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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WEDNESDAY,
FEBRUARY 8, 2006

The workshop came to order at 8:30 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, Assoc. Commissioner for Regulatory Affairs
RANDALL LUTTER, Ph.D.	Co-Chair, Assoc. Commissioner for Policy and Planning
DEBORAH AUTOR	Assoc. Dir., Office of Compliance, Center for Drug Evaluation & Research
ILISA BERNSTEIN, Pharm. D., J.D.	Dir. of Pharmacy Affairs, Office of the Commissioner
WILLIAM McCONAGHA	Assoc. General Counsel, Office of General Counsel
MOHEB NASR, Ph.D.	Dir., Office of New Drug Quality Assessment, Center for Drug Evaluation & Research
JEFFREY SHUREN, M.D.	Asst. Commissioner for Policy, Office of the Commissioner
STEVEN SILVERMAN	Acting Dir., Office of Compliance, Center for Drug Evaluation and Research

TONI STEFANO	Special Asst., Office of Compliance & Biologics Quality, Center for Biologics
TERRY VERMILLION	Evaluation and Research Dir., Office of Criminal Investigations, Office of Regulatory Affairs

AGENDA ITEM PAGE

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

8:32 a.m.

CO-CHAIR LUTTER: Good morning. Please, take your seats. We would like to begin. Good morning. My name is Randy Lutter. I'm Associate Commissioner of FDA for Policy and Planning.

I'm absolutely delighted to have the opportunity today to introduce you to Dr. Andy von Eschenbach. He is the 12th Director of the National Cancer Institute since its creation in 1937. In September 2005, he was named Acting Commissioner of the Food and Drug Administration. Nationally recognized urologic surgeon, Dr. von Eschenbach's distinguished career as a key leader in the fight against cancer spans nearly three decades.

We are very pleased to have him with us as the Acting Commissioner of the Food and Drug Administration and I'm delighted to have him provide introductory remarks to this workshop on the Counterfeit Drug Task Force. Please, join me in welcoming him. Thank you.

(Applause)

DR. VON ESCHENBACH: Thank you, Randy, and good morning, ladies and gentlemen. I have to tell you, in coming up to the podium, it is incredibly gratifying to see all of you here today, and how much we appreciate the turn out and your commitment and your interest to working together with us through just a very, very important set of issues.

I just had the opportunity to walk through some of the exhibits, and I have to confess that, as someone who actually started out his career in electronic physics, and then moved from that into pre-med, to see this technology and to begin to even imagine and envision what it will lead us to as we together embrace this future is an incredibly gratifying morning.

So it's a real privilege for me, as the Acting Commissioner, to open this FDA Workshop that focuses on this truly important area. And what our efforts need to be to combat counterfeit drugs and thereby improve the integrity and safety of our country's drug supply.

For many of you, this is my first chance

to introduce myself as the Acting Commissioner to the FDA. But in the short time that I have had the privilege to be with the FDA, I have to testify to the fact that it is truly an extraordinary agency, made up of unbelievably talented, gifted, committed people who are, like you, committed to serving the American people.

We are celebrating our 100th anniversary, and it's an incredibly important time to reflect on the past and the accomplishments and the achievements of the FDA, but it's even more important a time for us to pause and look at the future that's before us. The future that is reflected to some degree even in the kind of technology that is available in the exhibits this morning.

In the past, the FDA has been, and has established itself as this gold standard of professionalism, and of protection. And we are proud of that record, and proud of the privilege of being able to have that place in society. We recognize that, because of the past achievements of the FDA and its record, there are millions of us who go to sleep

each night never worrying about the food we ate, and more importantly, never concerned about the medicine we gave our child or our grandchild.

And we are committed to never having that change. We are committed, as we look at the future, to maintaining this standard of excellence. But we recognize that our future is going to be much different than the past. The challenges, the opportunities are changing, and changing at an almost breathtaking exponential rate.

For thousands of years, our approach to diseases has been based on what we could tell or observe with our five senses. 100 years or so ago, we moved from that macroscopic view of the world to a microscopic view of the world. We could begin, for the first time, to see things like cancer cells, or bugs that cause infection under a microscope. And that movement from the macroscopic to the microscopic was transformational.

But 10 years ago or so, we moved from that macroscopic and microscopic view to the molecular view. The ability now to begin to see, understand and

be able to deal with diseases like cancer and others, not just at the macroscopic and the microscopic level, but even more importantly at the molecular, the genetic and cellular level, and do that in ways that were unimaginable even a few decades ago.

That transformation within our very, very recent past, that transformation to the molecular era, is more than just simply a transformation. It is truly a metamorphosis. A metamorphosis in the sense that we are looking ahead at a future that is no more like the past than a butterfly is like a caterpillar. It is that profound. Our movement into the molecular era, the strategic inflection that we are currently engaged in is not changing one thing; it is, in fact, changing everything.

And that metamorphosis is driven not only by our explosive expansion of our knowledge and understanding of diseases at the molecular level, but also by the technologies, the tools that are being developed that are enabling us to expand and increase that pace of progress. It's a future that the FDA and all of us must look forward to from the perspective

that not one thing will change, but everything will change.

The future of medicine in this new era will be profoundly different than medicine in the past. It will change in ways, for example, that medicine will become personalized. It will become predictive. It will be much more preemptive, and I would also add that I believe it will be much more participatory with regard to the role of the patient.

We will be looking at opportunities in which our prescriptions to patients will no longer be based on empiric knowledge derived from a sample of a population, but being able to prescribe specifically and uniquely, based on our understanding of that particular disease and the patient with that disease, his own genetic and molecular profile, what we must, in fact, do.

No longer will we be basing decisions on statistical probabilities of success, but by virtue of our predetermined knowledge and understanding of pathways and mechanisms that are associated with that particular disease process and our understanding of

those processes in the patient itself.

This is an opportunity, an opportunity to begin to create a new future. And it's an opportunity that the FDA is fully embracing and engaging. As we look at our past and celebrate the record of accomplishment, we are focused on the future. And we are focused on the future in being able to serve the American people and, in fact, the world, in the same way we have in the past, by assuring them the rapid delivery of safe, effective and low-cost interventions that will change their lives and enhance their health.

One critical area that we must continue to face is the strategy in this change process to be able to assure the effectiveness and the safety of these interventions and the solutions that we will be providing to patients in the molecular era. And so as we have faced in the past, the threat of counterfeit drugs is real, and while we will do our part in regulation, we must also do our part in surveillance.

Counterfeiting of drugs is commonplace around the world. In some countries, the sick and the infirm are as likely to get a counterfeit product as

an authentic one. Fortunately, the vast majority of drugs for sale in the United States are genuine FDA-approved articles. The U.S. drug supply is among the safest in the world, and we have had very few counterfeits because of the strong pharmaceutical regulatory system.

But despite our high confidence in the system, FDA has recently become concerned that our drug supply is under increasing vulnerability and threat of attack. This disturbing trend, evident in the increased number of newly initiated counterfeit drug cases since 2000 or so, is evident in the increased efforts to introduce counterfeit drugs into the U.S. market.

In fiscal year 2005, the FDA Office of Criminal Investigation initiated 32 new counterfeit drug cases. Although this number suggested decline relative to a peak of 58 cases in 2004, we still are concerned about the dramatic increases in cases over the past five years. I will stress that these are only the number of newly opened cases. We have no estimate of the volume of counterfeit drugs involved

in each case. It could vary from dozens to many hundreds.

The number of newly opened cases also does not give us any insight into the prevalence of counterfeit drugs in the United States. Fortunately, most of these counterfeit drugs at issue did not reach consumers, but we must remain vigilant in our efforts to assure the protection of the American public. Makers of fake drug products are becoming more sophisticated in their counterfeit techniques, so we must become more sophisticated to combat them.

By using the latest technology and innovative ideas to sure up our system, we aim to put these counterfeiters out of business. In 2004, the FDA issued a Counterfeit Drug Task Force Report that set a frame work for the Agency to further secure our supply chain. The report detailed our strategy, and pushed for the adoption of electronic track-and-trace technology.

Let me make it clear. Our future is to embrace emerging information technologies. I am firmly behind the implementation of electronic track-

and-trace technology as one leading weapon we can use to combat the counterfeit drug problem. We are immersed in a technological revolution as we are immersed in this molecular metamorphosis. And we must use technology, in all cases, as a cornerstone to build upon.

We must use information and technology such as radio frequency identification as new opportunities that are essential for our ability to track, trace, and authenticate these new products and our drug products in the marketplace. An electronic pedigree to minimize fraud and mischief is vital in protecting American consumers.

I know that many of you who are here have already moved in that direction. But as a group, as a whole, I don't believe that we are moving fast enough. FDA had expected to see widespread implementation of electronic pedigrees by 2007, but that is not likely to happen at this pace. And so we are here again to talk, to communicate, to exchange ideas and work together in light of the continued stay to pedigree requirements, and to be able to implement these

pedigree requirements.

The longer we delay, the more opportunity is lost. Because of an apparent slow down in the progress to implementing RFID, I have reconvened the Task Force to assess the progress that has been made in adopting electronic track-and-trace technologies to look at the obstacles that have been encountered, and what measures we can take to adopt to quickly overcome these obstacles.

I have also asked the Task Force to address what, if anything, the Agency should do when the stay expires later this year. I have asked the Task Force to issue a report to me in May of this year. Chairing the Task Force are Maggie Glavin, Associate Commissioner for Regulatory Affairs, and Randy Lutter, Associate Commissioner for Policy and Planning. They are also moderating the discussion sessions that will occur today and tomorrow.

Over the next few days, the FDA is eager to hear from you and learn your thoughts, your insights, on this matter. We want to identify current barriers to adoption to find ways these barriers can

be overcome. We want to gather new information and glean fresh ideas from each of you as we come together to decide this important issue.

In this room today are a diverse group of people representing many interests. Many of you have different missions and different perspectives. But all of us have in this room one common purpose, and that is to improve the health and the welfare of the people we serve. If we can put aside our differences, our concerns about market share or suspicions about the latest technology, the result could benefit every citizen.

It is what I have called "progress with a purpose." We must put our minds together and act now, within that common purpose, to bring these revolutionary changes to the benefit of our public. Every day that a counterfeiter is out there, able to do their work, is a day we are endangering the safety of the American people, and the integrity of the great opportunities in this pipeline of being able to deliver them new and more effective solutions to their problems.

FDA is committed to maintaining that gold standard of professionalism and protection that we established over the past 100 years. But we will continue to make sure that the American people can depend upon us in the future to give them the most effective and safest interventions possible. We have many fine speakers and vendor displays in the other room to foster the discussions and facilitate the exchanges, and I really ask all of us to take advantage of having this experience and sharing our knowledge at this meeting.

I really want to end where I began by thanking you for your commitment and your interest in being here. We have a future ahead of us that can, in fact, revolutionize and change how we are able to assure the health and welfare of people. As we move forward in developing those new solutions and those new products, we need to have the infrastructure in place to assure the safety and the integrity of those products.

Modern technologies are leading us to a new era of molecular medicine and modern technologies

such as what we will be discussing and what you are witnessing here today will lead us to being certain that we deliver those new solutions to patients with integrity, and with safety. And you and we together will bring that future about. Thank you very much.

(Applause)

CO-CHAIR GLAVIN: Thank you very much, Dr. von Eschenbach, for being with us this morning, and for launching what promises to be a very interesting two days of discussion and exchange. I want to welcome all of you, speakers, vendors, and audience members, and thank you for participating in this public workshop. With your input, FDA will be able to institute policies that most effectively and efficiently combat counterfeit drugs in this country.

As Dr. von Eschenbach referred, in February of '04, the Counterfeit Drug Task Force issued a report in which we stated that the widespread use of radio-frequency identification, RFID, to track-and-trace the movement of drugs in the U.S. supply chain was a critical component of securing the U.S. drug supply.

After consulting with industry, the Task Force concluded that the widespread use of this technology would be feasible by 2007. Since that time, industry has made progress towards adopting and implementing RFID, but again, as Dr. von Eschenbach mentioned, we have become concerned that progress has slowed. Over the next two days, we will hear from speakers with a wide variety of perspectives about how best to prevent counterfeit drugs from entering the U.S. supply chain.

Specifically, we have asked our participants and panelists to talk about the use of electronic track-and-trace technology, incentives for and obstacles to widespread adoption of RFID, the state of the art technology that delivers electronic pedigree capability, issues related to the Prescription Drug Marketing Act. Finally, FDA would like to hear from you about the scope of the counterfeit drug problem in this country.

Many of you, particularly those who are involved in the drug supply chain, have first hand knowledge about the volume and type of counterfeit

drugs that are able to make it into the supply chain. We want to hear from you so that we can best tailor solutions to the problem.

Let me thank all of you who asked to speak, either as a panelist, or during one of the open mike sessions. We had many more requests than time would allow, but we still want to hear from you, even if you are not able to make a presentation at this meeting. So I urge you to submit your comments to the open public docket. You should have received information about how to do so during the registration, and, as I finish my remarks, I'll remind you on how you can do that.

Once FDA reviews all of the comments, both those that we get during this workshop, and those submitted to the docket, we will issue a report as requested by Dr. von Eschenbach. Again, we thank you for your participation, and look forward to a very productive and educational workshop.

I would like to begin by introducing the Members of the Counterfeit Drug Task Force, and what I will do, because this room is so long, and there are

people way in the back, when I introduce you if you would just stand up, so that the people back there can see who you are.

So, Deb Autor, who is the Associate Director of the Office of Compliance in the Center for Drug Evaluation and Research; Ilisa Bernstein, Director of Pharmacy Affairs in the Office of Commissioner; William McConagha, Associate General Counsel in the Office of General Counsel; Moheb Nasr, Director of the Office of New Drug Quality Assessment in the Center for Drug Evaluation and Research; Jeff Shuren, Assistant Commissioner for Policy, Office of the Commissioner; Steve 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; and Terry Vermillion, Director of the Office of Criminal Investigations in the Office of Regulatory Affairs.

And, of course, Dr. von Eschenbach already introduced Randy Lutter, and myself, Margaret Glavin, and we are the Co-Chairs of the Task Force.

A few announcements for speakers, these are kind of ground rules on how we will operate in a tight time frame. When your panel is announced, if all members of the panel could come to the table, and the table is here, right in front of me, each speaker has been allotted a set amount of time to make his or her presentation. When the time is up, the timer will display a red light. There is not a yellow light, but I understand that a minute before your time is up, the red light will start to flash. And if that doesn't work, we'll adjust from there.

We ask that each of you, please, limit your remarks to the time allotted, because we do have a very full agenda. When each of the panelists has completed his presentation, the Task Force Members will have an opportunity to ask you some questions. The meeting will be transcribed, so, please, be careful to speak into the microphones that are here, because that makes the transcript much more useable.

For all participants, we do have an ambitious agenda, so we are limited to one break this morning, and no breaks after lunch. So, please, feel

free to come and go as needed. This is a tight room. I have visited the ladies room, and if we had a large break, I can guarantee you no one would be able to use the facilities. So, please, come and go as you need to. That's perfectly acceptable, and again, we will have one break this morning, but beyond that we are going to really keep moving.

You are on your own for lunch. There are a lot of places to eat in the neighborhood, so you should have no trouble finding some place that you can get in and out of in the time allotted. And I'm sure the hotel staff will be happy to give you any recommendations they might have.

We are eager to hear your comments on this very important issue. And as I said, the docket is open, and we urge you to submit your comments to the docket. At the registration desk, there is a sheet which tells you how you can do that. So if you didn't pick that up when you registered, be sure to get that. In addition, at the registration desk, there is a box for comments. So, if you have comments with you today, or your presentation with you today, please,

just drop it in the box at the registration desk and we will make sure that those are part of the record.

The vendor display, which I had the opportunity to go through briefly this morning, will be open all day, both today and tomorrow, from 8:00 until 5:00. I strongly encourage you to visit the displays several times. I know I want to go back, because in half an hour, I think I only saw about six of the displays, and there are more than that. They are fascinating, very informative, and so I urge you to do that, both today and tomorrow, at every chance you get.

With that, I'm going to turn it over to Randy to introduce our first panel and start the meeting. Thank you.

(Applause)

CO-CHAIR LUTTER: For our first panel, we brought together some representatives from some of the major stakeholder organizations to discuss what it will take to effectively implement track-and-trace technologies into the pharmaceutical supply chain by 2007. We are really pleased to have such a diverse

representation across the supply chain to give us their perspectives on the state of pedigree, RFID, and PDMA.

I think everybody has the agenda in front of them, so I'll do the introductions very quickly. Carmen Catizone from the National Association of Boards of Pharmacy, Alan Goldhammer from PhRMA, John Gray from HDMA, Mike Meranda from EPCglobal U.S., Ron Moser from Wal-Mart, Kathy Smith from DoD, Steve Perlowski from the National Association of Chain Drug Stores, and Sara Radcliffe from BIO. Please, join me in welcoming all of them.

(Applause)

CO-CHAIR LUTTER: And in the interests of keeping to our agenda, I have made an autocratic decision to tax everybody one minute. If you speak faster than normal, you can probably get by in nine minutes instead of 10. And since we are at the beginning of a day and already running a little bit late, please, please, respect my advice on that note.

So beginning the presentation will be Carmen Catizone.

DR. CATIZONE: Thank you, Andy and Margaret. I'm a little nervous this morning, because the protocol for speakers is much more difficult than the question that we were posed to answer. So good morning to everyone. Good morning to the Task Force. Thank you for the opportunity to share NABP's expertise and opinions on this topic.

From the perspective of the State Boards of Pharmacy at NABP, we feel that the implementation date of 2007 for electronic track-and-trace technologies is possible, and must be possible, by 2007. The reason for our optimism and confidence is because of significant events that have taken place since the Task Force first released its findings in 2003.

First of all, the necessary regulatory frame work for the licensure and regulation of wholesale distributors is moving at an aggressive pace at the state level. Secondly, the pilot projects and innovative software companies, such as SupplyScape, have proven that such technologies are possible, and can meet the 2007 deadline.

