through from our task force and that I wanted to share with the FDA here today.

Several people have mentioned that there's been Pedigree legislation that's passed in several states. About 11 states to date have passed this legislation. There are probably ten to 15 states as we speak that have introduced legislation or are working on it. So I think the states are moving proactively forward based upon the concerns of the counterfeit drug issue and have done a great job.

I guess my second request of the FDA is to be sure that whatever work the FDA does, that the work complement the good work that has been done at the state level.

Now, the state licensing and wholesale distributors, as I mentioned falls under the purview of the Board of Pharmacy in most states and other

agencies. The thing that I want to point out to you here is that there are limited Board of Pharmacy and state agency resources.

We all know that there are budget cuts in several of the states, and so many of the states came to us and said, "We haven't performed facility inspections on wholesale distributors for 35 years. So could NABP assist us in developing some type of program where we would do the facility inspections and that portion of the process for them?"

So then was born the verified accredited wholesale distributor program, which, again, Carmen mentioned yesterday. We were very pleased to announce that CVS and U.S. Oncology have achieved that status. I'm not going to get into the details of it, but it's basically two phases.

There's a paper phase and a people phase, and the paper phase is about a ten page application. We ask for a significant amount of information regarding policies and procedures. We do criminal and financial background checks.

NABP has also developed a clearing house

for wholesale distributors. So we actually have an active database of disciplinary actions that were taken by the states on either wholesale distributors or individuals that are associated with those wholesale distributors. So we do those types of checks as we go through.

Once that paper phase is completed, we go in and do an on-site facility inspection, and then the awarding of the accreditation.

Indiana requires VAWD for licensure. Other states have adopted or endorsed it in different ways. Oklahoma; Idaho doesn't have any regulation or legislation, but through policy, one of the requirements is if you're a non-resident wholesale distributor, meaning you don't reside in that particular state, you have to show in order to become a wholesale distributor being able to distribute product into Idaho, you have to show a recent inspection report.

And I will tell you there are several states that do not perform facility inspections on wholesale distributors. And finally, Nebraska has

introduced some legislation, again, that would recognize the VAWD program.

We've been working with several other states to endorse this process as well, and any information that you need regarding the program could be found on our Web site or I'm happy to discuss with you.

So in closing, as everyone here has mentioned today, the counterfeit drug issue is a true patient safety issue. The NABP and the Boards of Pharmacy feel that it is our responsibility, if you look at what our mission is, is to do something to insure that counterfeit product doesn't get into the hands of the patient.

There's been significant progress in the states. We've been working very closely and complementary with the FDA, and we appreciate your efforts and good work. We would recommend that you set some sort of target date for electronic Pedigree implementation, and we are in total agreement that there should be some uniformity among the states.

We are for federal standards, yet state

licensure and enforcement of those particular standards.

So thanks, again, for the time, and I'll be happy to address questions during the panel discussion.

(Applause.)

DR. LUTTER: Thank you very much.

Our next speaker is Jim Dahl.

MR. DAHL: Good afternoon. As many of you know I worked on many of the issues being discussed at this meeting today during my time as a senior manager within FDA's Office of Criminal Investigations before I retired last fall. My remarks today are my own, but I hope to represent the collective opinion of the agents of the Office of Criminal Investigations.

I agree with many of my former colleagues at FDA that RFID technology has an outstanding future in the pharmaceutical industry, particularly in inventory control, track and trace, and product authentication.

However, all of us who served on the RFID working group knew very early on that 2007 was not a

realistic goal, and 2011 was a better target. I am not suggesting that FDA abandon its support of RFID; only that it be made part of a more realistic multifaceted approach to the significant drug diversion and counterfeiting problem.

The database supporting an RFID system must at a minimum contain the fields to comply with the PDMA along with the soon to be implemented, I hope, regulations. In my opinion, the new wholesaling law in Florida and similar efforts in other states are signals that the public wants a safe drug supply, and that a stronger federal law is needed.

This is an area where I think FDA can exercise leadership and call on Congress and the administration to strengthen the PDMA to bring federal drug wholesaling requirements up to 21st Century standards. The control and management of the database is probably the single biggest hurdle to full implementation of a comprehensive RFID system.

There are significant and legitimate reasons to keep this information confidential. Therefore, it is extremely important that an

independent, unbiased third party assume this role. This system will never work unless the entity holding the data is competent, trusted and respected.

I am aware at one time that NABP offered to serve in this position, and I believe that may be the best option.

I have been around enough criminals in my professional career to know that they will try to compromise any RFID system.

(Laughter.)

MR. DAHL: You like my Marine Corps slide, huh?

I anticipate there will be some successful efforts to neutralize the chips and to guess or copy the serial number configuration and counterfeit the chips, and there will be other schemes none of us have yet contemplated. The proposed system may not be perfect, but it is a big step forward from what we have now.

Over the last few years we have seen the dramatic rise in the amount of counterfeit drugs in the otherwise legitimate supply chain, and really that

is why we are here today.

Internet and black market sales aside, the single biggest contributor to counterfeit medicines in the nation's drug supply is wholesale diversion. Since OCI became operational in 1993, there have been literally hundreds and hundreds of convictions and arrests for the illegal wholesaling of prescription drugs. This category of FDA crime is the single biggest item within FDA in terms of total arrests, total convictions, total cases, and total work hours. Stop wholesale diversion and counterfeit drugs will almost entirely disappear from pharmacy shelves.

Stay with the status quo and we can all count on our at risk distribution system to show little or no improvement.

So what can be done? First, let the Pedigree regulations take effect. Since 1988, it has been a crime to wholesale a drug without providing a Pedigree. OCI has prosecuted some individuals for egregious violations and will continue to do so. But to let the state continue year after year, even in the face of millions of doses of counterfeit drugs, does

not make sense.

Those who argue against the Pedigree say the requirements are too time consuming and the Pedigree itself can be forged. These are not compelling arguments. The data required by the current federal law is simple information, available on common business invoices. Although forgeries can occur, this is not a guarantee that the crime will be successful. Ordinary due diligence by buyers might uncover the forgery, and it has been OCI's experience that having a forged document helps prove fraudulent intent and guilty knowledge.

In my opinion, two of the primary reasons why state and federal drug pedigree rules are opposed are, one, the seller does not want to reveal the true source of the drugs for fear the buyer will go around him on future transactions; and, two, the drugs are counterfeit or obtained illegally and the seller cannot risk identifying their true origin.

Of course, it is not just gray market sellers who are the bad guys. Unscrupulous buyers love the authorized distributor provisions of the PDMA

so they can obtain fully laundered products under a cloud of plausible deniability. If you thought the term "don't ask, don't tell" originated in the Department of Defense, you are wrong. It fully describes what diverters have been doing for years. Wilful blindness is a polite term for describing their actions.

If the FDA is serious about tightening the pharmaceutical supply chain, it must also develop improved industry guidance. I believe FDA can draft a more realistic guidance document so that two purchases per year of a manufacturer's drug doesn't make a small secondary wholesaler AD on 200 other products manufactured by the same manufacturer.

FDA's new guidance should call for manufacturers to define specific requirements for each of its authorized distributors. Manufacturers should also be encouraged to post their authorized distributors on a public Web site so that potential buyers can better evaluate transactions.

In the Federal Register notice, the FDA summarized the task force report with five bullet

points. While I agree that there has been progress on most of these topics, I would argue that FDA has done nothing significant with respect to increasing penalties for counterfeiters.

Before I left the agency last fall, I helped draft an FY 2007 legislative package to enhance FDA's criminal authority, but even if that effort eventually makes it out of HHS, DOJ, and OMB, it will likely be years before any results are achieved. New legislation is needed now, and FDA needs to initiate action at HHS, DOJ and the administration to make this happen.

I'd like to highlight a few of the changes needed. Administrative subpoena authority for use by OCI agents. This is a tool used by many other agencies, and it is desperately needed to help protect the public health. The Food, Drug and Cosmetic Act needs to be amended to provide for higher maximum penalties. It does not make sense that a person risks up to a ten year maximum sentence for counterfeiting a registered trademark, but only up to three years for counterfeiting a drug.

Title 18 of the United States Code needs to be amended to make Food, Drug and Cosmetic Act felonies specified unlawful activities for money laundering and to allow the direct forfeiture of gross proceeds from felony violations of the Act.

The Act also needs to be amended to modernize and approve enforcement generally.

The task force report summary highlighted in the Federal Register notice for this meeting says one of FDA's measures for protecting Americans from counterfeit drugs is to enhance regulatory oversight and enforcement, yet there have been no significant enhancements to that part of the agency most directly impacted by counterfeit drugs, the Office of Criminal Investigations.