In regard to the regulatory environment, a growing number of states have adopted regulations supported by NABP in response to the Task Force findings in 2003, are recognizing or requiring NABP's Verified-Accreditation of Wholesale Distributors Program, or have pending legislation and regulations addressing the licensure and regulation of wholesale distributors in agreement with NABP's model rules for the licensure of wholesale distributors.

As an important note in this regard, the State of Indiana required NABP's VAWD Program, and in effect set a national standard for the licensure and regulation of wholesale distributors. This is occurring because wholesalers that operate in Indiana operate across the country, and do so quite easily, and with an accreditation program in place now, will be able to operate even more easily in the other states.

An important announcement we would like to make today at this conference is that NABPS awarded accreditation to two wholesale distributors: CVS and U.S. Oncology. The accrediting of CVS and U.S.

Oncology is a major milestone in the protection of the public health in means to combat counterfeit drugs. It is a testament to the leadership of CVS and U.S. Oncology to assist the FDA and the State Boards of Pharmacy in combating counterfeit drugs.

Both entities represent distinct and important areas of the medication distribution chain. CVS is one of the largest, if not the largest, chain drug store in the United States. And U.S. Oncology is a specialty wholesale distributor. The accreditation of CVS and U.S. Oncology demonstrate that state regulation and the VAWD Program is viable, and disproves the criticism of some segments of the industry that this wouldn't be possible, and that the accreditation program wouldn't be operational.

With this regulatory framework moving forward aggressively, it's time to turn our attention to the track-and-trace technology, and the environment that must be created in that regard. In order to achieve the desired realistic goal of some degree of track-and-trace technology by 2007, we asked the Task Force to consider the following areas:

One, the development of standards. The wholesale distribution industry must work with all components of the distribution chain, state and federal regulatory agencies, and software companies to develop uniform standards for the design and implementation of track-and-trace technologies. This is a fundamental step that will direct the entire progress and path of implementation, and is also one of the biggest hurdles to be faced.

Echoing the comments of the Acting Commissioner, and Margaret, we, too, find it unfortunate that more progress hasn't been made in this regard. Without uniform standards and compatible design for the various technologies, the resulting system will be non-functional and cost prohibitive.

Secondly, we ask the FDA to continue to increase its leadership role in this area. The FDA's efforts concerning the development of uniform standards and track-and-trace technologies has been commendable. However, it has been a voluntary approach. And at this point, NABP believes that a voluntary approach may not be enough. Particularly

noting the slow progress of RFID, and electronic pedigree implementation in standard development.

NABP encourages the FDA to change its approach from voluntary to mandatory, and to identify key areas that should be mandated by the FDA in the states to move the standard development and implementation process along more quickly.

Third, the track-and-trace system available in 2007 will be a work in progress. All stakeholders must agree and accept the fact that the ideal system will not be available in 2007, and consideration given to the implementation of track-and-trace technologies that are possible based upon existing technologies, and reasonable costs.

NABP understands that the cost issue must be addressed and considered in this implementation of track-and-trace technologies. Unfortunately, the FDA, State Boards of Pharmacy and NABP have no control over the cost factors. But clearly a widespread implementation system will help limit and decrease those costs.

In conclusion, NABP thanks the FDA for the

opportunity to participate in the workshop and share our expertise. The State Boards of Pharmacy have sent a strong and unified message to NABP that implementation of track-and-trace technology by 2007 is necessary, and not something that the states wish to be delayed. The FDA, State Boards of Pharmacy, the wholesale drug industry led by HDMA, chain drug stores, software companies, and NABP, are working collaboratively to address the critical patient safety issues.

NABP wants to continue this collaboration, and wants to ensure that implementation of some track-and-trace technology will occur by 2007. Thank you.

(Applause)

CO-CHAIR LUTTER: Thank you. Our next speaker is Alan Goldhammer from the Pharmaceutical Research and Manufacturers Association.

DR. GOLDHAMMER: Thank you very much, Randy. I'll try to move through this as fast as I can, in keeping with the nine minutes here. I know that some of you in the far part of the room can't see the slides, or may not be able to see them well

enough. Just send me an email, and we'll get them to you.

I would like to cover PhRMA's priorities to make sure the supply chain is safe and secure. The key points here is the safe and secure supply chain prevents the introduction of counterfeit drugs, prevents diversion of drugs already in the supply chains, and it means the patients get safe and effective medicines.

How do we assure this? We need a systems approach, as there is no single magic bullet. We need innovative packaging technologies, improved business processes, regulatory clarity at the federal level, and improved wholesale licensure, along with active enforcement against counterfeiters.

PhRMA has had a number of ongoing activities over the last several years. We established a work group on electronic drug authentication. We have been engaged with other supply chain partner associations on a variety of issues. We have commented in depth to FDA on PDMA-related issues. And last spring, we issued a White

Paper on the path forward to achieving electronic drug authentication.

We will be happy to supply that White Paper to anybody who wants it. This is probably in very small print that's going to be difficult to read. I'm going to highlight the key points from that White Paper. First, all package units of targeted prescription medicines should contain a machine-readable serial number that includes the company identifier. The machine-readable code can be either a two-dimensional bar code, or an RFID tag. The chosen code should be robust and reliable in terms of readability, and cost effective.

We need standards. We also need an appropriate information technology infrastructure that can collect the information, and store it. Electronic authentication should initially focus on the end-user dispensing site, but is not intended to exclude other supply chain participants.

Operating rules must be established regarding the point of time authentication, and following dispensing of the package unit, or the

opening of the container if there are multiple dispensing amounts, steps should be taken to prevent the subsequent illegal use of the unit's serial number. Following the successful demonstration of the viability of dispensing site authentication, the technology can be added to other partners in the supply chain.

Electronic authentication is different. Package identification information is resident in the database. The electronic pedigree is simply a series of authentication steps. Each trading partner authenticates, and is registered in the database. The electronic pedigree really does not need to be passed forward, but can be examined at any point in time if the package is flagged because it did not have prior authentication.

Well, what do we need to do to realize this? We need to finalize RFID tag standards, agree on data fields, assess and address data management security, assess and address privacy issues. We also need to implement the PDMA pedigree requirements as an interim measure. This will add an effective security

layer, additional security layer, and will provide a real important incentive to move quickly towards electronic authentication.

On RFID standards, EPCglobal is actively working on tag frequency and content standard. We are active participants in that process. We believe it is also premature to consider whether standards should be incorporated into FDA regulations at this point in time.

We need to agree on the data fields. If one looks at the current regulations at 21 CFR 203.50, which are the PDMA data requirements, these are routinely provided on shipping orders from the manufacturer along with its business name and address. Data Element 6, which is simply the subsequent trading partners that accept that package unit, can be added, so the relevant information is already there to build a pedigree. But it's important to agree, particularly in the light of all the state activities, that these are sufficient.

We need to assess and address data management and security. We believe a distributor

database model for storing serialized information may be more secure and certainly there are easy ways to route this in the same way that the Internet routes various URLs to get one to an Internet site. If there is a need for secure electronic signature, we would note that we have already developed one. I would refer you to the SAFE-BioPharma website for further information on that standard.

We need to address and assess patient privacy issues. Patients may be concerned about RFID tags on medicines that these may be read by others, thus compromising confidentiality. EPCglobal has established a Public Policy Steering Committee. We are an active member of that and are working to address patient privacy issues at this point in time.

PhRMA believes that the PDMA pedigree requirements do need to be implemented. Even a paper system will provide an additional and effective deterrent against counterfeiting. We have commented to the Part 15 hearing, I believe, five years ago on this point, that view hasn't changed. While some have argued this is burdensome, it will act as a powerful

incentive to develop electronic solutions.

And I think my time is up, so I'll move on to the next one.

(Applause)

MR. GRAY: I will move this aside, if I can.

CO-CHAIR LUTTER: Our next speaker is Mike Meranda.

MR. GRAY: No.

CO-CHAIR LUTTER: From EP -- no?

DR. GOLDHAMMER: It's John.

CO-CHAIR LUTTER: I'm sorry. Sorry.

MR. GRAY: I would do Mike's speech, but he might be a little upset about that.

CO-CHAIR LUTTER: John Gray from HDMA.

MR. GRAY: Thank you, Randy. Good morning and thank you all for the opportunity to comment on behalf of HDMA and our strong commitment to continued safety, security, efficiency of the American healthcare supply chain. HDMA commends the FDA on the fact that you are holding this hearing today and giving us an opportunity to speak to you.

A little bit about us. HDMA represents the nation's primary full service distribution healthcare distributors. Our 42 members are national and regional companies, as well a family-owned businesses. Each and every day HDMA members safely and efficiently deliver over 9 million healthcare products to over 142,000 pharmacy, hospital, nursing homes and clinics across the United States for patients.

HDMA members serve as a central link and a sophisticated supply chain and as such we have a responsibility to work closely with our supply chain partners to safeguard patient health. We take the mission very seriously of the organization. We support manufacturers, pharmacies and the Government in the ongoing efforts to keep this U.S. supply chain as secure and efficient and highly regulated as it can be.

I would like to stress that every supply chain partner must share in this commitment. No one link in the supply chain can work independently and patients need us to work together to keep the medicine

safe and secure. I can assure you HDMA and our members take the lead each day in advancing business technology, legislative, regulatory solutions to protect patients from the increasing criminal threats to the supply chain.

One of the greatest threats, of course, is what we're here for today, counterfeiting, and it can occur at any point in the supply chain. That is why HDMA has become a driving force for technology-based anti-counterfeiting solutions. HDMA has and will continue to spearhead industry work groups as we have done for many years now in educational initiatives to bring together both top Government and industry officials to discus these problems.

Our goal as an association is to develop and implement business, legislative and regulatory solutions to provide a safe, reliable supply chain for patients 24 hours a day, seven days a week, which is what our members do in their daily work. We work towards this goal every day making constant improvements. We are conducting leading edge research and have worked on pilot projects and provide

educational forums and work toward broad-based solutions.

Already, the HDMA Foundation's, just this past month, well, past year really, ground-breaking research on the cost benefits of adopting EPC in healthcare. This study conducted by A.T. Kearney for the industry found that the leading benefits of EPC/RFID adoption include improve supply chain integrity and patient safety. These benefits increase as more products are tagged at the item level.

Just last year, the HDMA Board approved a proposal for the formation of a Joint Industry Initiative to facilitate progress on supply chain business and technology solutions. HDMA is in discussions with NACDS and manufacturers to develop an industry-wide road map to enhance patient safety, reduce this threat of counterfeiting and support continuous business improvements across our supply chain.

Separately, our research foundation is beginning a new project this month, last two months, with Rutgers University to develop requirements for

data management and data sharing in the healthcare supply chain, which we believe are key elements of this whole EPC/RFID concept. If the technology is in place and the ground rules aren't established, this will not work. So we have to get these kind of ground rules going and the purpose of this research over the next six months is to determine how the industry ought to manage data, what kind of databases, central or decentralized, we ought to be operating and thinking of.

We firmly believe that the standards-based electronic solutions are the best solution providing true track-and-trace capability and not a false sense of security for the consumers. We commend the FDA for working with HDMA and all our partners to explore what's practical and possible for 2007 and beyond. Track-and-trace solutions, you have already heard, are evolving. The industry continues to learn more about this technology and what it can do through pilots and real-world implementation, some of which are beginning to occur.

Armed with a new knowledge, I can say that

your industry, as original goal for implementing track-and-trace by 2007, may have been too optimistic. However, that doesn't diminish our commitment as an organization in an industry to see that the technologies do get uniformly applied as quickly as possible. I applaud the many companies here today who are developing technology solutions to work and increase the supply chain security.

We look forward to continuing to work with these companies to develop true track-and-trace on a consistent basis throughout the business. The standards currently being developed by EPCglobal with input from HDMA and our members and our supply chain partners, that work is going on today and will continue. Technology alternatives may exist now, but many of them so far are company-specific, proprietary and created to address unique business concerns.

In a supply chain where distributors are the center of a system, consisting of hundreds of manufacturers, thousands of different pharmacy settings, an endless array of competing systems will lead simply to technology gridlock. The patients we

serve every day are depending upon us to work together to improve and stay ahead of the criminal counterfeiter and improve the safety of the medicine supply chain.

They will neither tolerate blame across the supply chain nor the development of a plethora of, what I would call, semi-solutions that really don't track, trace or authenticate medicine products. As distributors, we understand and appreciate this. The solutions cannot start in the middle of the supply chain. Progress cannot be pushed along by a single link in the business.

We need the support of the entire supply chain. We must succeed collectively on behalf of patients and with all the trading partners moving toward a uniform system. Progress has been made, but I believe we can do more by uniting around common goals. Let's begin at the beginning with standards-based mass serialization and work with each other towards the end of the supply chain.

Time is now for the industry to come together and agree on uniform consist standards,

privacy safeguards and business solutions that ensure true track-and-trace. I want to emphasize that electronic track-and-trace solutions are just one element of an overall strategy to improve the supply chain security and patient safety.

HDMA has been working for years petitioning states and working with legislators to crack down on the criminals, who seek to obtain distribution licenses. HDMA has been leading the call for stricter, more uniform license standards, stronger regulations, tougher criminal penalties and have been advancing the best business practices among our members to help secure our supply chain.

We have also supporting HDMA the implementation of the final PDMA Act in tandem with necessary improvements that will reflect the 2006 marketplace. This will be a positive step to further insure the continued safe and efficient distribution of healthcare products.

Since Congress enacted the PDMA, the marketplace for medicine has changed dramatically. A vast array of biotechnology and genetic products have

been introduced with hundreds of new companies, thousands of new packages requiring many of them special handling. The delivery models today have also changed and distributors now serve, as I said earlier, more than 142,000 pharmacy settings.

The changes have made the system significantly more complex and require precise regulation to maintain the continued efficient flow of medicines patients need. This supplies an emergency situation, such as hurricanes or earthquakes, but also in every day situations when lifesaving medications need to be delivered just in time to patients. With this in mind, HDMA is committed to working with FDA on the implementation of the final PDMA Rule to address the changes necessary to ensure the continued safe and efficient distribution of medicines to patients nationwide.

We pledge to work with all supply chain colleagues, the NABP, EPCglobal, NACDS and others, PhRMA, and to advance the new and current emerging technologies. We pledge to work also with Congress to strengthen the PDMA statute to aggressively address

the threat of counterfeit products through uniform federal standards for the licensure of wholesale distributors.

In conclusion, the nation's healthcare supply chain is a true partnership. As distributors, we work tirelessly with manufacturers, pharmacy, Government and law enforcement to develop comprehensive anti-counterfeiting solutions to protect patients. We've got to remain vigilant, you've heard it already this morning, in recognizing the new threats of the supply chain. And we must continually implement the new processes to stay ahead of the criminals who attempt to breach existing security systems day in and day out.

No single solution will suffice. Healthcare distributors will continue to advocate for a comprehensive approach, will continue to advocate for stricter, more uniform licensing, adoption of a supply chain technology solution such as EPC/RFID and development of new research, such as the data management research we are working on and best business practices for distributors across the supply

chain.

The safety of our nation depends on each of us, all of us together in this healthcare partnership. Thank you for your attention.

(Applause)

CO-CHAIR LUTTER: Thank you very much, John. Our next speaker is Mike Meranda from EPCglobal.

MR. MERANDA: To comply with Randy's autocratic request, I'm going to perform an act of mercy in the beginning and spend a little bit less time talking about things our organization is doing and get right to the point on what we believe the FDA can do to help support the roll-out of RFID within the healthcare industry.

I do want to, however, start with a couple of comments to let you know the perspective that I bring on behalf of our community. EPCglobal is a technical standards organization focused on developing technical standards for the roll-out of RFID across a broad set of supply chains, which includes, but is not limited to, aerospace, retail, consumer products,

logistics, automotive and a number of other industries.

We also take a very broad view of the geographic coverage and we only build global standards. We also believe that strong standards, standards that can truly deliver the value they promise, come from standards that take into consideration the points of view of every part of the supply chain from manufacturers through distributors to providers and everyone in between. That creates value along the supply chain and in the end, I think, will support in the best possible spirit a safe and secure supply chain.

Our membership has grown quite quickly now. We represent more than 800 companies around the world comprised both of end-users and solution providers, so we have the technology community very involved with this. And I'll tell you a little bit about the contribution that they have made in just a moment.

Specific to the FDA, 30 of the top 40 pharmaceutical manufacturers in the world and 16 of

the top 20 manufacturers in the United States are part of the EPCglobal community and part of the standards development process, through either the top four retail pharmacies, four of the top six supermarket pharmacies representing more than 20,000 locations across the United States are involved in our progress.

Four of the top five medical device companies are part of our community and we have meetings in March for both providers and medical devices talking specifically about bringing them into the community, having them more actively engaged within the standards development process, again supporting that view that broad standards are the ones that contribute most and are most likely to achieve the objective.

EPC and the healthcare community. We continue to marvel, I guess, at the progress that the healthcare industry has made within the EPCglobal community. The community started about 18 months ago and, I think, has already pulled at least even, if not made more progress than the retail community and consumer products in identifying priorities, in

creating standards and then beginning to implement those standards in real-world scenarios.

The community currently is focused on five areas, pedigree management, including pedigree messaging standards, air interface standard for item level tagging, serialization, the ability to decommission tags, and network security. And we have worked with a number of the member of the panels and the FDA on the Unified Pedigree Coalition. We're working on that pedigree standard.

EPC/RFID is the best available technology. Fast read capability, ability to read authentic shipments with no line-of-sight needed. It takes advantage of best practices and data sharing, which we believe is fundamental to being able to serve all interests in an EPC implementation. And industry is actively moving towards standardization culminating, I guess, on a technology demonstration next month and moving very quickly towards implementation activities throughout the year and into next.

EPC has benefitted and the community has benefitted from a very, very strong public/private

partnership that we have with the FDA. And I wish the Commissioner was still here, because I would like to publicly thank the FDA for their very active participation in the standards organization in delivering requirements and feedback directly into the community, both for pilots as well as for our standards activity.

Current implementations prove that this works and you'll hear from some of the companies who are doing that after I sit down. Physics and standard challenges are being overcome. We have come through a pretty quick development of what's called a Gen2 standard for for UHF. What normally can take up to three years in other standards organizations, the standard was created within EPCglobal community within nine months and is already responsible for a price drop in equipment from .50 cents down to below sub .10 cents, very small purchase quantities which enables small and medium sized companies to begin implementing RFID faster than we had anticipated.