OCI's operational budget and special agent and support staff FTEs have been held essentially at the same level since the counterfeit drug task force first convened.

These two days have focused on technology and regulations, and both will certainly play a part in reducing drug counterfeiting and diversion, but

criminal enforcement must be the third prong on that sphere. Until FDA, HHS, the administration and the Congress recognize that fact the goal will not be achieved.

I'll be happy to work with the FDA or other interested parties, and I thank you for your attention today.

(Applause.)

DR. LUTTER: Thank you very much.

Our next speaker is Ron Bone from McKesson.

MR. BONE: Hi. My name is Ron Bone, and I'm the Senior Vice President of McKesson Supply Solutions.

And I want to start my presentation also saying thank you for the workshop, but more importantly, for the work that has been done by the FDA for the last three years as Jamie Hintlian reminded me, we started this process with Jumpstart over three years ago, and the FDA has been there all along with that, as well as completing a great deal of support in terms of information and what could and

couldn't happen to the HLS of the EPCglobal effort.

So I want to personally say thank you very much because I spent a lot of my life on that, and you've been very helpful for us.

Let me start by just giving you a brief background on McKesson. It is the leading supplier of pharmaceuticals and information and care management activities to reduce the cost and improve the quality across health care. McKesson Solutions empowers health care professionals with the tools they need to deliver effective and efficient supplies to the pharmaceutical customers.

Founded in 1833, with annual revenues of more than 80 billion, McKesson ranks as the 16th largest industrial company in the United States.

I'd like to, because HDMA has already presented through Lisa and Scott very focused issues that the wholesale community needs help from the FDA on, about the PDMA rule. McKesson purchases 100 percent of its pharmaceutical products directly from the manufacturer or the manufacturer's designated distributor. We sell them directly to our customer.

McKesson supports the requirement in the final rule for products that flow from the manufacturer through the ADR to the customer.

However, there has been, as you heard in other presentations, some real changes that hade taken place in the distribution marketplace over the last seven years. In some cases, manufacturers have designated contracted logistics suppliers to ship that product to the wholesale community. These are, in effect, an arm of the manufacturer.

The wholesaler receiving the product from the logistics provider is the authorized distributor. Therefore, no pedigree should be required between the two.

We would like to have FDA issue a guidance letter to stipulate that this practice is the same as receiving product directly from the manufacturer.

We would also like FDA to provide further clarification as to the definition of the pharmacy. In recent years, chain drug stores and member owned pharmacy cooperatives have consolidated purchases in the warehouses to substantially reduce cost in the

distribution system, and then they sell it directly into their member owned or financially owned institution pharmacy.

Therefore, these types of pharmacies should be included in the definition, and we've heard a great deal about this. On the state Pedigree clause, McKesson commends the states for their efforts to prevent pharmaceutical counterfeiting. However, we have significant concerns that the states are creating a patchwork of regulations as they relate to Pedigree.

FDA's leadership is essential to create a framework that permits nationwide distribution of pharmaceutical products with uniform regulations in this area. We urge the FDA to collaborate with the pharmaceutical industry and state regulators in determining and setting the parameters for serialization and electronic Pedigrees to be used across the nation.

One area in this that causes a significant amount of concern and that's emergency shipments, and we're especially concerned because there has become a patchwork of state regulations that will hamper our

ability to handle the emergency needs in the nation, and these can be such as Hurricane Katrina or the avian flu pandemic.

We have a recent example at McKesson that really illustrates this. Hurricane Katrina was a situation in which we had some advanced notice that that was going to happen in Louisiana. We have a facility in Slidell, Louisiana, that was taken out of commission as a result of the hurricane. Because of the advanced notice, we had actually moved product out of that facility to an adjoining state.

When the storm hit, we were immediately able to fill those orders from Texas and Tennessee and fulfill all of the requirements for our customers' needs, those that were still in business -- we had some serious challenges with everybody still being in business -- on the very next business day.

So we weren't hampered at all, but the key message there is we moved them from one state to another state to get prepared, and when we solved the problem, we solved it from another state. And you can see that there's a real concern that if we have a

patchwork of regulations that would not be possible.

And every year in another area of emergencies, every year we have situations which drugs must be urgently delivered to patients on weekends and holidays. Inconsistent and varying state laws will delay and may prevent us from providing this critically needed service when state boundaries have to be crossed.

There are also examples of time critical needs for medicines in the institutional marketplace where the manufacturer is actually shipping overnight these drop shipment products for those emergencies. Under current regulations that are being presented, we would have to have a Pedigree from the financial source, being the wholesaler, into that hospital before that medicine could be used, and therefore, delaying the time in which that would take place.

In closing, we commend the FDA for holding this workshop that will result in long term, improved, and safe, secured supply chain that incorporates serialization and electronic Pedigree capability. We look forward to continuing to work with the agency in

making sure that this is a better, safer supply chain in the future.

Thank you.

(Applause.)

DR. LUTTER: Thank you.

Our final speaker is Steve Haynes from the PDMA Alliance.

MR. HAYNES: Good afternoon and thank you for the opportunity to share my thoughts with you this afternoon. As you've listened to my remarks today, I would ask that you keep in mind what motivates them. My 25 years I spent in law enforcement has certainly given me a perspective on risks and the appropriate security response that we should take based on those identified threats and vulnerabilities.

In turn, my work over the past six years with various sides of the industry, pharmaceutical and other consumer products industries has provided me valuable insight into their concerns on the issues that you are attempting to address.

I'm here today balancing those sometimes unique and different perspectives.

I know your task force has closely examined the vulnerabilities and related risk inherent in our drug distribution systems -- and I emphasize "systems" -- and I'm certain your ongoing efforts and the efforts of the others here and the business partners within the industry have had a very positive effect on strengthening distribution controls and, in turn, strengthening the sanctity and the safety of our nation's drug supply.

I would like to take my time today, however, to make a few personal observations and recommendations for you to consider as you move forward.

First, I wholeheartedly agree with those who describe the problem of diverted and counterfeit drugs as significant and one that needs to be more effectively and perhaps more importantly, more immediately addressed. We have to first be concerned with today's drug distribution system and not necessarily the system of 2007 or beyond.

All too often I have listened to the debate about the extent of the problem. Is ten

percent of the pharmaceutical drug supply counterfeit? Is it one percent? Is it less than that?

Realistically, none of us know the answer to that question, which is a point I will address again in a few minutes.

What we do know and what this two day workshop had continued to highlight is that there are known vulnerabilities in the drug distribution system. The problems of drug diversion in counterfeiting are real. They're the same problems that led to the passing of the PDMA years ago, with the added twist now of Internet drug sales and the sensitive political issues related to reimportation, and they are the problems that don't offer the luxury of waiting for a future technical solution.

RFID, other E-technology is excellent, but is the answer for today and the problems that you're attempting to address today?

The vulnerabilities that we talk about combined with recognized criminal capability and intent translate to a significant risk to the drug supply. OCI statistics support that. Whether we're

talking about diversion for financial gain, consumer risk related to safety and efficacy, the increased potential for malicious product tampering or risks that are unique to our post-9/11 environment, we need to acknowledge first that there are risks that warrant action and warrant action today.

there are actions that should happen sooner instead of later. I'm careful here when I talk about risk and potential threats since the nature of diversion and, probably more importantly, our current work in this area probably do not give us a good understanding on the extent of the problem, but we certainly know that the vulnerabilities exist and the potential threat is there.

Another point I'd like to make is that following the tragedy of September 11th, we witnessed a government response that was significant in a number of ways, but perhaps most importantly in recognizing how we must adapt in today's threat environment through law, regulation and guidance, very specific supply chain security measures cross product industries, so beyond pharmaceutical were implemented.

In January 2002, just several months after the 9/11 attack, FDA CFSAN, their Center for Foods, issued a food security guidance document, which has since been and continues to be expanded upon, addressing recommended supply chain and security enhancements and involving farm-to-fork business partners.

That document and related government and industry guidance has been widely used within the food industry to raise the level of awareness to demonstrate the way FDA places on improved security controls and to help guide the industry in deciding what controls they will implement.

As you noted in your task force report, some security enhancements will require Congressional action. It is also recognized that agency regulatory initiatives can be a time consuming process. Operational and security guidance, however, especially realistic guidance that is prepared in conjunction with industry business partner involvement is welcome by industry, and I think you've heard that over the past couple of days, and it's a realistic, now

alternative for some of the legislative activity that Jim and others have talked about.

My current work with the PDMA Alliance has demonstrated how strength in communications between the industry and the agents and the agency helps both parties meet mutual goals. The question the task force must ask is: is there a better model or process the FDA can follow to more quickly develop and publicize pharmaceutical security guidance material for the impacted pharmaceutical industries.

While well defined best business practices or standards of care may not have the weight of law, they are imperative in helping shape a company's or industry's security response.

This is an area that has surprisingly been addressed over and over over the past couple of days, and I've been glad to hear a fairly consistent message. Delayed action at the federal level with respect to PDMA regulations or state's perception that federal law or regulations is not sufficient can and has led to overlapping, divergent, and sometimes confusing regulatory action.

The actual and pending legislation the various states have taken are a good thing, but you must ask would uniform state and federal regulations in this critical area allow for the industry to better implement and comply with what's needed. Would consistent law and regulation allow for improved regulatory oversight and enforcement?

I realize the task force has involved the states and other interested parties in its work. I'm hopeful that the benefit of uniform legislation that has been consistently emphasized these past two days has been kept forefront in your mind as you move forward with your task force work.

My last observation, and this is going to go off mark of anything else that really has been covered over the past two days, but I think it's extremely important as you look to 2007 and beyond and things that need to be considered. Today there's no coordinated, centralized effort that brings together the intelligence resources that are necessary to detect, prevent, and to mitigate pharmaceutical crimes. We will never get our arms around the extent

of the problem, the ten percent issue versus the one percent issue, unless we can adequately respond with a significantly strengthened intelligence capability.

We need to improve our ability to gather information and data unique to these crimes. We need a focal point for the collection, analysis, and dissemination of information. We need the necessary technical and analytical tools to do the job, and we need to build an analytical expertise in this critical health intelligence area.

I'd like to summarize now with four specific recommendations I would like the task force to consider as you move forward. I strongly endorse the immediate need for the federal regulation imposing a paper pedigree requirement. Law enforcement and security professionals certainly recognize that the provisions like the pedigree mandates found in Title 21 do not stop illegal activity. The laws and regulations do, however, add another security layer and when violated often serve, as Jim said, as a valuable investigative resource.

Your important work should not be clouded

by those who want to divert discussion to other agenda items of interest or the contention that perhaps there's a better mousetrap down the road. I feel the potential, like I said before, for RFID is significant, but it's not the answer for the problems of today. I encourage your group to recommend the lifting of the stay of the important Pedigree provisions found in 21 CFR 203.50.

Second, the FDA and CDER should continue its valuable work with those in the industry addressing the problems of diversion and counterfeiting, but the agency also needs to take the next step. That involves issuing guidance that will better define for the industry throughout the supply chain, the various industries throughout the supply chain, expectations and suggested best business practices.

The caveat here is the recognition that the value of this action can only be realized with strong input from and the involvement of the different industry parties that are represented here today.

The FDA needs to continue to work closely

with its state partners working towards a goal of consistent uniform legislation in the area of drug distribution, licensing, controls, and reporting. Again, this has been hit pretty hard over these past two days, but there is a need to insure that there is one effective standard on both the federal and state level which governs PDMA law.

The last recommendation I have comes back to what I was saying before with respect to the need for a stronger intelligence capability. The challenges in the area of pharmaceutical or health intelligence are significant. However, they do encompass many of the recognized and longstanding issues that are familiar to law enforcement and security professionals, that is, how to best capture information from diverse data sources and complex data sources and how to then maximize the ability to analyze, share, and provide a timely security response or investigative response to what has been identified.

The solution is to create a pharmaceutical crimes intelligence center with traditional intelligence analysis capabilities, capabilities that

have been successfully used in other security and enforcement arenas.

Thank you very much for your time today, and I'm looking forward to answer any questions that you might have.

(Applause.)

DR. LUTTER: Thank you very much.

We turn to a question and answer session. I'll continue the protocol adopted earlier today of following the United Nations rules. So members of the panel who have questions can signal their question by turning their tent right on end, and please specify whom you would prefer to answer your question if, indeed, you have someone specific in mind.

Steve Niedelman, please.

MR. NIEDELMAN: Thank you, Randy.

And excellent panel, excellent discussion.

This is for Jim Dahl. OCI has determined that basically all known counterfeit drugs, which have reached consumers through the drug distribution network, have made it into the system through illicit diversion, and you refer to that in your speech. What

impact would the elimination of the ADR provision and a universal Pedigree requirement have on counterfeits entering the distribution system?

MR. DAHL: Well, that would certainly help. The ADR provision is one of the items that is used to launder the Pedigree or basically erase any of the past movements, known movements of the drug. So, you know, certainly the current PDMA is not perfect by any means and needs to be revamped, and that is one of the areas that is a problem.

MR. NIEDELMAN: Thank you.

DR. LUTTER: Let me go to Maggie, and then I'll go to Steve Silverman and then Bill McConagha and then --

MS. STIFANO: My tag is on, too. My tag is on.

DR. LUTTER: Oh, okay. So then we'll do Bill after Toni after Steve.

MS. GLAVIN: My question is for Kevin Nicholson.

I believe you indicated in your talk -- and correct me if I'm wrong and I'm attributing it to

the wrong person, but I believe you indicated in your talk that you felt that a large or perhaps the largest source of counterfeits entering the system is through importation, personal importation, and Internet sales, and that was in conflict with what several other members of the panel said who indicated that the wholesale diversion is the major problem.

So could you sort of enlarge on sort of -- if I've gotten your position, what you said correctly, and correct me if I haven't, enlarge on sort of what data are you using to say that the wholesalers aren't the problem and the problem is at another point in the chain?

MR. NICHOLSON: Well, actually I believe the point was that in a legitimate supply chain that the wholesalers are the largest source of counterfeit possibility, and I was referring to, in general, considering both the legitimate and illegitimate sources; that a consumer or patient is much more likely to experience the threat of receiving a counterfeit product from a source, from an Internet source or from a foreign source.

And I believe that even the statistics that FDA has published on the number of cases that have been opened, that a large percentage of those are, in fact, from outside the legitimate supply chain.

MS. GLAVIN: Okay. I'm not sure that's correct, but thank you. You did clarify because I had not quite understood exactly what you were saying. So I appreciate that.

But I would be really interested if you could include in your remarks for the record -- I don't want to put you on the spot as to exactly what it was -- but your remarks for the record, any information you have on, you know, the extent of counterfeit products coming in through the sources you just mentioned, the Internet, et cetera. Because we would really like to have that.

So if you could --

MR. NICHOLSON: Yeah, I'll go back to my files and include that in my written comments.

MS. GLAVIN: Thank you.

DR. LUTTER: Steve Silverman.

MR. SILVERMAN: I'll direct my comment to Kevin Nicholson, but to the extent that other panelists want to weigh in, I'd be interested in your responses as well.

There's been a lot of discussion over the last couple of days that seems to set up an RFID system against a paper based system, and in fact, a large part of the most recent PDMA stay has been a function of providing an opportunity for the RFID system to develop.

At the same time we've heard from you and from others that for a variety of reasons that we're not quite there yet.

So my question is do the two systems really need to operate in opposition to each other or is there a problem with simply lifting the stay and then continuing to work on the agency's part to facilitate with industry implementation of RFID and when RFID in industry's view becomes sufficiently mature to either supplement or replace paper based Pedigrees, to allow that process to move forward?

MR. NICHOLSON: What I would say is

basically you're asking me should we remove the stay and then move forward with a Pedigree system that may, in fact, be paper with the eventual goal of RFID?

Well, I think what we believe is that if you -- first of all, there are problems with the PDMA that we feel need to be addressed, such as the ADR designation. So that's one reason that we're asking that the stay remain and that the rule be amended in certain ways.

Also, we believe that any Pedigree requirement that causes the supply chain to focus on other initiatives acts as a distraction to providing resources towards implementing RFID. As a previous speaker had mentioned, in Florida that they basically had to comply with the Florida requirements, they have stopped what they're doing and have implemented an electronic Pedigree system that, you know, is not RFID, but would meet the requirements of the Florida law.

So we would echo that.

MR. SILVERMAN: How long should FDA continue the stay?

MR. NICHOLSON: That's a very difficult question. It's very difficult to answer at this time because RFID is still -- if you're talking about -- I guess ideally you would stay the PDMA until RFID were widely available through out the supply chain, and from estimates that we heard yesterday, that's five to ten years.

But then again, I would add to that that if FDA believes that's unacceptable, then we have provided other opportunities or other ideas, other suggestions for a phased in approach, such as the normal distribution channel, and then within that using one forward and one back or susceptible drug lists and/or requiring pedigrees perhaps for brand products and not generics.

So, you know, we understand that what we're asking may not be acceptable. So we believe that maybe there could be a phased in approach that would, you know -- and then we believe that the normal distribution channel would harmonize greatly with what a lot of the state activity is, with what a lot of the state legislatures are adopting.

DR. LUTTER: Thank you.