Our recommendations. We need to continue to drive towards one pedigree standard absolutely,

that is critical and I think we have made good progress on that. In fact, as another testament, I guess, to the speed with which I believe the industry is moving, that work was completed in just over a couple of months. Far faster, I think, than even the participants thought that that would happen.

Successful implementations in our view focus on what's most important. It is very difficult, I think, and I'm not sure that there are any implementations that we are aware of where there has been a focus for every product from every supplier through every part of the supply chain immediately. That is a very, very difficult thing to accomplish.

So a phased approach and one that focuses on critical drugs versus everything that we believe would be much more successful and would directly solve the problems of counterfeit, would directly solve the problems of a safe and secure supply chain faster.

Work with industry as they learn. There is already a great partnership as tags are being tested on biologics, as work is continuing, we already have a great partnership, but we would encourage that

dialogue to continue. And again, thank you for your support.

Industry needs to continue to implement. That is happening. Many of the companies that are part of our community have more than 10 pilots going at any given time looking at particular issues and share pilot experiences. This is a challenge that we have to our entire community, including aerospace, including retail, including automotive and including logistics and that is share the good learning that is happening.

I will tell you from behind the scenes the most significantly positive thing I can tell you about RFID is that the companies who have invested the most, the companies who have started this the earliest are the ones who continue to invest more, are the ones who continue to implement more, are the ones who are learning more. That is the best testament I think I can give you about the success of this technology and about the promise that it holds to help the FDA deliver a safe and secure supply chain.

Thank you very much and I look forward to

the rest of the day.

(Applause)

CO-CHAIR LUTTER: Thank you, Mike. Our next speaker is Ron Moser from Wal-Mart.

MR. MOSER: Yes, thank you very much. I appreciate the opportunity. Basically, what I want to do is kind of quickly cover where we're at with the RFID technology. We began in 1999 working with the Auto-ID Center with some of the initial trials in testing RFID at the case and pallet level. We began in 2004, we worked with a small group of suppliers with one of our distribution centers to actually see in real-world how this merchandise was actually getting through and how we could actually capture information.

We began expanding that in 2005 with our top 100 suppliers in three DC's with 137 stores. This last January, we brought on our next 200 suppliers, five distribution centers, 494 stores and by the end of this year, beginning in January 2007, our next 300 suppliers and 1,200 of our stores.

Obviously, we feel like the pharmaceutical

industry can share in many of these same successes in being able to use this technology to track products going through the supply chain. To date, we have received 230,000 tag pallets of merchandise, over 9 million cases of tagged products and captured over 90 million EPC read events, which have improved both our in-stock in our shelves in our stores, reduction of excess inventory as well as faster movement of products.

A number of successes utilizing this technology within our own four walls. The reason we feel like this has been successful is through a number of different areas. And primarily, it has been with the collaboration of suppliers and retailers to come with a single industry direction and that was to be tagging cases and pallets of product. We utilize current technology that were in place at the time to be able to generate learnings, so we could move forward, but then take on Gen2 as that technology became available.

So we weren't waiting for the technologies to begin moving. I think that was one of the key

things. The second piece was we started small. We didn't go out and try and handle everything at one time. That was one of the biggest keys, I think, to the success of what we have been able to see with the RFID technology. We took small areas and began implementation in doing those that we could handle and we could actually begin getting quick wins.

Now, that was probably one of the key elements to the success of this. The other thing was we used existing standards. We didn't try and reinvent the wheel and come up with things we weren't already utilizing. That made implementation into our existing systems much easier and quicker to put into place. We required that the requirements or the business requirements drove the technology. We didn't try and make due with what was there. We demanded this was what the business needed and the industry came back with the technology to satisfy those business requirements.

All above, the success also required that we had to come up with ROI and that is that we had to look internally at where we could actually make

improvements that would justify the cost of using this new technology. We didn't look for incentives. We didn't look for those type things. We used what the technology could do to improve the business we were already at.

We feel like for the adoption several different milestones, obviously, need to be in place. Obviously, there does need to be a single direction in where we're going. It seems to be we're going off in a lot of different directions. And initially, we were going in the same direction with the case and pallet level until we went to a single direction, we were actually able to make momentum and begin moving forward.

Business plans that would simplify the implementation, so make sure that we did come up with those areas that actually allowed us to implement quickly and to move forward and to develop those ROIs. Those things that are going to actually help me drive the business and make me want to implement.

Mike had mentioned that the fact that those earlier doctors are the ones that are continuing

to improve and increase, because we see the advantages. A number of companies are seeing those same advantages and are continuing to expand the number of cases, the number of items that are being done. But it had to be done at a pace that everybody could work with.

The unified standards and frequency. Very complicated if we're going to be looking at just changing frequencies to be changing frequencies. We need to look at what's going to work and what does the business require and meet those requirements for the business. Mike also mentioned the universal pedigree. Obviously, the more fragmented, the more different ways that those things have to be done, the harder it is going to be to adopt.

And these are the areas that we feel like need to be addressed in order to achieve the adoption we need. Thank you.

(Applause)

CO-CHAIR LUTTER: Thank you, Ron. Our next speaker is Kathy Smith, Special Assistant for End-to-End Customer Support in the Office of the

Assistant Deputy Undersecretary of Defense.

MS. SMITH: Thank you. Good morning. I wanted to talk to you about what the Department has been doing on supply chain with RFID.

The Department has really capitalized on RFID to track material throughout its supply chain for more than a decade using its active RFID technology, and we have learned many lessons along the way about the importance of integrating the data that comes out of this technology into your systems and taking advantage of the technology's inherent deficiencies in your business processes.

And in 2003 we began to investigate using passive RFID for our supply chain at the case and pallet level, and in 2004 published our final policy. And so when we look at implementing passive RFID across our supply chain, we look at it twofold.

In one case we look at it as creating an end-to-end supply chain by enabling the various nodes along the supply chain to enhance the receiving, shipping and transportation processes working first with our suppliers on the very beginning of the supply

chain in tagging incoming material to the Department, and then in working with the services, the military services and defense agencies, on implementing the rest of the nodes along that supply chain all the way down to the customer sites to create that end-to-end visibility.

In rolling out passive RFID, we have been instrumenting our key distribution depots, first and foremost the two largest depots, one in Susquehanna, Pennsylvania and one is San Joaquin, California. These locations get the majority of our receipts. We are also then starting to instrument the remaining distribution centers in the United States here, as well as some strategic aerial ports that are key to the flow of material overseas.

We have also put the contractual requirements in place to implement tagging for incoming material. In 2005 the implementation, the clause, was created to insert in contracts requiring tagging of clothing and textiles, personal demand items, our weapons systems' spare and repair parts and prepackaged rations like the meals ready to eat that

you see the soldiers eating.

And all of those were key commodities that we needed for the operations that we're doing right now, and so we wanted to start out with those when they are being shipped to the two largest depots in Susquehanna and San Joaquin, California. So as of November of this past year, the clause is starting to be inserted in contracts as we speak on requiring tagging of this type of material.

For 2006 we're looking at adding additional commodities. We'll be adding packaged petroleum, construction/barrier equipment, medical materials when they are shipped to the remaining distribution centers and those strategic aerial ports.

It's important to note that pharmaceuticals, biologicals and reagents will not be included in the 2000 Defense Federal Acquisition Regulation Clause. We're anticipating they will be in the 2007 clause. We wanted to do this in phases to allow us to get ourselves instrumented as well as our supplier community to get up and running with the technology. And we have been providing training to

our contracting community, so we can help one another on the negotiation process.

We have also been working with the military services and defense agencies to build what we call the end-to-end supply chain as quickly as we can by focusing on where the majority of material coming out of those depots, from Susquehanna and San Joaquin, the locations of where they are being shipped to. We're then instrumenting those locations and then the location after that until we get all the way down to the customer sites over time.

And so we're working to synchronize all of the military departments' plans because, as you can imagine, we have thousands of bases and locations, customer locations, across the world and we want to work in a methodical fashion to build that end-to-end supply chain.

The next phase or what we're also focusing on is an RF enabling the internal processes at these individual nodes, so looking at the distribution center itself, how can I take advantage within that facility of using passive RFID to stow the material,

to make proof of delivery when you make deliveries onto a base. And so we're looking internally at distribution centers, at customer sites, at distribution centers within the theater, and each of these give us an opportunity for taking more advantage of this technology in the supply chain and we have already been doing some of these.

In fact, we have early implementations that are very promising in this area. At the Norfolk Ocean Terminal, they looked internally at their processing for receiving material and for loading large containers for onward shipment. And in using passive RFID, we're able to gain a 39 percent time savings in doing that job, just by having the technology and using it to track the material through the facility and to ensure it gets distributed to the right location.

One of our ships, the USS Nassau, also had the passive RFID, was being used for the receiving and sorting process. They have a challenge. As you can imagine, in about a seven day time frame they are loading up these ships for a six month deployment,

5,000 people, enough food, enough toiletries, enough medical supplies, enough spare and repair parts for all the airplanes and helicopters that they are taking with them.

So you can imagine what loading day looks like at one of these facilities. I had a picture and I regret that I didn't put it in here. It's really quite challenging. So they were able to, by taking that box and placing it on like a smart table, it was automatically reading what that box is and telling them exactly which storeroom, because there are many storerooms on the ship, which storeroom that box had to go to. And they could actually reduce the number of people they need to do the receiving process.

So there is a lot of exciting things going on even internal to our nodes. The Advanced Traceability and Control Transportation System is a supply chain application. These are engines that are coming back from Iraq that need repair and they are being tracked all the way back into the United States and to the repair facility.

And simply by adding a passive RFID code

in Iraq, when it came back and was automatically collected through the passive RFID portal, we were able to identify over 350 shipments that we didn't have a proof of delivery on. We had them. We didn't have to worry about losing them, but they were available for use that much quicker because we were able to hands free know that they had been received at that location.

So the way ahead for us is to publish the next phase of the contractual requirement for 2006. We're working with our Defense Acquisition Regulation Council and OMB on putting that rule out. We're working with the services and agencies on instrumenting those nodes and in creating that supply chain.

We want to keep in step with FDA as they continue to do some testing on the biologicals and reagents, so we can keep in step with our Roll-Out Plan and that that's in concert with their desires. And we want to continue to provide education and outreach to all of our suppliers. Thanks very much for your attention.

(Applause)

CO-CHAIR LUTTER: Thank you very much. Our next speaker is Steve Perlowski from the National Association of Chain Drug Stores.

MR. PERLOWSKI: Good morning and thank you for allowing me to be here with you today. During my presentation -- oops, this is the wrong presentation. I'm sorry. I get to speak twice. Aren't you all lucky?

Let me start with, and I will start going through, NACDS, the National Association of Chain Drug Stores. We represent companies that own and operate four or more pharmacies across the nation. We have over 200 companies that operate over 35,000 pharmacies across the United States.

As we look at today's question, it is important to share with you the action and progress that the industry, the pharmaceutical supply chain, has taken since the FDA Anti-Counterfeit Task Force was formed.

In July of 2003, then FDA Commissioner Mark McClellan called NACDS president, Craig Fuller,

and invited him to serve as a resource to this Task Force by pulling together a coalition of our members to provide recommendations from the industry about how we thought the FDA could meaningfully impact and reduce the incidence of counterfeit pharmaceuticals in the domestic supply chain.

Through the endorsement and involvement of the NACDS Leadership Council, a group of presidents and CEOs from retailers, distributors and pharmaceutical manufacturers and their staffs, NACDS hired Accenture to lead us through an exercise that sought to identify business practices, technology, prevention measures and regulatory and enforcement measures that the industry could adopt to address the economic incentives of counterfeiters and tighten regulatory loopholes that allow these criminals to operate.

Our report made numerous suggestions including these listed here. In the sake of time, I won't go through them. What has been done since your report was issued? Over the past two years the industry has moved forward on a number of these

initiatives. One of the largest changes involve the domestic distribution industry's move away from horizontal trading among wholesalers.

Notability, each of the country's three largest distributors have made public announcements during the past year on this matter. Individual pharmaceutical manufacturers have increased their vigilance in policing their own operations and to whom they are selling products. The SEC's actions during the past few years have also had a positive impact. Manufacturers now limit the amount of product in the supply chain due to sales recognition concerns, which has led to less inventory being traded in the secondary market.

Many pharmacies, both chain and independent, have made changes to their purchasing practices in order to ensure the integrity of the products that they are receiving and ultimately dispensing to their patients.

Most recently, some pharmacies are requiring certifications from their wholesale distributors stating that the distributor purchases

all products directly from the manufacturer. This certification all but eliminates the opportunity for counterfeit product to enter the supply chain.

During the past few years, as Carmen has said, numerous states have enacted legislation to help ensure the integrity of the prescription drug supply. One of the hallmarks and common elements of these state level initiatives is strengthening the wholesale distributor licensing requirements. These requirements have made a tremendous impact in removing unscrupulous wholesalers from operating within those states.

These steps taken by industry combined with some state level initiatives, state level legislative activities already in progress, are practical and immediate solutions to ensure the integrity of the legitimate supply chain. And, as the Commissioner mentioned this morning, the number of counterfeit cases has dropped over the past few years.

That doesn't mean we should not continue to move forward and look at emerging technologies. And, also, the industry has been actively engaged in

learning about and participating in the development of standards for using RFID in the pharmaceutical supply chain and piloting this technology.

NACDS and our members have been involved in a number of these efforts. We have seen the promise of the technology and we have seen some of the shortcomings. We have seen it evolve over the past two years and we look forward to playing a part in the development of this technology to a point where it can serve as a practical solution.

NACDS was a participant in the first multi-company pilot called Jump Start. This project was led by Accenture and included nine manufacturers, two distributors and three retailers. We would also like to point out that we could not have gotten as far with the pilot as we did if it were not for the assistance and advice of the FDA.

Our objective was to test the technology in a real world environment and to run a series of simulations to determine if we could, in fact, detect counterfeit product in the supply chain. Towards the end of the pilot, the study concluded that while we

could simulate an infrastructure to identify counterfeit products, the technology, both tags and readers, were not mature enough or reliable enough to be used at that time.

Perhaps the real benefit of the pilot was that it continued to have members from all levels of the supply chain talking collaboratively about making the supply chain more secure. As this pilot ended, EPCglobal was gearing up its interest in the pharmaceutical industry having created the Health Care and Life Sciences Business Action Group. This is the organization with the responsibility for developing RFID standards.

NACDS and our members have been actively engaged with EPCglobal. We are supportive of their efforts and encourage our members to participate in their activities. There are a variety of obstacles, however, to widespread adoption, technical, operational and financial.

From a technical perspective, standards have not yet been developed, although the process is moving forward with EPCglobal and other industry

stakeholders. To date there has not been any RFID solution that has been widely tested throughout the supply chain nor have we demonstrated the interoperability of any solution within the supply chain.

>From an operational perspective, there are a variety of business and trading partner issues, such as the utilization of the EPC, inclusion of the NDC in that number, data ownership, sharing of data and access to data. In addition, there is a large concern regarding the ability to adopt such a universal change in processes given the sheer number of parties within the supply chain, as John Gray mentioned earlier, including manufacturers, wholesalers and retailers.

Finally, the financial implications of widespread adoption of RFID are largely unknown. Considering this is still emerging technology, many of the costs have yet to be fully defined, especially in light of the size of this potential implementation. Much of the financial burden for paying for this technology will rest with wholesalers and community

pharmacies, both of which have little, if any, opportunity to offset large investments due to existing contractual relationships and continued reductions in reimbursement rates for pharmaceuticals.

We have learned over the past few years that by collaborating across the industry in ways we haven't in the past, we have made great progress in making our supply chain safer and more secure. We also know much more about the technology today and its current limitations than we did two years ago.

We also need to develop standards that facilitate adoption by recognizing the unique needs of each of the participants in the supply chain and that these solutions have to be affordable. The FDA should be applauded for the leadership it has shown in raising awareness of counterfeiting and helping to shape new approaches to enhance the security of the supply chain. It is important that you remain active in the development of these standards.

The biggest danger that American consumers face with respect to counterfeit drugs is from purchasing their medicines from international

pharmacies filling prescriptions for U.S. consumers. Unregulated mail order and Internet pharmacies are operating illegally today and in many cases, as reported in the press, are trading in unsafe counterfeit goods.

Additional regulatory and enforcement oversight is needed with these groups for they will not pay attention to any additional regulations as evidenced by the fact that they don't pay attention to the current regulations.

In summary, a tremendous amount of work has been done on this topic and to date we have come to understand that while this technology may hold promise in the future, there is still significant time to be invested in understanding its potential and determining how to achieve widespread adoption. In the meantime, the legitimate supply chain has implemented a number of initiatives to continue to ensure the integrity of the pharmaceutical supply chain.

For all these reasons, we ask the FDA not only to consider extending the effective date for the

relevant portions of the PDMA, but also revise the final rule to consider these initiatives. Thank you.

(Applause)

CO-CHAIR LUTTER: Thank you very much. Our next speaker is Sara Radcliffe from the Biotechnology Industry Association.

MS. RADCLIFFE: Good morning. My name is Sara Radcliffe. I am Managing Director of Science and Regulatory at BIO, which is the Biotechnology Industry Organization, and we appreciate the opportunity to speak this morning. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in 33 other nations.

Counterfeit pharmaceuticals are a threat to the public health. BIO commends FDA for its continued commitment to securing the nation's drug supply against counterfeit drugs and biologics. The American drug distribution system is the most secure in the world and, thanks to the FDA, drug manufacturers and distributors and patients have high confidence that the drugs that they are prescribed are

safe and efficacious.

Some estimates place the proportion of counterfeit drugs in foreign markets as high as 10 percent while counterfeit products in the U.S. distribution system are rare. Nevertheless, the presence of any amount of fake, adulterated, subpotent or superpotent drugs in the American pharmaceutical distribution system poses a threat to the public health. These dangers can be even greater with counterfeit or adulterated biologic drugs, which must often be injected or infused directly into a patient's bloodstream.

In recent years there has been a proliferation of counterfeiting and counterfeiters have become increasingly sophisticated at mimicking pharmaceutical packaging and labels, as well as overt and covert anti-counterfeiting technologies.