Next question, Toni.

MS. STIFANO: Yes. This question is directed to both Jim Dahl and Steve Haynes.

Steve Niedelman this morning, later in the morning, brought in the active pharmaceutical components, not finished pharmaceutical products, which are also subject to the PDMA, and then we heard, too, about the diversion of imports and so on. So that being the case, then a number of the active components are imported. So in that case, what and how do we initiate a Pedigree for them?

MR. DAHL: Well, I think that on formal customs entries into the United States, which is how most APIs are going to arrive, you're going to have essentially the Pedigree information there. I mean, the drug has to be listed with FDA. You know who the manufacturer is. You're going to have a customs broker involved. You're going to have invoices and shipping manifests and other documents that are going to supply those data fields. So I think perhaps maybe it's another duty that the customs broker performs

when it hits the U.S. port to then comply with the initial Pedigree, U.S. Pedigree that is formed right there, but I think the data is there. I don't see it as an insurmountable problem.

MS. STIFANO: Well, on top of that say it's not imported and say a small laboratory is producing active and they're going to ship it someplace else. Would the Pedigree originate from this small manufacturer that may not even be a registered facility?

I mean, how would you handle that? I'm thinking specifically about the botulinum toxin that traveled in interstate and was subsequently used as a final product and it was not. What could we have done?

MR. DAHL: You mean it was not a drug product?

MS. STIFANO: It was a drug product, but not in finished form.

MR. DAHL: Well, I think I'd have to think about that, but I think that they could originate the Pedigree. They should be originating the Pedigree.

That information is available to them. They knew who their customer is. They know they produced it, and essentially when they invoiced their customer, they are giving the information that's on that, that's required by the Pedigree with now.

MR. HAYNES: Those are interesting questions, and certainly the first one with respect to the imported APIs is of interest because, like Jim said, there's a natural customs paper trail, but the second half of that is FDA and others having a better handle on what's going on outside our borders as far as the manufacture with the APIs and the ability for inspections.

So it's not just one layer of security. It's not just the paper trail. There are a lot of things that would come into play there, and I hate to keep coming back to it, but again, a better database, a better intelligence model of who's doing what overseas where who the legitimate API manufacturers are for what companies would allow the agency to more proactively address a problem that may be arising.

Your example you gave of a domestic

situation is, you know, a supply chain is a supply chain is a supply chain, and if the FDA comes across a situation that receives some publicity and you say, "Well, do we have the regulations in place that address that?" and if the answer is no or they're unclear or that maybe there's room for improvement, that's an example of where fairly immediate guidance to the industry is going to have a lot of weight with how it's handled next time.

So if we feel there's a small loophole wherever it is within the many -- you know, wherever it is, with repackagers or whether it's with small APIs or whatever where things could be strengthened, that's where the FDA needs to step forward working with those in the industry to say, "What's the best way for us to address this?"

Then give guidance to the industry and I'm very confident that industry will respond.

MS. STIFANO: Thank you.

DR. LUTTER: Thank you.

Bill and then Jeff.

MR. McCONAGHA: This is a question for Mr.

Fowler, please. It follows up a little bit on what Steve was asking about earlier. Oh, I'm sorry. Mr. Nicholson. Excuse me. Mr. Nicholson.

Chain drug stores, retail drug stores are basically the last stop in the drug supply chain, and so it seems to me that if there is diverted or counterfeit product put into the system at any point, it's eventually going to wind up at this last stop, and for that reason I was surprised to hear you take the position that at least for the short term you were not favoring a strengthened Pedigree.

When Steve asked you about it, and in your remarks you cited this ADR issue as a major concern. I just want to make sure I understand your thinking on this. Is your policy driven by this concern about the chain drug store wholesalers and is that really what's at issue here? Is there anything else that causes you to resist a stronger Pedigree at this time?

MR. NICHOLSON: Well, the issue of the chain drug warehouses is definitely part of our concern, but also we are concerned about increases of cost and the supply chain that will be passed on down

the line to the pharmacy at the end with the pharmacy not having the ability to absorb these costs.

MR. McCONAGHA: I have another question. Do you want to defer to Jim?

DR. LUTTER: Go ahead, Bill.

MR. McCONAGHA: Okay. I have one more question, and, Mr. Nicholson, you'll be delighted to know it's not addressed to you.

(Laughter.)

MR. McCONAGHA: This is for Mr. Melville and Mr. Dahl, and anyone else who cares to comment on it.

I am just curious. In the beginning with Scott, do you have any sense if FDA were to let the stay on its '99 rulemaking expire in December and the rule and all of its provisions went into effect, how that would impact the secondary wholesale community?

As you, I know, recall, in 2000 we had heard from many members of the secondary wholesaler community that the effects of rulemaking would be devastating and would drive folks out of business, adversely affect the public health because the

communities the secondary wholesalers serve would not get the drugs they need, do you have any thoughts on that? Do you have any sense how the passage of time between '99 and now may affect that position?

MR. MELVILLE: I cannot speak on behalf of the secondaries and why they aren't represented here. HDMA represents the primary distributors who buy directly from the manufacturers. So I really can't speculate as to why they're not here.

I think as I mentioned in my testimony, you know, there's been a lot of talk about normal distribution, and I think the one thing that, you know, we've observed is that -- and if you look at the 11 states that have enacted tighter licensing legislation and many of them have tackled this issue of trying to define what normal distribution is -- there are many versions of normal distribution, and it's a very complex marketplace, and it's a very difficult marketplace to try to put into a single model.

So I can't explain as to why they're not here, but certainly from our perspective, HDMA members

are constantly revisiting our positions and policies and business practices to address issues in the marketplace, and counterfeit threats are certainly one of them. I think it has caused our members to look at this issue and change what had historically been a position asking for a stay and supporting implementation of the rule, but also recognizing that there are issues around ADR, the definition of ADR that simply don't have simple answers.

MR. DAHL: I'll comment on that, too, Bill. I heard this morning one of the representatives from Florida talking about the big decrease in the number of wholesalers licensed in that state after they put their law into effect, but I don't see that they're saying there's rampant unemployment because of that particular law.

So we heard a lot back when the PDMA was first stayed about all of these Mom and Pop businesses, and certainly some are, but there's too many Bonnie and Clyde business involved.

(Laughter.)

MR. DAHL: And, you know, one might argue

that let's put them out of business and let that be our biggest goal. You might also say that if the Pedigree goes into effect, the bigger problem might be for the bigger companies.

My friend Mr. Bone here might have a bigger logistical problem than a small Mom and Pop wholesaler because their volume is much less. So there's going to be economies of scale both ways, and it's going to have an impact, but I think the good outweighs the bad in this respect.

DR. SHUREN: Let me ask sort of a complementary question along those lines. Yesterday when we talked about electronic track and trace, we heard that for patient safety there were two values. One was the Pedigree and one was authentication of the product, and under PDMA where addressing Pedigree, we don't address authentication.

When we talked about Pedigree yesterday for electronic track and trace, we heard, at least my impression was from a number of folks, that you get the most value when you have a complete Pedigree and it runs across all the players.

Under PDMA that's not the case, as we well know, and we're hearing some discussion that we should actually revisit the law and change it and maybe change ADR that actually would cover fewer people or maybe the agency should interpret ADR in a way that also excludes some folks rather than being more inclusive.

Let me ask it the other way. If we were to revisit PDMA, why shouldn't we actually be broadening the reach of the Pedigree? Now, Ms. Nicholson addresses a little bit their sort of cost issues that came in, and maybe it's not worth it, but I'd really like to hear from everyone. Why not actually expand the reach of the Pedigree under PDMA?

MR. BONE: Well, let me address that. We support the PDMA, and I gave you a couple of areas where the change is taking place between the PDMA and the current marketplace, and we would like to see that piece addressed.

I think the critical piece for us is to launch an effective system that tracks the Pedigree from the manufacturer all the way through to the

pharmacy just before it gets to the patient. I think that's the most effective means that we have in front of us to make sure that no bad product gets into the system.

You've heard through two days' worth of testimony we're working very hard to make that happen. We're not quite there yet, and I think that we've heard some things about a phased in approach that may be helpful for us to get there. We need, in my opinion, to keep our eye on the ball of getting an effective electronic process in place that would eventually say that a Pedigree should be on every product. That's a critical element for us to keep the energy that we currently have in place, to make sure that becomes a realistic piece.

So the PDMA rule is an in between step in my mind. If the stay is lifted we can live within the stay, and then continue to give guidance that we need out to the industry and the states as to what is the long-term vision that we have for Pedigree compliance from manufacturer to the end customer.