Pharmaceutical supply experts are in a technological arms race to stay a step ahead of counterfeiters and industry has taken productive steps to secure drug products with holograms, color-shifting dyes and numerous other anti-counterfeiting

technologies. However, there is more that Government and industry can do to secure the drug supply and ensure patient safety.

Track-and-trace technologies offer tangible benefits. First of all, pharmaceutical product verification. Because the U.S. drug distribution system is composed of multiple points of entry for pharmaceutical products before they reach the patient, including sellers and purchasers, repackers, distributors, etcetera, there are also multiple opportunities for bad actors to introduce counterfeit drugs that then are passed down the supply chain to patients.

Biopharmaceutical companies neither produce counterfeit drugs nor do we have control over the entry points and the secondary supply chain. However, we recognize that these vulnerabilities can be reduced by either shortening the supply chain or making it transparent. Electronic track-and-trace technology, including RFID, could help create this transparency, disclosing the origin and distribution history of drug products. BIO supports its use within

the drug distribution system in a responsible manner.

First, and of foremost importance to the patients that the biotechnology industry ultimately serves, BIO believes that fully implemented electronic tracking from the manufacturer to the pharmacist will reduce the number of counterfeit drugs that enter the distribution system. If products carry serialized machine-readable tags, their authenticity can be verified through the electronic pedigree at every node of distribution. These multiple verification steps help to protect patients.

Also, improved supply chain management. RFID or similar technology can create more efficient supply chain management. In theory, with RFID tags and scanners deployed throughout the distribution channel, a company can track its products more effectively and efficiently with fewer lost, diverted or stolen products.

Track-and-trace technologies offer tangible benefits also in terms of potential public health emergency responses. Improved product tracking capability would allow greater ability to trace

biopharmaceutical products during distribution so they can be diverted to meet emerging medical needs during a public health emergency or product shortage.

However, obstacles have slowed RFID adoption. Technological limitations and business process integration concerns play a role. RFID technology is promising and the tags and readers are improving, but physical, technological and business practice limitations persist. The materials to which the tag is affixed or those in proximity to the tag, such as liquids or metals, can affect readability and negate the advantage of not requiring line-of-sight for readings.

Further, poor reliability of tags and inaccuracy of scanning can hamper product handling efficiencies and security. We also are concerned about factors that can mask or disable the RFID tags, such as copper, aluminum foil or static discharge. Presently, it is unclear how RFID technology will be integrated in many individual companies' business processes.

While FDA should encourage the use of RFID

technology, BIO believes a full complement of product-appropriate technologies must be deployed for full security of the drug supply. The door should be left open for alternative technologies to RFID. Secondly, there is a need for uniform adoption among distribution partners. Unless all parts of the distribution chain, including pharmacies, use track-and-trace technology, the system will not succeed.

Partial implementation may confer some benefit to patients and the distribution system as a whole, but BIO believes that a reasonably evolved track-and-trace infrastructure should be established along the supply chain before manufacturers are expected to affix machine-readable tags to their products.

Third, concerns regarding biological stability. Biotechnology products are complex. They are protein-based biologics that are produced by living systems and they are particularly vulnerable to changes in their environment. For instance, most biopharmaceuticals must be refrigerated at all times before being administered to prevent fundamental

changes that can render the drug ineffective or unsafe.

Some products also must be kept at a certain pH level. Others must be kept out of direct sunlight. To date there is not a complete understanding of how RFID tags and readers may affect the stability of biological products during distribution. Many companies have been hesitant to adopt the technology until these questions are answered.

Recognizing these unique concerns, FDA has begun research with the Center for Devices and Radiological Health, the Product Quality Research Institute and the Auto-ID Laboratories to evaluate the effect of RFID tags on biological product stability, liquid temperatures and storage conditions. BIO applauds FDA for initiating this research and we look forward to reviewing the results. BIO also encourages research to evaluate the use of RFID technology to monitor environmental exposures and the integrity of the cold chain.

Repackaging. Although most biologic drugs

are not regularly repackaged, repackaging does take place in the drug distribution chains and presents unique challenges for successful RFID implementation. No matter at what level of packaging the RFID is added, they are still tracking the package at best and may be discarded intentionally or unintentionally during routine repackaging. Additionally, without a clear mechanism for assuring that the RFID device is destroyed at its endpoint, the tag could be recycled and reenter the supply chain.

Finally, cost. A significant barrier to adoption, particularly for smaller biotechnology companies, has been the up front capital investment necessary to employ an RFID system. While the cost of implementing RFID appears to be dropping, wholesale investment in the technology is premature for many drug products such as for products that rarely are counterfeited.

Furthermore, unlike small molecule drugs which often are distributed through large wholesale distributors, biopharmaceuticals are more frequently distributed through small specialty distribution

channels that lack the economies of scale to maximize track-and-trace cost efficiency.

I would like to just talk about BIO's principles for track-and-trace implementation. First, patient safety is obviously the first priority. The biotechnology industry has developed more than 200 drugs and vaccines that have helped millions of people worldwide. Improving the lives and well-being of patients is our first priority. The adoption of electronic track-and-trace technology should be supported in a way that enhances patient safety and public health.

Second, high standards for supply chain integrity must be preserved. BIO agrees that a truly closed system would be the primary deterrent to counterfeit medicines entering the distribution system. Like the discovery and manufacturing of biotech products, the distribution of biologics is complex and technical.

The industry working with regulators should use a high degree of care and planning in the introduction of any massive distribution changes, such

as the adoption of RFID and/or serialization. BIO opposes any regulatory requirements that would force premature adoption of developing technologies or unproven systems.

Third, there is no single technological solution to counterfeits. There are a number of technologies that are currently available to secure the drug supply and other promising technologies are under development. Offering the industry a multiplicity of approaches recognizes the variations among drug products and between drugs and biological products. Deploying product-appropriate technologies will best challenge those who want to counterfeit prescription drugs.

Fourth, electronic pedigrees should be fully implemented. BIO has previously stated its support for the FDA's full implementation of 21 CFR 203.50. This rule, which has been on hold for several years, would require paper pedigrees for pharmaceutical products from which it would be possible to document the source of the product, the numbers and kinds of transactions between the initial

sale by the manufacturer and the final purchase by the end-user and other key information.

However, new information technologies can decrease the logistical and administrative burden created by paper pedigrees. And, therefore, BIO supports harmonized electronic pedigree standards. In terms of the role of FDA, FDA can accelerate the use of track-and-trace technology by providing a forum, such as the forum today, for information sharing among industry stakeholders in order to highlight best practices and promising new technologies.

Finally, we want to note that prescription drug importation invites criminal counterfeiting. We support FDA's opposition to drug importation proposals that would open up America's borders to unsafe or illicit pharmaceutical products. We believe it is crucial for FDA not only to retain its authority to control the entry of pharmaceutical products into the United States, but also to receive the resources it needs to enforce the law.

BIO believes that a number of national and state actions and statements are unfortunately

signaling that the United States is willing to become a marketplace for illicit prescription drug traffickers. We recommend FDA continue its opposition to efforts that weaken our border controls and invite criminal elements into our pharmaceutical distribution system.

In keeping with the nine minute rule, I spoke fast. So if anybody wants our slides or our statement, please, do contact me at sradcliffe@bio.org. Thanks.

(Applause)

CO-CHAIR GLAVIN: Thank you all of the panel members for some really good presentations. I think you have set a standard for the rest of the two days, both in the quality of your presentations and certainly in keeping within the time line even when it was very autocratically shortened at the last moment.

I am going to take advantage of my position as a Co-Chair to ask the first question and then I'm going to let the rest of the Committee, Task Force, ask you some questions.

But I would like to ask, and I would like

to address this to Sara Radcliffe and to John Gray, to give us an idea of your best estimate of the scope of the counterfeit problem in this country and what data sources might exist out there to help us all get a better handle on that? And I will ask John first to give you a chance to catch your breath since you just sat down and then ask Sara.

MR. GRAY: The data sources we -- at HDMA we do our own sort of industry fact book information every year, have an annual survey of the business and the members and manufacturers, and I will have to honestly tell you I got to check if we actually track counterfeiting data. I suspect we do and do report on it, but my guess is we get most of that -- data that I have seen published is information that you all release as far as the number of cases that come out.

Obviously, we get it off of media reports. We as an association, unless I'm mistaken, I don't think we actually have that data, but I will have to get back to you about that. We may. As I say, we do a very comprehensive survey, but it's more a survey of business practices and procedures and what's going on

in the industry marketplace sizes, and I can't sit here and tell you with specificity whether or not we actually track the number of cases or where we get that data from. It probably, as I say, comes from you all.

CO-CHAIR GLAVIN: Okay. Thank you. Sara?

MS. RADCLIFFE: BIO does not track in any way the frequency of counterfeiting, so I am relying in my statement on sort of public reports. But I think it is fairly well-recognized that the incidence of counterfeits in the United States is still fairly low. I have seen estimates under 1 percent versus in other countries, as I mentioned, 10 percent or more.

CO-CHAIR GLAVIN: Thank you. All right. Task Force Members? Yes?

MR. McCONAGHA: Good morning. I would address this question to Mr. Gray, please. Regarding the adoption or implementation of RFID, Mr. Goldhammer made reference to the need for kind of an information infrastructure and you also referenced --

MR. GRAY: Right.

MR. McCONAGHA: -- the issue of kind of a

decentralized versus a centralized database.

MR. GRAY: Correct.

MR. McCONAGHA: For kind of implementing an E-Pedigree system. And I was wondering if you could, please, just elaborate for us your sense of the merits of a decentralized versus centralized database.

MR. GRAY: Sure.

MR. McCONAGHA: And with that in mind, here is part two of the question. I'm curious if it's your sense that the industry really could establish a meaningful E-Pedigree without a centralized database.

MR. GRAY: A meaningful E-Pedigree?

MR. McCONAGHA: Yes, or just --

MR. GRAY: Oh, yes.

MR. McCONAGHA: -- you know, some kind of an electronic track-and-trace system that is really different from the current paper pedigree system in the absence of a centralized database.

MR. GRAY: Well, I have worked in two other industries that have gone through this process in terms of when technology enters the system. This started originally with linear bar coding back in the

'70s and it migrated into the '90s with the development of other forms of coding, and even to the point of data transfer among trading partners regarding simple sales of product and product sales movement and financial information.

All those industries have gone through the same struggle. What do you do with the data? There is data that will be collected at the pharmacy level. There is data that will be collected inbound and outbound at the distributor and there is data generated at the point of manufacture and shipment from the manufacturer.

All of those discreet trading partners have special needs for that data. They also don't need that data in the same form or format. A manufacturer will want data that as in the industry we'll call it scrub data. Companies like A.C. Nielson and Information Resources, Inc. will take data from retailers, scrub that data for particular manufacturer clients who will use it in their marketing and sales departments to understand what the product is doing.

I have sat through numerous discussions of

whether or not databases ought to be centralized or decentralized across those supply chains. In terms of access to the data, who has access to the data, does the pharmacy get unlimited access, the distributor? Does the manufacturer? Does the manufacturer only get access to the data regarding their product and not others? That goes with distributors as well as pharmacies.

You know, whether it's centralized or decentralized depends upon almost whether you like rain or you like sunny days. I have heard arguments on both sides of the case. I know Mike can probably speak to his organization. UCCglobal worked on an initiative called UCCnet for a number of years, which was again envisioned originally as a centralized database for tracking product information.

There were product catalogs included in that where you, as a manufacturer, can go in and look up items all across the supply chain and look at all aspects of those items, price, shipping information, packaging design and what have you. Industries have struggled with this. I would not sit here and even

pretend to say whether this industry should have a central or decentralization database.

As I said in my speech, we have launched a study. When I came into this industry 24 months ago and I saw this going on, the first problem I saw was this technology is great, folks, but when the technology is ready and you go to flip the switch and the rules of engagement are not set out between the manufacturer, distributor and the pharmacy, the movement of the data will not happen.

I will assure you all trading partners will sit and wait until there are understandable rules as far as access to data, what types of data will flow and where does the data reside? Should it be centralized? Should it be decentralized? And that is the purpose of the work we're doing at Rutgers University now. We're going to take about a six month look at this, because I personally, this is from my own experience, we have got to get the data management element done.

I am not, frankly, worried about the technology. It is going to take care of itself and I

agree with Mike. From my experience, this industry is ahead of the game compared to where it began because I was with the CPG industry when EPC began being talked about at the CEO level in the late 1990s. Pharmaceuticals was not there. They weren't even in the room when those discussions started.

So they have a good three to four year leap on it. I think Mike will agree, what this industry has done in a very short period of time is really nothing short of remarkable. Is it 2007? Probably not 100 percent implementation, but we have done a good job.

But the next key step is the technology is going to get there, but what are going to be, as I say, the rules of engagement? How is data going to flow? Should it be centralized? Should it be a Government database? Well, frankly, what access would the FDA have to a database like this?

And what about decentralized databases? Well, how many can you functionally manage? Do you have them privately owned by for-profit companies because, believe me, there are companies in the

database management system who would love to get their hands on this kind of data and charge for it.

So we have got to examine all of those aspects as an industry going forward. And I will tell you that makes the technology look simple and it has got to be done. So we have started that study now and the work with Rutgers has been begun in the last 30 days where we're going to try to get something out to the industry by the fall with an assessment of how we ought to go about managing it.

So I'm hoping, I know NACDS is probably going to be joining us on this Task Force, I'm hoping PhRMA and others can get it on it and we can talk as an industry. All right, folks, when we go to flip on these lights in the morning and EPC becomes real, what are we going to do with the information and what are the expectations?

CO-CHAIR GLAVIN: Jeff, I think you --

MR. MERANDA: May I make a short comment to that, very short?

CO-CHAIR GLAVIN: Sure.

MR. MERANDA: Thank you. Two very short

comments. The first is it's a great question because our very strong belief is that the value in implementing RFID primarily and substantially will come from exchanging data with trading partners, exchanging data with regulatory agencies. There are advantages to the technology. We have talked about line-of-sight. We have talked about fast moving.

That is all absolutely true, but the core of the underlying value behind this is creating visibility for the movement of things from one place to another whether you're coming at it from a law enforcement perspective, from a regulatory perspective, from a supply chain perspective, so that it's very easy in all these dialogues, this dialogue, it's very easy to get swept up into talking about tags and readers and all of that stuff, but the value is in sharing data.

Second, we believe very strongly that distributed -- there are several kind of code words for this, whether it's a federated data model or distributed data or services that are distributed and come together or a single, you know, that whole

approach we believe in the end will be significantly faster adopted, will be less expensive and will distribute the costs throughout an industry more efficiently than a single approach up front.

And we could spend days talking about the details behind that and we're very happy to engage in kind of ongoing dialogue on that point.

CO-CHAIR GLAVIN: I'm going to move on to a question from Jeff Shuren.

DR. SHUREN: This is directed to John Gray. Sorry, John.

MR. GRAY: I'll just leave the microphone here.

DR. SHUREN: We'll let you off maybe on the next question.

MR. GRAY: Okay.

DR. SHUREN: You had said that HDMA supports lifting the stay on FDA's PDMA pedigree rule.

MR. GRAY: Correct.

DR. SHUREN: You had also said that it's important that every member of the supply chain must work together.

MR. GRAY: Correct.

DR. SHUREN: If we were to lift the stay, does HDMA support the application of pedigree requirements, whether they would be paper or now electronic, for all members in the supply chain and, if not, why not?

MR. GRAY: Well, that is a very complex question because within the PDMA whether you pass pedigree or not depends on whether you're an EDR or a non-EDR and that is a conversation I know we're going to get into in detail tomorrow.

Our position on this is indicated very briefly, albeit very quickly, in my speech. We have looked at this and our members have said it's time to move on, time to get on with this and make the PDMA become a reality. Our assessment is this and this is what we asked for, your consideration going forward. There are elements. The supply chain in 2006 is not the supply chain of 1999 or 1988.

There are many new products. The bio is a good example of products that have come in, as indicated, that don't go through distribution the way

products used to go through, from A to B to C. There are variations on where the product dispensing sites--where they go.

There is complexity in that and there is complexity in how the product needs to be handled and how it has to be sold, and there have become increasingly the indications of very different structures from the manufacturers and how they want to go to market with their products, whether they go to all distributors or only some distributors or what have you. And the complexities in and around that I think are worthy of inspection as to whether or not in various circumstance pedigrees should or shouldn't be passed.

I mean, to get into that here would be an all day discussion, but I think that's what we're asking, the FDA to sit with us and look at some of the variations that have arisen now in the supply chain that are otherwise very legitimate ways product flows through this business today, under today's marketplace conditions, very legitimate, nothing nefarious or untoward about it, and that applying the PDMA as

currently written in sort of a cookie cutter approach from '88 might not fit current marketplaces.

I think we got to take a look at it and make sure that it will fit all these circumstances, because what we don't want to have happen is cut off some discreet supply channels that trade differently, quite frankly, than maybe some of the normal, you know, mainstream product flow.

And our ask here is, yes, lift that stay. The mainstream can cope with it, but we want to look at those other examples and make sure we're not shutting down very legitimate business supply chains that are currently developing, because it's not a monolithic supply chain. The distribution business is a complex business, whether it's pharmaceutical, food or consumer goods.

It is a very complex way product moves around this country and the things that have evolved particularly in the last few years with new items and new classes of trade and new dispensing sites I think warrants a re-look of the PDMA rule, as written, and see if we can accommodate some of those variations.

DR. SHUREN: Can I ask just one quick follow-up?

MR. GRAY: Sure.

DR. SHUREN: Just putting aside PDMA requirements, I know you're making a point that there may be certain circumstances where maybe requiring a pedigree for certain members of the supply chain wouldn't make sense because it may impede access, etcetera.

MR. GRAY: Correct.

DR. SHUREN: Do you think there would be situations, putting aside again PDMA requirements, where there is a need for having a pedigree for all members in the supply chain in certain circumstances?

MR. GRAY: For all members of the supply chain? I would probably -- that is an awfully broad statement because not all distributors are the same either. Some are doing specialty work. Some are doing broad line full service distribution. And I would probably have to say I don't think so.