MR. MELVILLE: And I would just echo Ron

and our member McKesson Corporation. Certainly until an electronic RFID oriented down to the serialization of a particular product is possible to apply a paper, literally a piece of paper, to the millions of products that get distributed on a daily basis would grind the system down, would shut the system down and create real supply chain inefficiencies.

So certainly, you know, HDMA believes that the electronic approach is essential to assure continued supply of product and an efficient supply of product. I mean, there's a lot of talk here about counterfeit products, and certainly that is priority number one, but also getting a product and making sure it's there at the pharmacy when you go there.

It's something I think everyone takes for granted, but there's an incredible infrastructure in place to make sure that hospitals are staffed or supplied with products, that pharmacies are, and there's a tremendous value to that, and there would be a tremendous public health implication to interrupting that ready, available, and efficient supply of product.

So it's a very delicate balancing act, and it's one that is very challenging for sure.

MR. NICHOLSON: With respect to the ADRs, NACDS would certainly support amending the PDMA to reduce arbitrariness so that chain drug warehouses would have the opportunity to become designated as ADRs.

MR. McCONAGHA: Can I just follow up, Mr. Melville, on your answer?

I mean, you talk about the volume of paper potentially grinding things to a halt. I mean, obviously, right now some paper is being passed because there is still a law on the books, and just kind of playing devil's advocate, we heard from Mr. Dahl in his presentation that the information that one would need to put in this Pedigree is generally information that's easily accessible from other documents, such as bills of lading, invoices, things of that nature, that are already provided in commercial transactions.

And so I'm just curious. In what way does filling out this paper, having this paper follow these

products, even if it were a universal pedigree, somehow grind the system to a halt?

MR. MELVILLE: One thing I go back to, I think Mr. Dahl said that since 1988 it has been a crime to wholesale a drug without a Pedigree, and I don't believe that's correct. Certainly the PDMA states that if you're an authorized distributor of record, that a statement of distribution history is not required in that sort of situation.

But the fact of the matter is in your presentation this morning you mentioned the statute is in effect, and that if you are not in ADR and don't meet those requirements, that a Pedigree is required under current law today.

So I think the reality is that, you know, the vast amount of product does move through that very tight supply chain between a manufacturer or a third party logistics provider, a distributor, an authorized distributor of record, perhaps another authorized distributor of record or a smaller regional distributor into the pharmacy itself.

So there is a relatively narrow

distribution supply chain. There are many variations to that, but the bulk of the drugs do move through that chain. There are many variations to that, but the bulk of the drugs do move through that chain, and I guess I would suggest that products that move through that chain have fewer entry points for counterfeit, and I would imagine have proven themselves to be not the source of counterfeit products. It's when product moves over repeatedly throughout the supply chain that entry points can happen.

I guess I'd also mention, too, that the counterfeit task force report mentioned that counterfeits can be entered in any point along the supply chain whether it's on the shipment from a manufacturer to a distributor. Samples can be distributed. Let's remember that the PDMA was about that as well. It can be at the pharmacy level. So there are many entry points, and we have to be diligent in addressing each of those points.

As far as shutting the system down, again, it's the volume; it's the efficiency, and I'll ask Ron

to comment on that because he has to operate and manage those organizations at his firm at McKesson Corporation, but it's an incredibly automated system. If you've never been to a large distribution center, I think you would be amazed at the efficiency, the technology that's incorporated, and the volume that gets delivered on a daily basis.

And until that technology is widely adopted in uniform and standardized, to apply anything short of that I think would have significant supply chain disruptions, and again, I'll ask Ron to comment on that.

MR. BONE: Yes. One of the things that I've run into in talking with state regulators on this is there's not a clear perception of what we really do in the supply chain. Many people think that we receive full cases into our facility, and we, in turn, ship those full cases out to our customers, and that's not how our supply chain really works. We do receive the full cases in. We break them up so the pharmacy can order just what it needs.

And the fact is that very few of those

transactions come to us with electronic information from the manufacturer that we would need to pass that piece of information that you just referred to on to the Pedigree and on to our customers.

So when we're sitting here at this juncture without RFID and the transmission of this information inbound to us, it puts the burden on the wholesale community to translate what is not electronic into an electronic piece and get it to our customer.

So with the time that we're looking for is the change that has to take place in the marketplace, the flow of the information along with the flow of the product.

So you would be welcome to come into our facility and see. It's an amazing place to go in, particularly at night.

DR. LUTTER: Thank you.

We have two more questions. Maggie and then -- oh, no, three -- Maggie and then Jeff and then Ilisa Bernstein.

MS. GLAVIN: Thank you.

This is for Mr. Dahl. Given that I believe from your testimony you believe that we need to enhance our efforts, we, the FDA, need to enhance our efforts to combat counterfeiting of prescription drugs in the U.S., and I know you probably can answer this very easily.

Can you identify two or three actions or enhancements that would bring us further along? What would be the key ones that if you were king you would put in place?

MR. DAHL: Well, legislation, people, and money. Those are three. I mean, you know, there's 185 agents as you know spread across this big country that's very few. There's more FBI agents sitting in Maryland than there are OCI agents nationwide. There's probably four times as many FBI agents in Maryland. So that's one area.

Resources, other resources, support personnel, they need tech people. They need analysts in each field office. They need travel money. We need an international presence. We need some improvements in the laws that I talked about. All of

those can go to help stem the problem.

MS. GLAVIN: thank you.

DR. LUTTER: Jeff Shuren, please.

DR. SHUREN: This is a question for Mr. Melville.

You had said that HDMA is already actively working with Congress to seek introduction of legislation to establish a uniform federal standard for the licensure of pharmaceutical distributors. The first question or clarification, and I may have a follow-up depending on your answer.

Who would you then see as licensing wholesalers? Is this going to remain as a state function or is this now going to be a federal licensure?

MR. MELVILLE: The HDMA board in October announced its position that it supported a uniform federal standard of licensure of pharmaceutical distributors. That really involves two elements, uniform federal standards and licensure.

Our proposal, our position is based on a federal licensing and actually if FDA were to be the

licensing authority, a single license that the federal government would give for distribution, but I think really the key element that our members are looking for is the uniformity, that a single federal set of standards that they can build their operations around, their compliance around, and insure, quite frankly, that regardless if a patient is in Idaho or Wyoming or Florida or Texas, that a single standard that is consistent across the states is being applied.

Again, given the nature of the threat, given the interstate transport of products, and given the need in our minds that has been eloquently discussed over these last two days to have an electronic system to really be able to track these products through an RFID system, it's not until there's a single federal standard we believe that that can be done and that 50 different states' standards would really impede adoption of that technology.

So for licensure, if it was by the federal government, which is the position that you support, as you know, resources are tight, particularly post-9/11, and as we just heard, we don't have enough or one

position is maybe we don't have enough criminal investigators out there if we did the licensing that's resources.

Would HDMA therefore support paying fees to the federal government for licensure?

MR. MELVILLE: Absolutely. We pay fees today to state regulatory authorities for our licenses, and if a large distribution center is licensed in 50 states, it's paying 50 fees right now to be able to ship product into those states. So certainly any element of a federal approach here would involve an appropriate fee for the license.

Let me also add that, you know, we would envision and would hope and, as you heard from the states this morning, there is a desire there to have a continuing role in enforcement and perhaps in licensing. We're very open minded, and we certainly would support that. The states in our approach would continue to have a very important role in this area.

And I'll also add that the National Association of Boards of Pharmacy in an accreditation type approach would continue to have a very important

role in this area, and I'll also add that the National Association of Boards of Pharmacy in an accreditation type approach is something that we think there is attraction to from a consistency perspective.

So, you know, if there is a single federal standard that a state was enforcing against or that was being contracted out to a third party accreditation organization to be inspecting against, that's a model that we think could work for our industry and ultimately for the benefit of patients.

DR. LUTTER: Ilisa Bernstein.

DR. BERNSTEIN: This question is for Scott.

I just want to make sure I fully understand your position. You said that PDMAs should move forward with some changes or amendments, but that FDA should move forward on the stay, but that PDMA should -- you're going to seek legislative changes.

Are those tied or are those separate? Do you see that PDMA could move forward with whatever changes? I'm not sure what changes you had in mind, but independent of legislative change and action.

MR. MELVILLE: Yes. We are supporting two actions. One is implement the PDMA rule. The second action is to work with the legislatures to provide any additional statutory authority that FDA would need to provide and create a uniform standard for licensure, and so those are certainly two different actions, and Congress particularly in an election year we know will not move very quickly in certain situations and will be deliberate. We can't count on any action by Congress.

What we can count on is a rule and the law that's on the book today and the rule, and that's why we're asking to move forward with the rule.

DR. BERNSTEIN: Not to put you on the spot or anything, but as you know, we have a decision to make. So if there are some changes that you have or amendments, unfortunately we cannot convene another meeting like this to do that. So I would highly recommend that you or anyone else submit those to the docket.

MR. MELVILLE: Would that be, if I could ask for clarification, amendments to the statute or to

the final rule?

DR. BERNSTEIN: To the rule.

MR. MELVILLE: Absolutely, we will do that and submit those recommendations before the docket closes.

DR. LUTTER: Steve.

MR. SILVERMAN: This is a question for Ron Bone.

Ron, in talking about some of the challenges that your firm faces were the stay to be lifted, you talked about the fact that for certain types of shipments you may not have electronic information that you would otherwise be able to pass on with shipments, which would obviously otherwise serve to satisfy the Pedigree requirements.

I'm just wondering. Is it your position that if you and the other major manufacturers following a lifting of the stay were to go back to -- excuse me -- you and the other major wholesalers, following lifting of the stay, were to go back to the manufacturer to supply you, that there would be any impediments to getting that information in electronic

form.

MR. BONE: Well, the rule since we buy all of our product directly from the manufacturer, the rule as it states does not require us to pass Pedigree. There are a few things that we have that we purchase that are from a manufacturer's arm, that as we understand it now, we would actually have to pass a Pedigree forward. We would have to create that Pedigree. It's a very small portion of our total business. So that's not something that would be an impediment to saying, "Go ahead and lift the stay."

The challenge that I was trying to express was that if we were looking for something more in terms of getting the Pedigree in place without having the infrastructure and a standard set of requirements across all states and having EPCglobal publish a standard on that, grabbing that electronic information from a manufacturer, and I'm assuming that they're included in the requirements here, and passing that forward is not a problem as long as it's all electronic.

One of the things that I didn't mention

earlier is there is no paper in a DC anymore. The paper has been removed. We don't pick from paper. We don't ship out using paper, et cetera. We have become a paperless environment. So just the concept of paper Pedigrees that don't have the electronic piece to that is counter to all of the improvements that we've made in the supply chain to lower the cost of the distribution of the product.

DR. LUTTER: Thank you.

We have time for one more question, I think, and then after that we'll proceed to an open mic.

So Bill.

MR. McCONAGHA: A very quick question for Mr. Haynes, please.

You had mentioned in your remarks that you felt it was important as a next step that FDA lift the stay or I should say let it expire in December 2006. Is that your personal view alone or is that the position of the PDMA Alliance?

MR. HAYNES: Personal view.

MR. McCONAGHA: Okay. Thank you.

MR. HAYNES: Bill, that's not to, you know, imply the alliance would not. It's an issue I did not vet with the alliance before coming. So I'm not going to take a position on what the PDMA Alliance might say in that regard.

MR. McCONAGHA: Okay, great. I didn't mean to put you on the spot. I just wanted to make sure for the record that we understood if it was your view or the organization's, and I take it at this point you can just represent it's your view.

MR. HAYNES: Correct.

MR. McCONAGHA: Okay. Thanks.

DR. LUTTER: I see one more flag in the air. So, Ilisa, please.

DR. BERNSTEIN: Thank you. I think it will be very quick.

It's to Eleni. You had said and Carmen mentioned yesterday that you're doing away with the list of susceptible products because the states weren't adopting it. I must say we found value in that list at least to point people, and we have got a number of questions. So what drugs are most

susceptible counterfeiting, and we say, "Oh, NABP has that list," which was very useful.

I think you mentioned that there were 11 or 12 other states they're contemplating changing the regs or someone out there or the laws. Are any of the other ones using that? No?

MS. ANAGNOSTIADIS: No, to the best of our knowledge, it appears that there are stakeholders in the states pushing forward pretty heavily with the normal distribution channel, and to the best of our knowledge, at this point in time none of the other states that are actively creating legislation are introducing the concept of the national specified list of susceptible products.

DR. BERNSTEIN: I think you raised a really interesting point though that we heard over the past few days how people are calling for phased in approaches and that one of the phases was focusing on susceptible products, and without that list, which was very helpful, who would you think? Would that be the states with the stakeholders or the manufacturers? Who would you think to do that list and maintain that?

MS. ANAGNOSTIADIS: I don't know. I guess it depends on the direction that the FDA decides to go, whether it would be a phased in approach. Certainly NABP would be happy to pick up that list if the states were going to move in that direction, but at this point in time, since there is no use, we've decided to stop the list.

DR. LUTTER: Thank you very much. Please join me in thanking this panel for a very informative discussion.

(Applause.)

MS. GLAVIN: We're going to move now to the open mic session. We have six individuals who have asked to speak at the open mic. I'm going to call you up in the order in which I have the sign-in sheet, which I assume is the order in which you signed in. I'm going to ask you to limit your remarks to five minutes, which I think we can do because we are a little bit ahead of time.

Also as I call you up, I'm going to ask you if you have a card with your name on it with you. At the end of your remarks, would you stop by the

table over here on my left and leave that card with the recorder so that we have an accurate representation of who you are in our final record of the meeting?

So with that, Robert Phillipson. Do I have your name correct? Okay, and you are with Covert Security Solutions.

Okay. Thank you. That's perfect. Thank you.

MR. PHILLIPSON: Well, first off, thank you very much for hosting this meeting and to the task force and also thank you very much for the companies that have done a lot of research and work in bringing a lot of these issues to the table.

I had three concerns when I signed up on this list. Two of them have been pretty well beat to death in this meeting.

FDA, please continue the leadership for setting standards for electronic Pedigree, which is chain of custody. That's a plea. And RFID is not the only way to have e-Pedigree.

Secondly, security is only as good as the

weakest link, and handling of the data appears to be the weakest link. I would ask that you would look for standards in that field, especially regarding the people that work in handling that data.

My third point is more controversial. Yesterday Paul Rudolph said it very well. RFID works well in tracking pallets and large boxes. It does not function as well in tracking smaller items. Perhaps a high grid RFID bar code new technology solution is in order to be able to do some of the things that you accurately point out needs to be done now.

While the FDA's public position has been not to elect a single technology, in fact, RFID has been selected. The stated goal is to protect the consumer from fraudulent medicines and protect the supply chain, not to insure the companies that have invested a lot of money in RFID get repaid.

The community is not the only group with this problem. Citizens Against Government Waste recently sent a letter to the head of Department of Homeland Security, Secretary Chertoff, asking him not to elect for RFID for the driver's licenses for the

real ID act because of the financial burden it will place on the states and the individuals, which is the same problem you have because this money is all going to be passed down to the consumer.

Does the election of the RFID then drive consumers away from you and to foreign products? The election of RFID does effectively cut off innovation of new technology, not just the improvements in RFID, but the improvements that come from other types of technology that have come up that can provide Pedigree data, trace and trace technologies.

I suggest that FDA set standards, but leave open the technology that can meet those standards.

Our company has -- this is a small commercial -- our company has an innovative improvement in this regard in print technology in which the printed mark contains data at a highly encrypted level, which solves some of the problems you've discussed. This permits secure serialization with a unique identifier, and it's a near fail safe authentication, scalable, and low cost. It's useful

in marking at the lowest level, and it's not affected by moisture or proximity to other marks or metals or any of these issues.

American innovation can solve a lot of these problems if we are permitted to compete. At this point in time we're not.

Thank you very much for this time.

MS. GLAVIN: Thank you very much.

And I remind you if you can to leave a card. Thank you.

Our next speaker is David Bear, and if I have your name wrong, please correct me, with PharmoRx.

DR. BEAR: Yes. I am David Bear. I am a physician, Professor of Psychiatry, and I started a group called PharmoRx.

Again, I thank everyone here for the chance to listen to an interesting discussion. One question that I've heard repeatedly is what can be done to accelerate the technology of RFID track and trace and e-Pedigree, which I think is a powerful technology.

And certainly method of augmenting it, making it more powerful, leveraging it would make it more attractive. So I'm going to speak for a hybrid system as well.

Track and trace is an elegant way of finding out where diversion occurred in the supply chain, but the materials diverted, the packages, the bottles, whatever, are gone, and those pills in those bottles are going to be stripped out of the bottles and they are not trackable. They will enter an inventory of abusable drugs that lead to a lot of bad things.

If those pills had serial numbers on them and the serial number, for example, was represented in the table of contents of the RFID tag, the situation would be quite different. When the diversion is immediately detected, those serial numbers in the system we have developed are available to the DEA, police departments and every licensed wholesaler so that these are stolen pills. Anyone who traffics in them is committing a criminal act. They lose value, and of course, the thing we hope for is it deters the

whole crime.

So the combination of writing and inscribing code on pills and RFID, I think, is an elegant solution to track and trace or at least an augmentation.