I think you would have to look at the special cases because, again, as indicated by BIO, it

has evolved and it has become far more sophisticated than it was even 20 years ago. I would hesitate here to say that.

CO-CHAIR GLAVIN: I'm going to go to Steve and then to Randy and, if time allows, to --

DR. BERNSTEIN: Ilisa.

CO-CHAIR GLAVIN: Ilisa. Oh, and Ilisa. We may run out of time, but we'll get more panels and more questions.

MR. SILVERMAN: I'll direct this question to John and Alan on the one hand and to Carmen on the other. Sitting here this morning it seems like, in some respects, there's two different perspectives.

On the one hand there is the view that RFID and electronic track-and-trace is promising down the road, but at this point there are a sufficient number of high level questions and issues that need to be resolved as a predicate matter that it's not ready to be rolled out in any kind of a meaningful way at least right now.

On the other hand there seems to be the view that RFID, while it may not be the only solution

and may not be as mature as it will become, is sufficiently useful right now to begin introducing it in a phased approach.

I'm curious whether or not you share the view that there are these two different perspectives and, if so, is there any way to bridge the gap between those perspectives? And to the extent that you hold the view that RFID is simply not ready for widespread introduction at this time, if FDA lifts the PDMA stay later this year, does that mean that RFID or other forms of electronic track-and-trace are not viable options for satisfying the pedigree requirement?

DR. GOLDHAMMER: I'll go first. I think when we looked at this a year ago when we were working towards preparing our paper, that is why we made the statement of providing an option for using 2D bar codes and RFID, because it might provide a better glide path.

Obviously, bar codes require line-of-sight reading, which RFID chips don't. In an ideal world we would love to have everything tagged with RFID. At the time we wrote the paper, the business -- you

couldn't argue a business case, at least that's what our companies were telling us, to move forward to full-fledged RFID.

I think the other critical issue and, you know, notably absent at this meeting today, is what do we do about generic drugs? I think over 55 percent of the scripts that get written today are for generic drugs. Are we expecting to tag and build this similar infrastructure at the manufacturing level for all of those as well? So there are a number of policy decisions that need to be made.

I think what we were looking at is if we can do this as a phased-in approach, we can solve the technological problems and I think the problems that John solved, which are probably of a far greater magnitude in the end. That is the data sharing to resolve those as well.

DR. CATIZONE: Steve, I would agree with what you're saying. There are two different camps here. And to speak quite candidly, the paper pedigree system is a wish and a prayer and it's worthless in most instances. So agreeing with John Gray, to lift

the stay to advance the concepts would be important, but to try to implement the concepts in the manner they were first proposed back in 1999 would not be effective.

We have moved beyond the ADR concept. We have moved beyond the list of susceptible drug products and we have conceded in a sense to the industry to allow for normal distribution recognizing that a paper pedigree system is ineffective and is not going to curtail counterfeiting like RFID technology would.

We're asking for implementation of any form of RFID as a starting point, so that people begin the process and move forward rather than delaying implementation until the system can be built entirely, which will delay this process until who knows when and continue a system that is worthless and unsafe for consumers.

MR. GRAY: I would certainly echo that on paper pedigree. You know, it's not worth the paper its written on, quite frankly. You know, any industry today in the 21st century looking at either providing

security or safety and looking at a paper-based solution is pretty -- actually it doesn't even pass the laugh test, quite honestly.

So we really have to move on and look at the existing technologies and that is why our approach is -- I completely agree with Carmen and Alan. A phased-in approach is a good approach. Let's start there, but let's combine it with some of the things I have been saying.

You know, it's not only about the drugs itself, but let's strengthen licensing requirements. Let's keep the criminals out of the supply chain. Let's also emphasize the best business practices in terms of inspections, in terms of criminal background checks on individuals. I mean, there is a multitude of things that go into this, that it's not black and white.

It's not EPC or nothing. It can be EPC phased-in with other activities that will enhance the overall perspective of, you know, the whole safety of the supply chain. So there's a lot of things that can be done in concert with this phased-in approach of

EPC. It's not just EPC and we'll just hope for the best. It's EPC with other things, due diligence that needs to be done by the whole supply chain. And so I'm in agreement here with my colleagues.

MR. PERLOWSKI: >From a retail pharmacy perspective, I guess our point of view is if the requirement is for pedigree down to the pharmacy, having just a few items on a list doesn't work. We have to have the -- in that case, we would have to have the total investment in the infrastructure on day one, and that is not just something our industry can afford to do right now.

If you look at a phased-in approach by items, a point of view would be to look in, you know, move that pedigree as far up the supply chain and then use a certification program between the pharmacy and its wholesaler or look at from the time -- if the shipment is going to a retailer's distribution center, which a number of pharmaceuticals do do, then that's where it stops. You know, keep it as far upstream as possible.

There is not enough money, at this point

in time, or time on the part of the people staffing the pharmacy to jump this far into the game, you know, sooner rather than later.

CO-CHAIR GLAVIN: I'm going to go to Randy and then to Toni and then Ilisa.

CO-CHAIR LUTTER: Two quick questions to Kathy Smith of DoD. You mentioned that in 2007 there would be a procurement guidance, I guess, pertaining to pharmaceuticals and biologics and RFID chips. Would that be at the level of the pallet case or bottle?

And my second question to Ron Moser of Wal-Mart is that you mentioned extensively your experience with RFID at Wal-Mart, which I think is potentially quite illuminating for all of us, because you have done it earlier and your scope is much broader. But I didn't hear you say whether you have plans to use chips at the level of the individual package, the bottle or whether -- so my question to you is what are those plans, if any?

In particular, would they only be for controlled substances or for pharmaceuticals product

from abroad? Maybe you can take those in turn. Thank you.

MS. SMITH: Our requirement in 2007 is again at the case pallet level. It would be at the shipping container having an RFID tag on the shipping container. If it happens to be a larger item like a TV and it's one little box in a shipping container, it would be a one-for-one, but for pharmaceuticals, biologicals, it would be case and pallet for DoD for 2007.

CO-CHAIR LUTTER: And would you have plans to go to a lower level than that or is that not yet contemplated?

MS. SMITH: Ultimately, we will be going to the lower level. We're going to be focusing on what we call our unique identification items. They are items that cost more than $5,000 or are flight safety critical items, critical weapons system repair parts and that kind of thing. And so we would be focusing on again the item packaging for those items and that's -- but that's further down the road.

MR. MOSER: As far as pharmaceuticals go,

currently we do have some controlled drugs that are currently being tagged at bottle level. It's a fairly small quantity. Only today about four suppliers and about 20, roughly 20 SKUs that are actually being tagged at the bottle level. Those are currently at the 900 MHz frequency that we are doing.

For the most part, we are able to read the contents of those packages. Our plans will be to be able to monitor shipments going from our distribution centers to our stores for verification of the contents before they actually open the cartons for product that's in there. It's still a fairly small percentage, at this point, in order to achieve 100 percent of what's actually being shipped to our individual stores, but that's where we see going forward, that we will be using that technology for.

CO-CHAIR LUTTER: And do you have plans to extend the use of RFID chips at the individual bottle level to more products other than those four controlled substances?

MR. MOSER: The four, you mean, suppliers?

CO-CHAIR LUTTER: Yes.

MR. MOSER: Yes, it's about 20 SKUs, but, yes, we do.

CO-CHAIR LUTTER: Um-hum.

CO-CHAIR GLAVIN: Toni?

MS. STEFANO: Yes, Steve asked part of my question, so that's good. The second part of my question though, since there is this seeming diversity in terms of opinion, if we were to go to a phased-in approach, and this is being directed at BIO, since you did raise the issue that has been of long concern with the impact of RFID on proteins and the like.

If we were to do a phased-in approach, how do you propose handling some of those unknowns? You know, again, the protein, the impact on proteins and, in particular, some of the vaccines that must remain frozen. You know, that's a two part question. I'm not sure how RFID works if the product has been frozen. So any proposals here on how we would handle that diversity or phased-in approach?

MS. RADCLIFFE: I think at this point, you know, one of the things that we're all looking forward to is the information that will come from FDA from the

CDRH effort and the Auto-ID Lab. So there's just information that we're lacking in terms of how one would go about a phased-in approach.

I think, you know, the thing to do would be to focus on those products that are most likely to be counterfeited and also that present the greatest issues if they are counterfeited. But I think in terms of any kind of plan for the phased-in approach, that still has to be developed.

MS. STEFANO: Part two is, again, what would you propose to do for those products that we are waiting for information on? Do you have any suggestions?

MS. RADCLIFFE: As I said in my statement, I think, you know, one of the most important messages here is that there has to be a multiplicity of approaches available to manufacturers. And at the end of the day, the manufacturer should be the ones responsible for picking those technologies that best suit their products. As I said, we are on record as supporting the implementation of PDMA, including the paper pedigree requirement.

I think John Gray very articulately stated the fact that across the system, in 2006, we're really facing a very different situation from 1999. So I'm sort of -- you know, in terms of those particular products that may be affected by RFID, we will have to find other ways to approach them. And there are, you know, multiple technologies already being implemented. Some of them are on display in the next room by our companies to address these issues.

MS. STEFANO: Thank you.

CO-CHAIR GLAVIN: Ilisa?

DR. BERNSTEIN: I'll be fast. I know that we're running out of time here. I have actually one question and a comment. First, to Sara from BIO. It's no secret that we have been trying to get more data about the effect and impact of RFID on biologics and that we are going to be doing some of the studies ourself and that others are doing it out there. But I think from your members, in particular, it would be really helpful if there is anything that your members have or data information to share that would be helpful to share with us on that.

The other question I have is for Carmen and when the 2004 report came out, a number of states were moving at a very rapid pace over the last couple of years to change and strengthen their laws. And I was wondering how you see that pace? Is it continuing on a rapid level? Is it slowing down or is it kind of leveling off? And with respect to the VAWD, it's nice to hear that some people are being certified or entities are being certified or accredited under VAWD. And I wonder if other states are moving towards adopting that as well?

DR. CATIZONE: Sure. We see the pace among the states to introduce legislation or increase the license requirements as increasing. We probably have about 12 to 15 states now where we have active legislation under consideration. And in those states, the legislation is all very similar, as I mentioned earlier, to what NABP supports to our model rules.

We only see this increasing as the legislators meet throughout the year and throughout next year. So if our bill wasn't considered this year, we know it's on the docket for next year. We

are excited with the VAWD accreditation and besides Indiana, there are four other states that are recognizing VAWD accreditation and allowing wholesalers who have not been inspected in other states to then be able to become licensed in their state as out-of-state wholesale distributors, if they become accredited by NABP's VAWD Program.

And clearly an implementation plan like Steve discussed with some of the products being tagged and then a certification of the wholesalers through a system like NABP's VAWD Program would be something NABP would support as well.

DR. CATIZONE: Okay.

CO-CHAIR GLAVIN: Thank you very much. I'm going to very quickly announce that we have a very short break. We're going to go to 10 minutes on our break and so I would ask the next panel at the end of that 10 minutes to be seated up here, so we can start right back in. Thank you, panel members.

(Whereupon, at 10:36 a.m. a recess was taken until 10:48 a.m.)

CO-CHAIR GLAVIN: Thank you, panel, for

being in place and we're going to start the session immediately. I have two quick practical issues. One, I have been asked by the recorder if people would be conscious of speaking directly into the mike and being close to the mike when you speak, so that we have an accurate recording of the meeting.

Second of all, for people who are standing in the back, there are some seats up front that are not occupied. It's a little bit like church, the front two rows aren't completely occupied. So if you have been standing, please, come up front and find a seat for yourself.

Could I ask people, please, to if you are not seated, at least stop your conversations, so that we can begin the next session? Thank you. We're having a panel now who are going to address the need, what is needed for us to be able to have widespread implementation of RFID.

In the 2004 Task Force Report, we called for widespread implementation of electronic track-and-trace technologies by 2007. We said this based on credible information from supply chain stakeholders

who were confident that this could be realized. It now appears that this may not occur and the next two panels, the one we have here now and the one immediately after lunch, will discuss what is needed for widespread adoption of RFID, what are the obstacles, what are the incentives that are needed and what do they see as a realistic time table for adoption.

So I would like to briefly introduce our first panel of stakeholders: Tom McPhillips, Pfizer, Mike Rose of Johnson & Johnson, James Class, Partnership for Safe Medicines, Steve Perlowski, NACDS, Lisa Clowers, HDMA, and Doug Scheckelhoff of the American Society of Health-System Pharmacists. Thank you very much for being with us today. And we will start with Tom McPhillips of Pfizer.

MR. McPHILLIPS: Good morning. I am Tom McPhillips. I'm Vice President of the U.S. Trade Group for Pfizer, Inc. and I appreciate the opportunity to be here today and share some of our perspectives on behalf of Pfizer. Pfizer remains strongly committed to providing patients -- I'm having

trouble, hold on, a little technology challenge. Thank you.

Pfizer remains strongly committed to providing patients with safe and effective medications of the highest quality. We share the FDA's concern for the risk to patient health posed by counterfeit drugs. I believe constant vigilance and continued action is appropriate to ensure patient safety. Counterfeiting is a global issue and an increasing threat to the health of our nation and its citizens.

Pfizer believes that counterfeiting issues must be addressed on many fronts, including enhanced business practices, regulatory and legislative solutions, heightened enforcement and the employment of technology. Pfizer has undertaken initiatives in all of these areas since the rise of counterfeit threat these past few years and based these on our own experience with counterfeits.

As part of my remarks today, I would like to share with you key points relative to RFID implementation and some thoughts on legislation. More specifically, I plan to cover Pfizer's experience with

RFID/EPC Viagra Pilot Program, what we believe may be obstacles to implementation adoption. The role the FDA can play, our thoughts on the time table for RFID implementations, our recommendations for standard setting and some thoughts on non-technology actions to secure the channel.

A little more than a year ago, Pfizer announced the commitment that by the end of 2005 we would begin shipping Viagra in the United States with RFID tags and create an authentication capability for use by companies distributing and dispensing Viagra. We selected Viagra as it is Pfizer's most frequently counterfeited product around the globe and because it has allowed us to minimize the number of teams, facilities and packaging lines involved in our pilot.

As promised, on December 15th last year, our first product was shipped to our U.S. customers and our authentication capability was launched a few weeks later. A key objective of RFID Pilot Program was to learn more about the technology and the business processes that such an approach requires, including mass serialization and the RFID technology

itself.

Our pilot program for Viagra required us to create many new capabilities. We created a mass serialization process. This is a process that allows us to generate and assign unique numbers to each bottle, case and pallet of Viagra and write them to a high or ultrahigh frequency RFID tag. We also needed to develop ability to write and read EPC numbers at a high rate of speed. We established this capability on our existing packaging lines to write and read at rates of two bottles per second or roughly 7,000 packaging labels per hour.

We also created a backup system that involves the application of a two-dimensional bar code to the label with the exact same EPC as on the RFID tag. Of course, all these capabilities would be meaningless without our own ability to assess the tag's performance during our packaging operation. This also became a critical part of our work.

Once we accomplished all of this, we equipped our logistic centers to capture the numbers and finally we developed that authentication

capability, so that wholesalers and pharmacies could verify the EPC. This was a very detailed process and involved over 70 Pfizer colleagues working thousands of hours and with costs approaching $5 million, but we achieved our goal. Our records were pursued in a way to be scalable while maintaining our productivity.

A number of key decisions needed to be made during this project. They ranged from the choice of frequency to efforts to ensure privacy. For that reason, we decided not to use the NDC number in our EPC numbering schemes. While we understand that not including the NDC number might create operational challenges, we believe that the overriding concerns, at this point about privacy need to drive our decision until a cost-effective and secure way to include the NDC can be created.

Therefore, given concerns about delaying the testing needed for RFID and mass serialization, we moved forward without including the NDC. Frequency choices were made based upon an analysis of the basic physics characteristics of HF and UHF, benchmarking use of RFID across similar industries, our existing

knowledge of UHF deployment, the types of hardware and tags available on the market to achieving tagging at each level and input from the supply chain.

Pfizer also decided to include a two-dimensional bar code as a redundant backup technology to the RFID tag. We did this in an effort to address readability issues and exception management concerns. In addition, the decision was made to disclose the use of RFID on the Viagra container label.

Pfizer's Viagra Pilot Program will provide key insights in the viability of the widespread adoption of RFID. We now have a greater application -- appreciation for what it takes to apply RFID/EPC tags within our four walls. We also know it's just not about applying the tag. We must learn about how to best handle the data generated and about exception reporting. We must gain greater insight into the distribution channel participant's needs.

We must understand further the business process implications and the costs associated with RFID. What has yet to be determined is the acceptance, performance and utility of the tag product

in the market. The next phase will require a high level of collaboration amongst trading partners. We have been engaged in discussions with several of our supply chain partners to understand the plans for authenticating Viagra and are encouraged that they have plans in place to begin authenticating in select sites during the first quarter of this year.

As we look to the future of RFID and its success, we are asking ourselves what else is needed. There must be a continued and expanded collaboration to obtain real-world experience with RFID and mass serialization throughout the distribution channel. This will clearly require a significant investment. As we move forward, we will be seeking feedback on the performance and utility of RFID tag products under the normal day-to-day use.

Through this, we hope to gain a greater understanding of the benefit and effect of targeted or total system use of the new technologies. The resolution of data access issues and sharing of information must also be rectified with access to the data by manufacturers being an essential element of

tracking appropriate distribution of our medicines. Research is also needed on the feasibility of tagging all pharmaceuticals, such as biologics and liquids.

Finally, and yet just as important, is the fact that decisions must be made on RFID standards and the use of appropriate tags in a cost-effective manner that provides robust information.

Regarding the FDA, Pfizer believes the FDA should continue to actively participate and, where appropriate, facilitate the discussions on the feasibility of implementing RFID. Today is a great example of the vital role that the FDA can play in this area. The FDA will also be needed to make decisions on any container label changes to packages that need to be applied or for product testing.

Nevertheless, Pfizer believes the industry should take the lead in determining how best serialization could be applied both in the near-term and the long-term. Numerous issues must be addressed before a specific time table can be established before it's possible to estimate a time table. The issues I referred to earlier need to be resolved. Certain key

questions, including how the data will be shared and whether all pharmaceuticals will be tagged, must be resolved.