Now, what about authentication? What is authenticated, for example, in a bottle of pills that has an RFID tag with a very dense code? The answer is the bottle, and are the pills inside legitimate? Well, that depends on how much you believe in the seal of the bottle. There are rather elegant microsurgical techniques for opening seals and removing things. If the RFID tag is on a label and, again, it can be removed surgically, could that label be placed on a different bottle? And the materials inside an authentic bottle may not be real pills. What could they be? They could be counterfeit.

We know the North Koreans are pretty good at doing this, and they have the surgical technology and so forth to do it. They could be poison pills. So I think the realistic possibility that an authentic bottle misleads us into security about the pills then

has to be considered.

Now, how can we help this? If the pills have serial numbers and a method which we have submitted to the federal docket, those numbers will be legitimate code in the sense that they were written in the factory and they were not exhausted because we tracked these pills until they're consumed by patients.

And if they are legitimate, they could represent only one pill in the universe, and that's a pill that we have taken a picture of in the factory because using visual storage capability today, literally you have a pill print possible for every single pill.

So pill authentication would be a very powerful way of amplifying what is now container authentication, and I think clearly up some vulnerabilities.

Now, again, very briefly, we've heard the word "serialization" as if all this is trivial, just write on a lower level or something. Writing on a pill is not like writing on a Nokia phone, and that's

what two years of R&D has done. Writing on a pill has to be small because the real estate is limited.

When our pharmacological partner or pharmaceutical partner submits material to the FDA next week, obviously the question is is it safe. Have we left the active material unaffected? Have we avoided dangerous metabolites?

The code has to be durable. It can't be rubbed off as pills are used daily. It can't be easily effaced and so forth. So I think the actual details of what we call secure coding are interesting. I agree with the last speaker. I think innovation could be helpful here, and I'm sure we'll have competitors. I'm really not aware of many competitors at the moment.

Now, again, last point. The reason I as a physician became interested in this problem is a different domain. It's not the supply chain. It's the very large problem of post prescription abuse. I think, again, using 9/11 as an analogy, let's try to connect some dots, and I'm speaking to the FDA now.

The National Institute of Drug Abuse has

declared post prescription abuse, patients who take too many pills, patients who sell their pills, patients who fraudulently claim their pills are missing so that they get more pills, this is a priority.

It's the result of deaths. In the state where I practice, Maine, more people die to prescription overdose last year than from automobile accidents. The cost is very conservatively estimated at $110 billion.

So, again, it would be nice to harness these technologies to that problem, and the system we use involves registering pills which could well have RFID as their indices with serial numbers and the pills written within to register them to prescriptions, not to individual patients. So the federal privacy regulations are respected, and then pills become trackable.

There very strong deterrence to either a patient selling a pill or a patient claiming that a pill from his last prescription is lost. So we can put these things together.

Now, the very last point, I promise. I've talked to a number of good people today who have listened to this and said, you know, for the social good, these are very important issues post prescription of use, but honestly, there's no industrial, no financial incentive to do it.

Supply chain protection means protecting, The number of pills sale post prescription of use is a more difficult thing to argue for industry.

I think that's a mistake and very briefly, who are going to be buying pills in the future? The largest buyers are going to be Medicaid and Medicare programs by far. To a government program, a patient who becomes addicted at age 18 and needs a lifetime of treatment is a direct cost. Individuals who are addicted and steal drugs for year and require police, those are direct costs.

So a pill, an abusable pill, whether it's an opioid, anxiolytic, psychostimulant, is very valuable, and I would hope that the buyers will eventually realize this, and again, we are dealing with a global manufacturer who appreciates just this

point.

Rimoxy, which some of you know is designed as a somewhat tamper resistant oxycodone, has been valued very, very highly as a patent. If I had a minute of time, I'd tell you why that and two other designs that I've developed for tamper resistance will always be resistance. They will never be tamper proofing.

So that again, the serial coding and coupling it to RFID technology is to me very powerful and reasonable.

Thank you.

MS. GLAVIN: Thank you very much, Dr. Bear.

If you have a card and would leave it, I would be grateful. That will help our record.

DR. BEAR: As a doctor I never carry cards, but my colleague will bring one to you. Thank you.

MS. GLAVIN: Terrific. Thank you so much.

Gregg Metcalf of Nosco. Is Mr. Metcalf with us?

(No response.)

MS. GLAVIN: Okay. Dan Matlis of Axendia. And again, I invite you to correct either your name or your company as your affiliation if I've gotten them wrong.

MR. MATLIS: Thank you.

First, I'd like to join all of the other speakers and all the other folks in commending and applauding the FDA for listening to the constituents. I think it's very, very important to get everybody in the same place and to have this discussion around this critical issue.

I look forward to a cooperative approach to addressing this very important patient safety issue, and as Dr. Agwunobi said this morning, at the end of the day, it's about our families, our kids, our siblings, our patents, and ourselves who are affected.

I have a comment and a question. The first thing I'd like to reiterate is what's been spoken a couple of times, the fact that there's a lot of talk about RFID, and I'm an electrical engineer, and I think there's a lot of promise in RFID. I do

believe that the technology is ready, but technology should be looked at as an enabler and not as a silver bullet or as a solution to all the problems.

At the end of the day people who have clearly defined the problem up front, what is it that we're trying to resolve. There is a very important patient safety issue that we're trying to address, and what we should be looking at is what's the issue, and then let the technology folks come up with the standards, with a clear, concise standard so that they're open, so that we can all interoperate and really looking to the agency to enable that as well.

Just as technology is an enabler, in a way regulatory compliance is an enabler as well. There's nothing like setting a date or a line in the sand for something to happen, to set at the end goal. And I believe that's very, very important.

The second issue is more of a question. A lot of what we heard about over the last couple of days has to do with, first, the fact that I think somebody mentioned it yesterday; a paper Pedigree is not worth the paper that it's written on. We've been

hearing about e-Pedigree and the IT infrastructures that are required and repositories, whether they should be centralized in RFID and bar codes and digitally signing a record, and so on and so forth.

But all of these electronic systems need some guidance as well, and my question would be when will the FDA issue a final position on electronic records and electronic signatures on which all of these other systems are based upon. I think it's very, very important for us in the industry to get a clear understanding or a final result or an end goal so that we can use that as a foundation to building all of these technology systems which are needed, which are required and would have great benefit.

Thank you.

MS. GLAVIN: Thank you very much. And, again, if you'd put your card down.

Peter Frei of Hapa Ag.

MR. FREI: Well, ladies and gentlemen, what is our goal here? Our goal is an icon feeding. That's at least what I understood yesterday from Andrew von Eschenbach. By the way, Eschenbach is a

town in Switzerland, and I am from Switzerland. I am from a company half of which is a printing company in the pharmaceutical industries for printing in line and packaging line.

Anti-counterfeiting is our goal. At least it says it out here. For anti-counterfeiting, what do we need for that? Several speakers said we need a unique serial number, a unique serial number that cannot be counterfeited.

We also need means to check this unique serial number very easily, and this unique serial number should be under final item or the last small item, such as a bottle or such as a blister. You know, Europeans are working with blisters. So I hold up a blister.

Now, on the final item, it means even this is final items. You can pull them apart. So it could be the last pill on that final item.

Now, a unique number to put on this here, what can we do for that? RFID? RFID, I understand they have a unique number on it, which is good. Whether or not this is random or whether or not it's

counterfeit or whatever, I'll discuss here. But putting RFIDs on every single tablet here or at lease on a blister is pretty much a challenge financially and also for the whole supply chain.

RFID, if you want to check that easily, it's probably not easy to read that as a consumer because I don't have a machine back home, and your kids don't have it, and your wife or your husband doesn't have it.

So we cannot read that. It's not easy. You cannot check it over the Internet. So you're depending on someone who tells you it's trustworthy.

Again, like others said before, printing. Imagine if you were able to print a unique code on the last item, a unique code which is random, which is not counterfeitable as it is like made out of an alphanumeric number as David Dillon said it yesterday, as Microsoft does it, a unique number where guessing the number is less likely than winning in the lottery.

So everybody can read this number. Everybody could go on the Internet and check this number and get a feedback whether or not this final

drug here is really a counterfeit or not a counterfeit.

Finally, I would like to say RFID is a really good tool Our company uses that RFID also in our machines for tracking and tracing. For tracking and tracing RFID is perfect, but for anti-counterfeiting, for the purpose you're looking for here, I would suggest go bottom up and first get an identification on the last drug as you actually stated as the goal, and get every consumer. Give him the responsibility also or the possibility at least to check his final drug. Go on the Internet, do it with Hot Line, whatever, and check this identification, and only then he is sure that the chances are less than winning the lottery that he's holding a counterfeit drug in his hand.