If I were to pull out a crystal ball for a minute and take a view, we would anticipate that it would be possible to implement tag and go to what we would call higher risk products within about three to five years. However, it's likely to take several additional years beyond that to adopt RFID for all prescription medications.

The investment would be large. As I indicated earlier, the cost of Viagra, today's costs, with just five dose package combinations, costs almost $5 million. Pfizer supports the process used by EPCglobal to establish standards that are specific to the pharmaceutical industry. However, to be successful, there must be broader participation by community and hospital/pharmacy.

Moreover, while standards are under development, guidelines on critical issues such as privacy, EPC numbering and frequency should be developed. At Pfizer, we recognize the need and

benefit of RFID technology to combat counterfeiting. However, from what I have personally witnessed in my daily activities, I know that the implementation of RFID may be years off, yet our war against counterfeits cannot wait. That is why we continue to support the implementation of pedigree requirements.

A universal pedigree is our ideal, but it must be a pedigree that is effective and is able to make sure that the distribution channel is not breached. Pfizer is a staunch supporter of legislation being enacted in the states. There are a number of key provisions that offer important solutions to the immediate challenges we face, solutions that provide help until a meaningful universal approach can be achieved.

A key element of the legislation is stricter licensing and bonding requirements for wholesale drug distributors, to make sure regulators know who is providing lifesaving medications that ultimately reach the patients who need them. In addition, the model creates a requirement pedigree that must be created when a medication leaves the

normal distribution channel.

Generally speaking, this is the distribution from the manufacturer to the wholesaler or chain warehouse or to the pharmacy to the patient. We regard this as important, since movement otherwise introduces risk.

CO-CHAIR GLAVIN: Can I ask you to summarize? You've run out of time.

MR. McPHILLIPS: Well, thank you very much for the opportunity to speak today. And to echo Carmen's point, the states are moving rapidly on legislation.

CO-CHAIR GLAVIN: Okay.

MR. McPHILLIPS: Thank you.

CO-CHAIR GLAVIN: Thank you very much.

(Applause)

CO-CHAIR GLAVIN: Mike Rose from Johnson & Johnson. And I will give you a heads up when you are at one minute, since apparently the light wasn't working and I apologize that that didn't work for you, Mr. McPhillips.

MR. ROSE: Thanks, Maggie.

CO-CHAIR GLAVIN: Yes.

MR. ROSE: Johnson & Johnson wants to thank the FDA for hosting this forum today. It's a very important forum. And the Johnson & Johnson family of companies has long supported the use of new technology standards and processes to protect our products and to enhance the security of our prescription, as well as non-prescription product supply chains. So it's in the spirit of our past track record that I make these comments and recommendations.

Clearly, as we look at our supply chain, the integrity of the worldwide supply chain has been challenged, as evidenced and discussed in the previous panel and I'm sure we will get into in this panel and subsequent panels. There is a lot of joint responsibility here. We must collaborate. We also need to ensure that the integrity of medicines delivered to our patients, you know, is genuine. You know, they have to be genuine products and authentic products. And we also have to constantly challenge our existing practices within the industry.

Securing the pharmaceutical supply chain. What we want to do here is I want to address a couple, four items. I want to give you Johnson & Johnson's perspective on this, also some key industry questions, areas for FDA guidance and involvement and also proposed industry actions.

We have all seen these numbers. There was a question earlier to the panel of the pervasiveness and the data that people work from. We work from the FDA's numbers at J&J and these are the numbers that have come out of the FDA's report around the prevalence of counterfeit drugs.

We believe it is a collective obligation within the supply chain. Securing the supply chain is one of our most critical industry issues. It's a very large issue for Johnson & Johnson. We must ensure that patients and healthcare professionals receive genuine products and 100 percent pure to the original form.

Manufacturers, distributors and Government must work together to ensure patient safety. And we also have to strive for continuous improvement. Not

just in the areas of technology, but we also have to look at policy process as well. Acceptable practices of the past will not ensure the security of the supply chain in the future.

Major areas of concern. We are recognizing and we have seen difficulty in identifying counterfeit drugs due to increased sophistication of the counterfeiters. Numerous potential entry points to the legitimate supply chain, proliferation of Internet pharmacies and also we recognize we need a system in place to track-and-trace products. And we believe that the electronic system and the pedigree need to work hand-in-hand.

Johnson & Johnson specifically, we have taken quite a bit of action in this area. In 1999, we joined the MIT Auto-ID Labs, very specific comments around RFID on this slide and we were a primary mover in getting that organization going. We formed a J&J RFID Research Center back in 2003. We also tested a wide variety of frequency of tags. And there is no simple solution here as noted by other speakers. And we have been a participant in industry pilots.

We have participated in the Jump Start Pilot most notably. But we also participate in the Industry Standards Group, the EPCglobal, Health Care Life Science Group, Unified Drug Pedigree Council. We have also been -- I serve on the board of EPCglobal Board of Governors as well. So we have been very active. We take this very seriously. We think it's extremely important that we really lead and participate in the development of good standards.

As I mentioned before, we don't believe that a single solution here will work. There is a lot of focus here around one technology. The technology is important, but whenever you interject technology change, it's very, very important that you look at the impact on policy and process as well. So we do support uniform pedigree. We also believe that we have to look at the responsibilities of the different parties in the supply chain as it pertains to the pedigree and the maintenance of the pedigree.

We also have to look at the various track-and-trace and authentication technologies, not just RFID, but we are looking at other technologies outside

of RFID. And we also have to look at increased surveillance.

When we look at policies and practices, let me just take a minute on this. It's a bit off the track of RFID, but we think it's very important that we need to be looking at tracking-and-tracing product flow. It's no longer optional for our industry. We also have to start looking at various practices within the industry. We believe that alternate source purchasing should be eliminated. We also believe that repackaging operations should be regulated by the FDA. That's a huge concern that we have.

Returned goods should be only restocked after pedigree has been reviewed and assurance that the product has been properly stored and handled properly. And we believe that destruction requirements must be stringently enforced.

Let's talk about implementation of industry-wide track-and-trace. While there is a lot of focus on tagging a product and that certainly is a start, we also believe that it's very important that we look across the supply chain. All parties have to

participate in this. Authentication will require continued investment in human and financial resources to maintain and update accurate pedigrees, to provide transparency throughout the supply chain of this information.

Authentication of packages by supply chain parties are the foundation of electronic track-and-trace. So we believe that fundamentally once an RFID chip is applied or a 2D bar code is applied, that information needs to be used and needs to be used to authenticate the package. Continuing investments must be made to ensure the system is not defeated by counterfeiters. We know they are very devious. They are out there. They are going to be looking at this as an opportunity to gain the system and we have to continue to invest in upgrading the system.

Mass serialization, we believe, is the key component here. So if we step away from the technology and we come back and say what's important here, it's the unique identification of the product. We believe in the interim until RFID is more widely adopted that serialized linear and 2D bar codes are

also an option here. And we need to address that.

We believe, also as Pfizer has looked at, it works very well as a backup system to the RFID chip as well. Pedigrees, we believe that there should be uniform code. We appreciate the efforts of NABP and other parties that have been working on this. We believe that that uniform code should be adopted on a state-by-state basis and we welcome that adoption.

Our evaluations at the end of the day demonstrate that we cannot do this alone. One party can just not move ahead without the development of very strong standards.

With respect to privacy, it's very important for us to protect the privacy of the consumers of our products and our patients and doctors who use them as well. And so we believe that to the greatest extent possible, end-users of our products should have the option of disabling or removing RFID tags when they are no longer needed. We recognize that there will be situations where RFID may be built into the product over time, but there has to be a way of disabling those tags.

RFID must be adopted in conformance with regulatory laws and as well as our own J&J consumer privacy and security policies, which we can make and it's available off of our website as well.

Key industry questions. The question about why RFID has not moved forward I think is reflected on this page. There's a lot of questions that need to be answered. What business practices need to be changed? What technology standards are required to support those changed business practices? What tag frequencies will be used? Will the NDC number be included in the electronic product code?

How do we envision RFID being used further down the supply chain? How will the information be stored, secured and accessed by the various parties in the supply chain? These are enormous questions that require a lot of thought and a lot of hard work to move through.

Possible areas for FDA guidance. We applaud the FDA for bringing this group together today. We recommend that there are more forums like this where we get together and share learnings and

share views around the adoption of RFID. In addition to that, we think it is very important to look at the electronic pedigree information content, utilization of digital signature to sign the pedigree, inclusion of the NDC in the electronic product code and also the compatibility of bar code information and the information on the RFID tag.

As we mentioned, the various formats of bar code could be used as a backup mechanism for RFID. How do we coordinate across those different formats?

We have three areas that we would propose for actions for the industry. One, industry standards that specify how RFID will be deployed must be developed and broadly implemented. We support and will continue to support the EPCglobal standards process and these are some of the areas that, as you can see on the slide, we're looking at, tag frequency, product numbering, data access, data security.

Two, business practices must be modified to ensure that all supply chain parties are reading the information on the RFID tag and properly maintaining and disclosing electronic pedigree. We

think this is very important from a manufacturer=s perspective to be able to help in the surveillance and also the identification of suspected counterfeit incidents.

Thirdly, a comprehensive industry adoption program must be initiated and including representation from all supply chain parties with clearly defined milestones. So we believe this is very, very important for the successful adoption. There is a lot that needs to be discussed, as we mentioned on previous slides and as other speakers have mentioned. So we believe that this Comprehensive Industry Adoption Program is critical for the successful and timely implementation of RFID electronic track-and-trace.

So in closing, moving forward is our responsibility to do everything we can to ensure that our patients get exactly the medication they are prescribed. And Johnson & Johnson is committed to working with our other parties in the supply chain to further flesh out and define how we will adopt electronic track-and-trace. Thank you very much.

(Applause)

CO-CHAIR GLAVIN: Thank you. Our next panelist is James Class of the Partnership for Safe Medicines.

DR. CLASS: Thank you very much. On behalf of the Partnership for Safe Medicines, I would like to thank the Food and Drug Administration for holding this workshop and considering the issue of consumer education in relation to counterfeit drugs and RFID. I'm going to be a bit of a red herring on this panel, because as everyone else is telling you how to expand the use of RFID, I'm going to tell you what we all have to do regardless of how fast it gets adopted.

While the membership or the partnership represents a diversity of viewpoints on the best methods for pedigree and technological solutions, we all agree that patients and consumers deserve to get the quality medicines that they rightly expect. While we greatly admire the effort to construct an electronic pedigree system, we believe that adoption and expansion of RFID will not necessarily alter the

demands for consumer education on safe medicines.

Rather, we believe that we need to continue to collaborate in order to communicate potential safety risks and to develop proactive solutions that empower consumers and patients.

Founded in 2003, the Partnership for Safe Medicines is a coalition of patient, physician, pharmacist, university, industry and other professional organizations committed to protecting the public from counterfeit or contraband medicines. We have roughly 50 U.S. partners and are presently developing a wing in Europe where patient groups are becoming increasingly worried about supply chain issues.

Today we would like to comment on a relatively small portion of the questions that FDA submitted in advance of this conference. Our comments will pertain to the following kinds of questions, namely what is the type of education that is needed, what messages should be conveyed and who should develop consumer education programs.

In addition, there was a fourth question

about RFID getting into privacy issues. We are going to respond to that in the docket and we're glad to see that there is a subsequent panel on this which will take it from a much more expert point of view.

The first question, which is on the type of education, in itself presupposes that a new type of education is needed "as the use of RFID in the drug supply chain becomes more prevalent." We would like to suggest that this type of education will be the same that we need right now. In fact, we would like to note that this education is needed all the more since public discourse continues to oversimplify RFID.

For instance at the end of a Today Show episode with Journalist Katherine Eban, the consumer reporter suggested that we will soon have a system like EZ Pass, sorry, it=s Speedpass up there, that will protect our medicines. Legislators in the U.S. House of Representatives have wondered why we cannot just simply set up an RFID-based system like that at FedEx or UPS where tracking information is available real-time to everyone.

And of course, many people will assume

that even partial deployment of RFID will ameliorate all safety concerns everywhere and with every type of medicine, including biologics. Thus, without casting doubt on RFID's promise, we should not promise the public a world without problems. We should conduct education that does two things. Communicates risks and dangers, but empowers them to do something about it.

In recent years, FDA placed advertisements on counterfeit medicines and we, at the partnership, have tried to play a role as well. Our website safemedicines.org contains ways to stay up to date on the news and we actually do a weekly news survey for experts that I would be happy to distribute to anyone here. Please give me a business card. You can also listen to an abridged form through iTunes in a podcasting. You can sign up for the SafeMeds Alert System, which is a direct consumer counterfeit alert network and it's actually a member of the FDA's Counterfeit Alert Network.

We also send out warnings from Health Canada, for instance, with regard to Tamiflu recently.

We give people a Safe Drug Consumer Guide which pulls together all the possible safe ways that people can save on medicine in the closed U.S. system and this is very important, because affordability sometimes is an issue that can lead to risk for consumers.

And we also try to list or link directly to the VIPPS system of the National Association of Boards of Pharmacy and this is critical that you go straight to the page that lists the pharmacies that are legitimate, because many reporters just point people to the NABP homepage, but they don't draw them down far enough to a place where it's completely useful. You've got to go to places where consumers will find it useful. They will go there in one link.

And finally, one of the major things that we have going on this year is a health policy conference in San Diego which we will have plenty of materials for out on the handouts table that we invite everyone to, because it is about counterfeit drugs and international crime and what we need to do together.

So taken together, these tools we believe comprise a kit for patient safety that gives patients

ways to communicate with Government and industry officials without raising undue alarm. This kit should be the core of future patient information activities regardless of the type of technology used to create a pedigree system for the U.S.

Now, the partnership plays a useful role in bringing independent experts together with industry leaders from a variety of sectors in the pharmaceutical supply chain. The FDA performs an invaluable service in fighting counterfeit drugs with the tools of regulation and law enforcement. Neither group on its own, however, will make a significant impact on the public consciousness.

In order to be effective, consumer education must come from the sources that people trust the most. In this case, that responsibility falls on two kinds of organizations, patient groups and consumer groups. On a positive note, the National Health Council, an umbrella organization of patient groups, is moving forward with plans to launch a major media campaign on the topic.

Consumers groups such as the National

Consumers League have drawn attention to counterfeits in the past and hopefully Consumers Union will find greater interest in the subject in the future. And ultimately, we believe there is a great potential role for the AARP, since its members have the largest share of prescriptions.

In conclusion, while RFID and other electronic pedigree tools offer great promise, technological experts cannot successfully tackle counterfeiting without engaging the public. All sectors of industry have the chance to engage the public proactively or to wait for a potentially explosive situation.

We are very thankful that all of you have gathered here today under FDA leadership to discuss the adoption of RFID, but we would submit that the expansion of RFID does not alter the basic needs of consumer education to communicate risks and means of empowerment. The Partnership for Safe Medicines has striven to create tools to that end that complement the work of FDA and of the various sectors of the supply chain.

To make these successful, we need to harness the growing interest in the topic among consumer and patient groups. FDA and industry's expertise is necessary and useful, but this is a case where we must engage the public. Thank you.

(Applause)

CO-CHAIR GLAVIN: Thank you very much, Mr. Class. Our next panelist is brought back by popular demand from the first panel and that's Steve Perlowski of NACDS.

MR. PERLOWSKI: Good morning again. I would like to focus my remarks on the following areas. What is the data carrier for item information, what should be the numbering scheme that we should be thinking about, talk a little bit about data management that we went through in the earlier panel and then finally the electronic pedigree. We plan to address the other issues you have raised in our written comments.

Why RFID versus 2D bar codes. The pharmaceutical supply chain moves billions of containers from manufacturer to distributor to

retailer or hospital/pharmacy. Collectively, supply chain participants have invested billions of dollars to make the system as efficient as possible and to reduce excess inventory in the supply chain. Distribution centers whether owned by a retailer or by a distributor are designed to be extremely efficient in order to meet the unique needs of the supply chain.

I would now like to take just a moment to conduct a little demonstration for you to demonstrate why we are so against 2D bar codes as the primary data carrier. I have here a case. If this case had RFID on it, I would have already read all the items in the tag and been able to move on and receive the product.

If I have a 2D product and I have to identify each individual bottle, a receiving clerk has to open every case they receive. They then have to take out each individual bottle, orient each individual bottle as they are going through to receive the product. And then they have to put the bottles back into the case and then they have to seal it.

During this little demonstration, I was able to read four or five products. Imagine if the

case had 48 pieces, 72 or 96 items in it. And remember, this industry ships and receives millions of cases every year. A requirement to open every case we receive and ship to pick out each bottle, then scan each individual bar code versus the ability to read a tag as it passes through the door without the line-of-sight requirement would add millions of dollars of labor time to the supply chain each year, as well as limit our ability to move products quickly through our systems resulting in excess inventory, product with less shelf-life, more returns and quite likely more out-of-stocks at retail, which potentially would impact patient safety. RFID could potentially positively affect all of these areas.

As we look at RFID, we are extremely concerned by some that suggest the numbering scheme that is included in the EPC number would not include the NDC. The National Drug Code has provided a method for drug profiling since computerization of pharmacies that has evolved into one of the most valuable tools used by pharmacists and technicians in providing appropriate care to their patients.

The NDC and its intelligent structure are commonly used in the entire drug delivery system having a system that does not require line-of-sight for electronically identifying pharmaceutical products could add even greater value to the supply chain in the following areas, distribution, dispensing, patient compliance, reimbursement, inventory management, reporting, rebates, patient safety, formulary management, benefit management and manufacturer reporting and analysis.

However, creating a system that does not carry the NDC would be of little value to retail pharmacy and would preclude our supply chain from realizing the full potential of this technology. Thus, RFID would then be viewed by the retail community as a cost with no clear benefit.

I'm going to slowly advance through the next three slides which demonstrate all the areas where community/pharmacy relies on the NDC. First, in the area of patient safety. Now, let's look at the supply chain logistics applications. And finally, once we get in the pharmacy.

As you can see, retail pharmacy needs to have the NDC number electronically available, so that we can continue to serve our patients in the best manner possible. And what is the impact on pharmacy if the NDC is not included? Should a pharmacy have to go to every vendor's website to obtain the NDC on every bottle? And again, there is billions of bottles in the supply chain per year. A number of additional investments would be required by retail pharmacy, including the fact that not all retail pharmacies have Internet access.

And what happens to the system if a pharmacy has problems logging on to the vendor or manufacturer's website to obtain the NDC? There is also a huge cost to develop systems to interface with each of the various vendor websites. In addition to this cost, there would also be an increase of cost in labor, as we estimated would add at least three seconds to every transaction. And when you are dispensing 3 billion prescriptions per year, three seconds times 3 billion is a lot of time.

Also, when we receive products at the

pharmacy level, whether it's from our own internal distribution system or from a wholesaler, there is numerous -- we receive bottles in totes that contain numerous bottles from multiple manufacturers. And then we would run the risk of not being able to serve the patient if there was a breakdown in anyone's network. The supply chain would also grind to a halt.

And even if we received the NDC/RFID cross reference with an ASN from a vendor, first, not all pharmacies have this capability, and while it may reduce response time per transaction, we still have a number of issues. First, there would be a huge cost to develop systems to receive and validate cross reference from various vendors with different systems. And it would still add time to each transaction.

The risk to patient safety remains when the NDC is unavailable due to problems receiving or processing the cross reference tabs from vendors. And think how large this cross reference table would become in a serialized world where every NDC would have multiple, millions even, numbers associated with that NDC.

The NDC has been used for many years throughout the pharmaceutical supply chain. Manufacturers, wholesalers, retail distribution centers, pharmacies and third-party processors all have specific functions built into their work flow which are dependent on the NDC. Creating an RFID system which does not include this number could be reinventing the wheel.

Any requirement to look up an NDC every time we attempt to move a bottle, take inventory, which we do on a regular basis, dispense a drug, etcetera, would add time and cost to community/ pharmacy. We understand that there are legitimate concerns regarding patient privacy and using a numbering system to ensure that even if a tag is read by a rogue reader, it would not identify the product.

However, we believe that there are other opportunities to build privacy and security shields into the system. Therefore, we strongly support the notion that security and privacy be built into the tags, frequencies used, the reader and the use of consumer notice and choice for community/pharmacy to

support RFID. We need to have the NDC number included within the EPC numbering schema.

This will allow pharmacies to develop processes that may generate a positive return on our investment. When we talked to our members about data management, we believe that a peer-to-peer network is far and away the best choice for moving information between trading partners. It leverages current capabilities. It is already scaled and it would not require significant additional investment and development time.

I would like to also emphasize that inefficiencies and risks associated with relying on a central database as a real-time reference source, we will add response time to every read, patient service will be at risk when the central database is unavailable or compromised. We prefer receiving the pedigree and authenticating data directly from the trading partners, so that we can perform validations and look ups within our own internal data network.

By beginning with a peer-to-peer system, we feel the industry can move forward faster and will

also give the industry time to address the other issues around data management. As we think about an electronic pedigree, it is clear to us that given all the data that it will take to populate the pedigree fields, that the pedigree should begin with the manufacturer.

For a distributor to populate the required fields, we would have to go back to the manufacturer anyway to obtain that information. Additionally, it would be much more efficient for the supply chain for the pedigree to be initiated at the point of manufacture. The information could be added to the pedigree as the product moves throughout the supply chain.

Finally, it would be very beneficial for the industry to have a single pedigree standard. This would eliminate complexity and make compliance much easier. Thank you for your time. Our industry has welcomed the strong support and interaction with the FDA towards the development of RFID technology and standards and we look forward to continuing that in the future. Thank you.

(Applause)

CO-CHAIR GLAVIN: Thank you very much. Our next panelist is Lisa Clowers with HDMA.

MS. CLOWERS: Thank you for inviting HDMA to participate on the panel to present our views to you this morning. I would like to address the following key points: Number one, patient safety is of paramount importance to HDMA and its distributor members. We believe that EPC/RFID holds the most promise for improving the security of the healthcare supply chain. In order to become a reality, mass serialization at the item level is required.

Number two, EPC/RFID pilot progress and standards development is very positive. However, there are still many issues that need to be addressed, including the business processes associated with data management and data sharing.

Number three, HDMA supports a phased-in approach for EPC/RFID tagging. This approach will allow for more timely widespread RFID implementation.

Number four, HDMA believes that two-dimensional bar codes only serve a role as a redundant

technology to RFID tagging. Any other use of two-dimensional bar codes is merely a distraction from the best solution for the healthcare supply chain.

And I would like to thank my counterpart Steve Perlowski for his demonstration.

Lastly, HDMA believes there is no single solution to address the counterfeit problem and that a multilayered comprehensive supply chain strategy is needed to further protect the safety of the U.S. pharmaceutical supply. This must occur across all members of the supply chain. Counterfeit drugs are a supply chain issue and all stakeholders must invest in supply chain solutions.

HDMA has been the leading healthcare trade association promoting the adoption of current and emerging technologies such as EPC/RFID. We hold firm our position that EPC holds the most promise for tracking, tracing and authenticating a products movement across the supply chain. EPC/RFID is an invaluable tool that can be used to combat market entry of counterfeit products, further secure and improve the integrity of the supply chain and enhance

patient safety.

As criminals who seek to introduce counterfeit or adulterated products into the supply chain become more sophisticated, so too must the technologies that manufacturers, distributors and providers employ to defeat them. For any true track-and-trace system to be viable, mass serialization at the item level must be developed in a standard format and supported across the healthcare supply chain.

Lack of industry focus on a single approach leads to investments and short-term technologies to the detriment of RFID progress. FDA's Compliance Policy Guide for implementing RFID feasibility studies and pilot programs was an important and essential step in moving this technology forward. The policy guide clarified the Agency's position on labeling and current good manufacturing practices in RFID tagging. These studies significantly enhance the understanding and operability of this technology in the healthcare system.

However, the industry needs more guidance

from the FDA on the tagging of biologics and other specialty products. Although the industry is moving forward in the development and adoption of EPC, it will take time and an unwavering commitment on the part of Government and each partner in the supply chain to realize adoption of EPC/RFID in a measured, meaningful and universal way. A uniform regulatory approach and focused open and consistent EPC/RFID standards are required to move forward.

Supply chain partners, commercial vendors and Government agencies are working together to develop the necessary standards for communication of tag items across the supply chain. Other technologies such as two-dimensional bar codes may be available today, but they require line-of-sight scanning, which will slow down an effective distribution process and negatively impact the highest service levels patients expect and deserve.

Pursuing temporary two-dimensional bar code solutions will merely divert human technology and capital resources away from EPC-RFID at a critical time in the adoption process. HDMA believes that two-

dimensional bar codes only serve a role as redundant technology. EPC/RFID represents an opportunity to significantly improve supply chain integrity and business efficiencies. According to an HDMA Foundation study, EPC/RFID is much more accurate and more efficient than paper pedigrees or alternative electronic tracking methods that do not involve the serialization of individual products.

The study goes on to recommend a phased-in approach for tagging pharmaceutical products. Priority 1 products would include drugs most likely to be counterfeited. Priority 2 products would include products with special handling or storage needs. And Priority 3 would include products used in hospital environments.

We are pleased to report that tremendous progress is being made to promote the development and adoption of EPC/RFID. Late in 2005, HDMA cosponsored an RFID Summit with the National Association of Chain Drug Stores to provide further education on the development of utilizing RFID technology. The support from industry participants was overwhelming. HDMA

will continue to collaborate with NACDS and other supply chain partners to create forums for the development of data management and data sharing recommendations and technology solutions.

While industry momentum toward implementation of EPC/RFID has increased in the last few years, several challenges remain. Technology issues, including tag read rates which must be at 100 percent in the health care supply chain still exist. Interoperability of tags and readers and infrastructure enhancements needs to be addressed early on before critical mass of pharmaceutical product is tagged.

We remain confident that the technology will develop and mature in time. More important, however, are the business issues we have heard today, including data management and data sharing and patient privacy concerns that may cripple widespread implementation of EPC/RFID if left unresolved.

In our ongoing effort to further assist the industry in moving toward implementation of EPC, the HDMA Foundation launched a new research initiative

to address the key issues of data sharing and data management across the healthcare supply chain. This is a monumental project that will provide the guidance for a transformational industry change and will allow for widespread implementation of EPC/RFID.

Specifically, the research will discuss the business case for sharing data, provide strategies for moving from a transactional to a collaborative business model and recommend a road map for managing information. In many ways, these issues are cultural and far more challenging than remaining technology concerns. In order to achieve true track-and-trace solutions pharmaceutical and manufacturers must tag their products using standard unique serial numbers and health care distributors and providers must develop the appropriate infrastructure for tracking, tracing and authenticating products.

As with any new technology, excitement can overshadow reality. Before widespread adoption can occur, standard real-time systems have to be designed and trading partners have to integrate new technologies into current business practices and

legacy system. These changes and processes take time to implement. As the Acting Commissioner stated this morning, moving from macroscopic to microscopic, it was monumental. It was paramount. And not one thing changed, but many things changed. It will take us some time.

As industry participation increases, more products are tagged, reliability of the technology improves and more standards are developed, our journey toward EPC/RFID widespread adoption will evolve. The safety and security of the nation's prescription drug supply chain requires constant vigilance in the face of increasingly sophisticated threats. The FDA plays an essential role in facilitating the development of EPC/RFID standards and adoption.

The FDA's guidance in the area of EPC/RFID and its possible effects on biologics and other standards setting -- and other specialty products is critical. HDMA commends the FDA for its ongoing support of the standards setting work conducted by EPCglobal, by actively participating in the healthcare and Life Sciences Business Action Group, by

participating in the standards setting process, FDA facilitates the establishment of uniform standards and best business practices.

In closing, HDMA members are committed to strengthening the integrity and security of the U.S drug supply. Our members' primary responsibility is to ensure that authentic pharmaceutical products are handled, stored and ultimately dispensed to patients safely and efficiently.

We will continue our vigilance in this are to ensure that all patients receive authentic, unadulterated product. Thank you for your time.

(Applause)

CO-CHAIR GLAVIN: Thank you very much. The final member of this panel is Doug Scheckelhoff of the American Society of Health-System Pharmacists. Mr. Scheckelhoff?

MR. SCHECKELHOFF: Well, this is a tough spot to be between Lisa Clowers at the podium and just before lunch, but I will do my best. My name is Doug Scheckelhoff and I'm the Director of Pharmacy Practice Sections with the American Society of Health-System

Pharmacists.

ASHP is the 30,000 member national professional and scientific association that represents pharmacists who practice in hospitals and other components of health systems. ASHP is pleased to provide comments in response to FDA's notice of the workshop. We believe that the adoption of RFID track-and-trace technology is vital to all of our mutual concerns about counterfeit drugs entering the nation's drug supply chain.

I would like to start off by making one thing very clear, however. We believe that the current focus of RFID technology to track products through the supply chain is well-placed. While there may be a point in the future where the use of RFID tags at the unit dose, individual tablet or capsule level is desirable, we believe that the first priority in hospital drug administration verification technology should remain with bar codes.

Our data has shown dramatic increase in the adoption of bedside bar code technology to improve the safe administration of medications in hospitals.

The percentage of hospitals using bar code medication administration rose from 1.5 percent in 2002 to 9.4 percent last year. And if you look at hospitals that are 200 beds and larger, the number approaches 18 percent.

While we still have a ways to go, we must remember that we're still two months away from the final implementation of the FDA's bar code regulation. We do not want to send a signal to hospitals that they should hold off on the implementation of bar code technology at the bedside because point of care RFID is just around the corner. In fact, a great deal of work and study will need to be done before that might become a reality. Bar code technology is here now and at the point of care it saves lives every day.

It's noteworthy though that despite the clear benefit that unit dose brings to patient safety, many manufacturers have chosen to stop producing unit dose packages leaving hospitals no choice but to expand their own repackaging operations. In fact, reports have shown a 30 percent drop in unit dose packaging over the last five years. This has resulted

in inefficiency in the U.S. healthcare system and an increased opportunity for error.

ASHP also encourages the FDA to consider the implications for hospitals as the Agency contemplates actions or recommendations related to RFID technology. Many of the pilots to date have been in chain drug store settings and other types of settings and hospitals and other pharmacy environments are very different. Their needs are different and the implications will also be different.

A key role for RFID in hospitals will also be to manage inventory and prevent diversion. The need to assure product availability while keeping the least amount on the shelf is critical and could be improved greatly with the proper use of technology such as RFID.

There have been several reports of large scale drug diversion, diversion of high cost drugs, primarily injectables, from hospitals. The largely manual systems in place in most hospitals do little to prevent this from happening. ASHP supports the use of this type of technology, RFID, to track products,

tighten the system, prevent theft and losses to hospitals and to avoid another entry of adulterated product into the supply chain.

And now to some of the issues that were raised in the Federal Register, specific questions to be answered today. On the question of when RFID tags should be turned off, the issue around when the tags should be turned off in hospitals is much different from those surrounding products dispensed in community pharmacies.

In nearly all cases the drug package, vial or bottles are discarded after a patient's dose is prepared. If the tag is not turned off, there is the potential for an active RFID tag to be disposed of in the hospital dumpster and readily accessible to criminals seeking empty containers for redistribution of counterfeit products. The tags must be deactivated before packaging and containers leave the pharmacy or at least have the numbers inactivated.

Regarding the question of ownership and transparency of data, ASHP believes that the RFID data must be transparent to the dispensing pharmacist

regardless of the ownership of the data and where it might reside.

While there are many possible models for how supply chain data could be managed, it's an essential requirement for hospital/pharmacy end-users that there be transparency and a paper trail back to the manufacturer. The hospital/pharmacy should be able to review where products have traveled if they have been through more than just the manufacturer and the initial wholesaler.

On the question of how to affix RFID tags to products, RFID tags should be affixed to products in a way that allows both the tracking of the product, but also the prevention of diversion.

Tags can be affixed to the outside of the container, which will help track products through the supply chain, but this does not always help thwart issues around drug diversion. There is value in having tags that cannot be easily removed or deactivated, either embedded in the product itself or in the label, particularly for high cost drugs which are prone to diversion.

Regarding the question around continuing the stay of the effective date of PDMA regulations, rather than continue the stay of PDMA beyond the December 1, 2006 date, the Agency should set a firm target date by which it will require either an electronic or paper pedigree.

Regarding the question around minimum standards for wholesaler licensing, the FDA asks how effective state standards are in enforcing wholesaler licensing laws and regulations. The Agency also asked how a universal pedigree might alleviate concerns raised by barriers individual states place on passing a pedigree for a drug that moves from state to state with different pedigree requirements.

The problems that our members have seen are reflective of the reality that those who intend to deceive know well where the regulations are most easily ignored. Given the national and international nature of the drug supply chain, ASHP believes that the stakes are too high to allow a fragmented regulatory framework to govern pedigree requirements. Adequate resources should be funneled into a cohesive

national policy that is more likely to result in more uniform and stronger enforcement.

In conclusion, ASHP believes that a secure tracking system for drug products is an imperative at this time. The FDA has stated that adoption and widespread use of reliable track-and-trace technology is feasible by 2007. Nothing should stand in the way of this implementation. Thank you.

(Applause)

CO-CHAIR GLAVIN: And I think the prize for the most intrepid panelist who not only came on last, but has the smell of something burning as he is speaking, you were wonderful. You never wavered. Thank you all and, Randy, you're going to take questions?

CO-CHAIR LUTTER: One housekeeping matter. There are a variety of chairs that are not occupied at this end of the room and I see about a dozen people in the far distance who can barely recognize the faces at this table. I encourage you to come forward and occupy. I see four vacant chairs on my left and maybe one or two on the right.

Anybody in the audience who has a vacant chair next to them, please, raise their hand. And if you're too shy now to come sit in the vacant chairs at 10 minutes before lunch, perhaps after lunch you will be willing to do so, so as to make yourselves more comfortable.

A second brief housekeeping comment is let me just reiterate a little bit the purpose of the questions and the charge to the questioners on the Task Force.

We're very interested in having panel discussions in a question and answer format for this public meeting so as to help crystalize our understanding about the views being presented by various stakeholders and experts in the drug industry and in the distribution and in the healthcare, among healthcare providing organizations.

The best understanding about the obstacles to electronic track-and-trace will come from this dialogue and these questions and answers. The best understanding of the merit of measures to overcome these obstacles will also come from the questions and

answers. So the reminder to the Members of the Task Force is when you think about questions to ask the members of the panel, please, ask ones which you think will clarify and crystalize the nature of these obstacles and the measures to overcome these obstacles.

I would like to ask only one question of clarification if I can find my notes here, and that pertained to Lisa Clowers of HDMA. And you said that manufacturers must tag their products. So my question is do you mean all products including, for example, generics and, if so, when?

MS. CLOWERS: Based on the study that we conducted through our Health Care Foundation with A.T. Kearney, as I stated at the end of my testimony, we would recommend a phased-in approach and we do have that information in the study.

Priority 1 products would be those products that are highly susceptible to counterfeit. Priority 2 products would be any products that have a high charge-back volume or other specialty product concerns. And, lastly, we recommend hospital

environment products.

As for generics, we don't have a formal position on that right now. I think there is some more work that has to be done in that area.

DR. BERNSTEIN: Can I ask a follow-up on that? So Phase 1, Phase 2 and Phase 3. Is Phase 4 the rest? Where are the --

MS. CLOWERS: We actually didn't get that down, detailed into the study, I will tell you. We haven't gone that far. Really, it was just the first three. There was a wave of three products. As I mentioned earlier, I think as manufacturers tag their products, we'll find out that there are other lessons that we need to come together on.

Just in this panel alone, I think you saw one manufacturer that chose to use an NDC. You saw one manufacturer that chose not to. That is an industry issue that needs to be addressed.

CO-CHAIR LUTTER: Other questions? Jeff Shuren?

DR. SHUREN: This goes to a comment that was made by Mike Rose. You had said that there were

four possible areas for FDA guidance and I will just read them out. Electronic pedigree information content, utilization of digital signature to sign the pedigree, inclusion of the NDC in the electronic product code, and I think you're raising this as a very big issue and there are a very wide array of opinions on it, and lastly compatibility of bar code information with the information on the RFID tag.