Thank you.

MS. GLAVIN: Thank you very much.

Bob Spiller.

MR. SPILLER: Hi. Thanks for allowing walk-ons.

I don't make or sell anything that they

buy, and I don't make or sell anything that you regulate. I'm a retired person. I am one of the 300 million people who will buy what they sell, and if problems happen, I will eat the mistakes.

(Laughter.)

MR. SPILLER: I think we are here ultimately because of a fear, a fear the Congress felt of counterfeits and diverted drugs in 1988 and because of our continuing fear that that can happen.

I analogize that fear to a tiger. Pick an animal you're afraid of, snakes or elephants or something else. So four little observations about the tiger. We need to know the public does, how big is the tiger; how many are there?

I know it's hard to determine the scope of the counterfeit problem, but the public will be much more supportive of your efforts if you can estimate, quantify, scientifically determine the likely size, incidence, prevalence, rate of counterfeits.

We have an industry that can estimate the size of planets on foreign suns by watching the perturbations in their orbits. We can certainly get

an estimate of the percentage of counterfeits that afflict us, and that will make you stronger in regulating them.

Second, please hobble the tiger and not the guard dog. You're the guard dog. When your regulations are stayed, you're hobbling yourself. The public, I think, wants you to control the counterfeits and the diverted drugs and not to allow others to force you to delay your regulations, as this one, if I have listened carefully, has been for 18 years.

Eighteen years is a generation. It's not these people who have lobbied Congress to push you to have a stay. It's probably their parents.

(Laughter.)

MR. SPILLER: And so I hope when you have these regulations finally effective you will find a way to ask the public and the industry did these 18 years of stays and delays help you. Did they help your company? If not, would you tell your lobbyist to knock it off?

Another thing about the tiger is remember that the tiger does not only kill out of hunger. We

think of counterfeits and the high risk of counterfeits as basically expensive drugs. Not all the people who want to hurt you care about whether the drug is worth anything or whether they're going to make any money.

So when you're thinking about what tier of drugs to regulate, please include the generics. Generics move fast. They're widely used. They would be a vehicle for some of the bad people that Haynes reminded us about that are awake 60 percent of the day will try to use.

So please don't restrict your regulatory efforts only to high value drugs or previously counterfeited drugs.

Finally, please don't ask the tiger to pay for the leash. If you become dependent upon user fees for licenses or registrations, the tiger will have you customize the leash for its comfortable fit and its weak links. The tiger will eventually tell you how far he can be pulled.

So I urge you not to become dependent upon user fees. Thank you very much.

MS. GLAVIN: Thank you.

Let me ask once more if Gregg Metcalf is here.

(No response.)

MS. GLAVIN: Okay. Well, then that concludes our open mic session, and I'm going to hand it over to Randy to wrap us up.

DR. LUTTER: Thank you very much.

I think I have a somewhat unenviable task of trying to offer a summary at the end of what's been an unusual two days. Let me begin by saying please submit comments to the docket, and you can submit both the comment that you prepared formally to present here if you were a presenter or amend those based on something that you may have learned here or something that you discovered to be important between now and the next two weeks.

I'd like to begin by thanking all of the panelists. To me this was a very educational experience because in large part the quality of the presentations and the dialogue that results from everybody here.

I'd also like to thank everybody in the room, including everybody who wasn't a panelist. This is fundamentally essentially a cooperative endeavor. We collectively have a problem with counterfeits. We collectively have some responsibility to solve it, and any solution that is successful requires cooperation among the different stakeholders, and this is just one part of a step to find that solution.

So I'm grateful for their help. I'd like to offer a special word of thanks to the FDA staff who made the delivery of this conference such a great pleasure, and particularly Ilisa Bernstein, who is sitting to my right, because I found the execution to be great. I even got a cold drink in the middle of the afternoon when I needed it.

And I'd also like to offer a word of thanks to the contractors who provided the technical support and the communication with California because they didn't know that Washington was also within reach by airplane.

(Laughter.)

DR. LUTTER: Let me just review a brief

background. We're here because we perceived last fall at the rate of adoption of RFID, which we've tried to describe only as the most promising electronic track and trace technology, but we had perceived that that had slowed.

We earlier had projected that there will be widespread adoption by 2007, and as of last fall, we perceived that that was at risk.

So the questions before us today and yesterday have been what obstacles exist to prevent a faster adopting of electronic track and trace technologies to comply with the pedigree requirements of the Prescription Drug Marketing Act.

And also, what measures can we adopt to help overcome these obstacles?

I think this has been a very good conference and offered really significant educational value, and I mean that in a broad sense, to us. We've had two really good keynote speakers. I'm delighted that both Dr. von Eschenbach and Dr. John Agwunobi were able to participate.

The Acting Commissioner showed support for

a variety of technological solutions. The Assistant Secretary for Health showed concern about the potential tragedy from not adopting the best available technology to prevent counterfeit drugs from reaching the sick and the infirm. Those are both two very important messages.

We've had some remarkable speakers. Yesterday morning we had what I thought was a very good panel of eight members of a keynote group representing the most important stakeholders. We also had 26 other speakers, talking about RFID. Today we had 16 speakers and a half dozen speakers at an open mic.

So I'd like to offer a very brief summary of what I heard, and these are my own reflections. If you think I didn't get it right, you can please write into the docket and say it was a little bit different than that, but this is my unconsidered, not very deliberative summary of just a few messages.

And they're grouped a little bit in terms of the areas where there has been some sort of agreement perhaps and areas where there has been much

less of one.

With respect to the former, and pilot projects in particular, vendors, wholesalers, and some manufacturers appear to have agreed that pilot projects conducted to date mean that providing real time electronic pedigrees is feasible in production environment with single wholesalers. So, in other words, there's not a Pedigree being implemented or a wholesaler sells a product to another wholesaler and sells a product to another wholesaler again before it goes to a retailer.

In discussions with vendors, I believe that some of the vendors have hybrid authentication Pedigree labels. For example, two dimensional bar code and RFID, and these are important because they might work during a relatively lengthy transition to a more widespread even universal RFID adoption.

A couple of basis points on the economics, if you will. The first one is that the business case for manufacturers to adopt RFID authentication is strong for some products, e.g., those likely in relative terms to be counterfeited. But that same

business case may not be as strong, may not be strong at all for products more broadly, e.g., including generics or other low value products. That's on the one hand.

But then on the other hand, several of the vendors, and I think this was also echoed during the discussion today, have suggested that the cost will fall sharply, but by an unknown amount following widespread adoption. So there hasn't been a lot of discussion of what the price is, and I think that's probably consistent with the idea that price measures to date are going to be overtaken by events following widespread adoption of a future date.

Where that leaves us is that the key challenges, the scope, and the timing of a transition to industry-wide use of electronic track and trace. That's really my perception of where we are now.

We've heard from the states. I thought that discussion was very enlightening. They wanted the authority to enforce laws against counterfeiting and laws requiring Pedigrees, but they also wished to reserve the discretion to modify standards for

electronic Pedigrees.

We had an interesting discussion this afternoon about the future of PDMA Pedigree requirements. You can tell I'm now getting to an area where there's much less of a consensus or a single statement of fact, and there's a broader set of lighter variety of interpretations of the same fact or the same issues.

There was no consensus on whether Pedigrees should be given with a manufacturer or with the authorized distributor of record or who would have to provide the Pedigree, whether it would extend to all, including the manufacturers, or simply the non-ADRs.

There's no consensus on the ideal timing, in particular, whether we should set a date of X and what that X might be by which there should be a mandatory industry-wide use of electronic track and trace Pedigrees.

HDMA offered a couple of interesting comments. There should be a single federal standard required for wholesale licensing, but then some

speakers, including the National Association of Boards of Pharmacy have stressed the importance of setting a definitive date to adopt electronic track and trace Pedigrees.

Paper pedigrees we've been told are not practical, that they would grind distribution to a halt. This is not intended in any way to be comprehensive or authoritative. I'm just trying to offer you a preliminary collection of some of the impressions that I've been left with.

Let me turn briefly to next steps. These presentations that you saw today, the PowerPoint presentations or anything else that's been up on this screen we will try and post on our Website as soon as possible, likely tomorrow. It will be underneath the counterfeit drug section of the FDA webpage.

The docket closes I believe it's two weeks from today, closes two weeks from today. Please, again, submit comments. We will read your comments. We value them. We welcome them. We will issue, as directed by the Acting Commissioner of FDA, a report in May on our findings, and we look forward to

continuing very much a discussion with you then.

And we, again, appreciate your participation at this conference.

Thank you very much.

(Whereupon, at 3:50 p.m., the conference in the above-entitled matter was concluded.)