I would like to ask each of the panelists very quickly to say if you agree with this list or if you disagree, what would you change? Let me start with Doug.

CO-CHAIR LUTTER: As Moderator, you have less than a minute because we need to also take other questions, so please gauge your responses for a minute.

MR. SCHECKELHOFF: Could you repeat the list again?

DR. SHUREN: Electronic pedigree information content, utilization of digital signature to sign the pedigree, inclusion of the NDC in the electronic product code and compatibility of bar code

information with the information on the RFID tag.

MR. SCHECKELHOFF: And the question is?

DR. SHUREN: There will be a pop quiz at the end.

MR. SCHECKELHOFF: And the question is around priority of those issues?

DR. SHUREN: Do you agree with the list or if you don't agree, how would you change that list?

MR. SCHECKELHOFF: Well, I think that the content of what is on the tag is probably the most critical. I think that the NDC number, whether that should be included or not, I think that there's a lot of pros both ways and I think weighing that is something that the industry needs to do, all the stakeholders to think through what the implications might be.

MS. CLOWERS: On behalf of HDMA and its members, I would like to answer the question by yes, yes, yes and yes.

MR. PERLOWSKI: That would be the same for NACDS.

DR. CLASS: On account of the fact that

just about everybody up here is one way or another unconsciously in the partnership, I have no comment.

MR. ROSE: Do I need to comment?

MR. McPHILLIPS: I would agree that the FDA can offer -- we would benefit from the FDA offering some guidance on these particular areas.

DR. SHUREN: Okay. Thank you.

CO-CHAIR LUTTER: Other questions from the Task Force? Deb?

MS. AUTOR: Thanks. This is somewhat related to Jeff's question, but maybe a little bit broader, and some of you alluded to this, but if there was one concrete step that you could take if you were at FDA over the next six months or so to drive forward widespread RFID implementation, what is that concrete step that you would take that we're not already taking?

CO-CHAIR LUTTER: To whom are you --

MS. AUTOR: And that is to whoever in the panel wants to address that.

MR. SCHECKELHOFF: Set a date.

MS. CLOWERS: Okay. Maybe I don't agree

with that one. I will give you a little history. HDMA was involved a couple of years ago when Mr. McClellan was in charge of the FDA and we put together a Product Safety Task Force. Manufacturers, distributors, pharmacy, everybody in the healthcare supply chain came together and looked at what are the business and technology requirements that we need to do in order to implement this technology.

I think forums like that are very important. I think getting FDA's guidance and feedback, such as today, from every member of the healthcare supply chain is a key issue. And then you can have more knowledge to make the decisions that you will need to make.

MR. PERLOWSKI: I guess, you know, we submitted comments to the FDA a few years ago and I think, you know, we did not put a date in. We said at some time in the future RFID tagging would be available at the item level. And what I would say today is we know a lot more today about the technology than we did then and we will continue to learn more and more about the technology.

The amount of dialogue in my membership was elevated significantly by your having this meeting. I think that would be the most concrete step you could take, is continue to have these sessions and continue to keep track on where we are and some of the issues.

Hopefully, the next time we meet the issues that were raised here are not the issues we're looking at. We have a new set of issues. But keep bringing us back together to communicate with you about where the industry is and rest assured that we're making progress.

DR. CLASS: On the public side we have had some uniform comment from the wide array and, you know, to get it with the public anyway you have got to make it absolutely 100 percent crystal clear that you can turn these things off and that some teenager with an RFID scanner will not be able to tell what's in your purse.

MR. ROSE: I'll come back to the need for standards. I think it's very important to have FDA actively engaged in the standards process. So I would

just say commit people that can participate in this process, because it can help us address some of the questions that I raised in my presentation. So if you can dedicate someone to participate on a full-time basis to this, that would be very, very helpful.

MR. McPHILLIPS: I want to echo what Jim said. Anything that the FDA can do to help address the question about privacy, you're already doing testing, I understand, but that's critical. That needs to be done as we move forward in time.

How and where to apply the label on a container is another issue that needs to be resolved. Those that have done it already have done it with consulting the FDA, but it needs to become more standardized. There need to be guidelines on that.

Beyond that, I would echo what everybody else said. These forums are very valuable to continue the momentum moving forward.

CO-CHAIR LUTTER: With respect to the suggestion that FDA look at privacy, let me take this opportunity to say that late this afternoon there is, indeed, a panel at a hotel in Bethesda on privacy and

many people may find themselves well-positioned to benefit from attending that panel by attending this room at about 4:15. So we welcome that suggestion and look forward to following up on it promptly.

MR. McCONAGHA: I just wanted to follow-up on that comment.

CO-CHAIR LUTTER: Bill, follow-up question?

MR. McCONAGHA: If I may just follow-up on the last two comments about standards setting. I think all of you in your presentations identified the issues of standard setting and that kind of everybody being on the same page is one of the practical and real obstacles that everyone faces in implementation, widespread implementation of RFID, both as a trace-and-trace technology and authentication technology.

I am curious. Is it your sense with the leadership of EPCglobal and others on this issue that the industry is moving towards those standards voluntarily? Is there an impasse? Will market forces or the spirit of cooperation take care of this and drive the industry towards a common sense in adoption

of standards or is there a need for federal leadership, for lack of a better term, on that issue?

MR. McPHILLIPS: I'll take the first one. I think EPC is driving towards those. It's not a simple solution. You know, there are a number of different people that need to be heard from on the issue and you need to build to a consensus. So I believe they are making progress. I think we will get there sooner rather than later.

FDA's involvement in that process, which I believe they have been participating, should continue and we really encourage it to continue in those meetings that are going on through the EPC.

MR. ROSE: Yes. I think we are making very good progress. Mike Meranda put up a slide, how quickly we have moved, and it's quicker than what has been done in fast moving consumer goods. So I think we are making very big, great progress there, but I think some of the issues that we articulate around data sharing, they aren't necessarily industry standards issues. They become now issues of agreements between the various parties in the supply

chain.

So I think we can move through the standards discussion. We're making very good progress. Now, after that though, then we have to get into discussions of how will we change our business practices and then also then implement the technology to support those business practices.

So this is a multi-step process. We shouldn't look at standards being the only issue here, and we shouldn't leave this panel discussion thinking once the standards are done all work is over with. There is still quite a bit of work that needs to be done in the industry.

MR. McPHILLIPS: If I could just follow-up with one quick comment to Mike. You have got to look at it from a policy perspective, to what extent that we're going to use this technology for this particular application of thwarting counterfeiting, too.

MS. CLOWERS: If I may, I would like to just add one thing if I may. Six years ago I don't think you would have seen the collaboration certainly by the associations that represent the stakeholders in

this room. HDMA is working very closely with NACDS and PhRMA and ASHP on other initiatives.

So I think that has helped drive the momentum certainly at EPCglobal and companies. Certainly, 18 months ago there weren't as many members of the industry involved with EPCglobal. So it is very, very encouraging to see that progress.

CO-CHAIR LUTTER: Other questions? We have time for two more.

MR. McPHILLIPS: Could I offer one more comment to what Lisa just said? When you look at this issue, you should not look at it just as the technology applications that have occurred. You should look at all the other things that have changed by the individual businesses or within the states themselves to enhance the patient safety or to secure the channel for the movement of the product.

So although it's all about perspective, you may think that it has been slower than one would expect, but many of us would say it has actually been moving right along and other things have been done to secure the channel without the application of this

technology as extensively as one might have envisioned by this point.

CO-CHAIR GLAVIN: I have a question for Mr. McPhillips and that is having gone through the experience of using RFID in what has amounted to a pilot in some ways, what would you do differently?

MR. McPHILLIPS: Do differently. That's a tough question, Margaret. You never -- when you start out with an initiative, there are so many different twists and turns you can go.

CO-CHAIR GLAVIN: Yes.

MR. McPHILLIPS: I don't know that we would have done anything differently. We had to just make decisions with the information we had at the time and we know that some of them or all of them we need to remain open-minded about. You have heard various opinions here today on this panel on some of them.

We don't want to lock ourselves into any fixed solution that prevents us from going in other directions moving forward, so we just had to make decisions along the way and some of them may not turn out to be the ones that we ultimately employ. But

absent of making them, we would be still sitting back up in New York, you know, drawing things on the wall and not getting very far.

CO-CHAIR GLAVIN: Okay. Thank you.

CO-CHAIR LUTTER: I have one final question before lunch and I address it to Mike Rose and Tom McPhillips. I think you have both said that progress is good toward implementing, I think, RFID. And my question is two years ago the FDA issued a Task Force Report that projected widespread use of RFID by 2007 based on a variety of comments that we had received.

And this meeting was called largely because of a perception that progress toward that goal has slowed and I think that view is -- so do you question the slowness or are we still on track to achieve widespread adoption by 2007?

MR. ROSE: Randy, I want to go back to the comment I just made. I think the progress that we have made is in the development of standards, so that is the first piece, so that is we're making good progress there. In relation to the FDA's recommended

guideline of 2007, however, it's clear a lot of other work needs to be done.

So we have to look at our business practices and processes. We have to look at the technology we're going to deploy once those standards are in place and then we're going to have to look back into how we're going to adopt that technology into our systems, back in our operations, whether it's the manufacturer, retail pharmacy or distributor. So there is still a lot of work that still requires to be done.

CO-CHAIR LUTTER: But if the standard setting is enjoying good progress and the changes in business practices are the next step, what can we do to help facilitate that?

MR. McPHILLIPS: Continue participating like you have been along the way with the standard setting and the other inquiries that have been made to the FDA about placement of labels and things like that, just continue the participation. Your involvement will, as Steve indicated earlier, generate continued excitement or interest around the industry

and that would be helpful. And you would maybe also bring further insight that allow decisions to be made quicker, too.

CO-CHAIR LUTTER: Final questions?

MS. AUTOR: I may get booed for asking this question, but I will do it anyway. It's a follow-up to Randy's question as well as to Mr. Scheckelhoff's comment that we should set a date.

If you all had to set a date for implementation of RFID throughout the supply chain at the item level, what date would that be?

MR. McPHILLIPS: Let me ask.

MS. AUTOR: And that's to whomever wants to answer.

MR. McPHILLIPS: Let me ask a question of you, Deborah. Lisa talked about a concept today of phases or people mentioned should it be targeted or every single product, so that I would have to throw it back and say what are you referring to?

MS. AUTOR: Well, that would be an option. I mean, would you set the date in a phased way and, if so, ballpark what those dates would be.

MR. McPHILLIPS: Well, I think that is an important decision that needs to be made as to how this technology is going to be used as we move forward in time. But, as I stated earlier, to get it on products that you would appear to be a threat, I would say it would be three to five years out before you would have that broad application for products that you would consider to be a higher risk product. And whether you go beyond there or not is one of those policy questions. I think we all have to get to that answer, too.

MR. ROSE: I think also a complicating factor for the high-risk products, I echo Tom's comment on that, I think if we focus on those. Many of those high-risk products are biological products or their solutions and they are not covered under the FDA guideline that came out in 2004. So we still have work to do and the question that comes in is do we have to commission long-term stability studies to understand the RF effects? If that is, that is going to drag this out. So there is still a fair amount of unknowns.

The other element is around the standards. What frequency will we use and is it compatible with the various packaging types? There is a whole series of questions that need to be answered here, not the least of how will the processes change as we look at our other supply chain parties.

CO-CHAIR LUTTER: Thank you very much. I think people are ready for lunch and I am delighted to have such a frank and informative dialogue. Please, join me in thanking the panel.

(Applause)

CO-CHAIR LUTTER: We'll see everybody back in this room at 1:30 on the dot, please.

(Whereupon, the workshop was recessed at 12:09 p.m. to reconvene at 1:32 p.m. this same day.)

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

1:32 p.m.

CO-CHAIR GLAVIN: Good afternoon. We're ready to start the afternoon session. Panel members, thank you for being in your seats and ready. I have just a couple of housekeeping announcements to make before we get started.

First of all, if you want an opportunity to speak at the open mike session tomorrow, there is a sign-up sheet at the press table. Open mike will be by sign-up only. So if you want to speak at the open mike tomorrow and have not signed up, please, do so at the press table.

Secondly, tomorrow morning at 8:30 our new Assistant Secretary for Health, Dr. John Agwunobi, will be here tomorrow walking through the displays and the vendor displays. Dr. Agwunobi is the former Commissioner of Health in the State of Florida and he is now the Assistant Secretary of Health for Health and Human Services. So if you have an interest in being there for the walk-through, that will be at 8:30 tomorrow morning.

I would like to urge you when you submit your written comments for the record to be as specific as you can in terms of recommendations and concerns. We will be looking to those comments as we move forward in this process. As you heard this morning, the Commissioner has tasked us to provide him a report in May and we expect that we will be asked for recommendations. And so the more specific you are in your comments, the better able we will be to take those into account in coming up with recommendations.

And then, finally, we have had a computer problem and so we have had to switch out computers with the presentations on them. The presentations on this computer are the presentations as of last night. So if you made changes this morning, I apologize. You will not find them on this computer. I apologize for that, but I didn't want you to be blind-sided and think something you had changed -- that terrible typo that you had corrected is still going to be there.

So with that, the panel this afternoon is on technology and research. Thank you all for coming back from lunch on such a timely basis. And we're now

going to continue with our second panel, and this panel is going to address what is needed for widespread RFID implementation.

And the panel members are Dan Engels of MIT, Krish Mantripragada of SAP, Laura Osburnsen from Unisys, and I apologize if I am mangling anyone's name. Let's see, Milind Mehere of OAT Systems, Narendra Srivatsa, NJ Packaging, Randy Stigall, UPM Rafsec and Siamak Zadeh from Oracle.

So with that I would like to ask Dan Engels to begin his presentation. These presenters have seven minutes and I believe if you watch this, it will go from green to red and I will also hold up a one when you have got one minute left.

UNIDENTIFIED SPEAKER: Does that mean we're number one then?

CO-CHAIR GLAVIN: Yes, absolutely. Okay. He's not ready yet, not quite there.

DR. ENGELS: I would like to thank the FDA for inviting me to speak today. It's a great pleasure and honor to be here before you and espouse upon some of the things that are very near and dear to my heart.

For those of you that are not familiar with the Auto-ID Labs at MIT, we are or at least our predecessor, the Auto-ID Center, was the developers of the EPC system and I was fortunate enough to be one of the founding members of that team that developed that.

So without further ado, let me begin by reminding us why we're here. We are here to talk about three technical things, serialization, RFID and pedigree. I will maintain my technical perspective on those by beginning with pointing out the obvious. Remember that serialization, RFID and pedigree are not the same thing.

They are separable, independent concepts, independent technologies all of which we can take and implement at different time scales with different technologies, maintain benefits. Granted, the whole is much greater than the sum of its parts, but we still bring great benefit by implementing any one of these three things.

Something was pointed out very clearly this morning, of course, that technology that exists today is more than sufficient to implement

serialization, RFID and pedigree. Technology as it exists today is able to do what we need it to do to implement those three basic things.

The problem is what is the ROI and the business case for the price points and other issues that we have today? RFID is not widely implemented for supply chain management. IT systems don't exist for pedigrees. We have to implement all of those things. Those are all learning curves. That is a big hurdle to overcome. Serialization, well, we need to agree on one. NDC was proposed, but NDC is not a serialized number. Serialized NDC? Maybe. We can talk about that as well.

So let's talk about some quick technical notes. Let's look at serialization. Serialization should be used to uniquely identify every item whether it's at the case, pallet or item level, the sellable unit or usable unit of dose. And we should make sure that when we use a serialized number, it's a one time use number. We assign it once. We use it once. We never, ever use it again.

What this really means is that when we

design a serialized identifier, we have a names base that exists that is going to last us for, you know, maybe 100 years, hopefully longer. And our 96 bits, definitely enough to identify every molecule in the universe. 128 bits, well, even if we're hacking it up we can do a lot of interesting things with that.

We want to make sure that we allow identifiers for multiple names bases. The NDC is a very U.S.-centric number. We are talking about pharmaceuticals. This is a global industry. When we have identifiers, we need to make sure that whatever we use for unique identification or serialization is able to encompass, at least in its representation form, numbering schemes from around the world. We have to make sure that we have that.

We need to worry about security. We need to worry about privacy particularly when we're talking about RFID carried numbers and, of course, do we want to close out or maintain status of this number so that once we have used the product, we have got some database somewhere, maybe with the manufacturer, maybe a God registry, that maintains the current status of

that product so it reduces the amount of counterfeiting that can happen with that particular number.

For RFID just remember that RFID is an automated identification technology. All it does is carry a unique identifier. If you spend a little more money, you could have user memory, so not only does it carry unique identifiers, it can carry more information about a product. I can have sensors on it. I can have all types of functionality. These can essentially be little microprocessors that are actually much more powerful than the 8086 for those of us that remember back that far.

The functionality and the frequencies are going to vary greatly for these. 1356 reads very well through liquids. 915 doesn't. It can still read through some of it, but I have got some issues there. We're talking about laws of physics, unfortunately. You know, we want to use RFID for that automated collection of data, so that we can get that human out of the loop.

However, when that tag fails when I have

got someone in the supply chain that does not have an RFID reader, but might have a 2D bar code reader, they still have that human readable or at least non-RFID backup technology, such as a bar code or an infrared type of printing technology. And, actually, I would suggest that the FDA should mandate the backup technology and suggest RFID.

Pedigree. Just remember pedigree is just chain of custody. We need to implement those systems and we can do physical encapsulation of the products. That is we can work on aggregation as well and we can worry about maintaining it centrally, distributed with the product, etcetera.

Remember that we have got existing time lines in place. I actually believe that the existing FDA time lines for pedigree, at least as PDMA describes it, as well as suggestions for RFID are very, very feasible. I think we can work forward from those today. That doesn't mean that we need to have everything done. The phased approach is actually where we want to begin because we have a lot to learn.

Particularly if you look at serialization,

well, we still need to come up with that serialization scheme. June of 2006. Why don't we have one already here in February of 2006? The industry has been working with EPCglobal for several months now. We need to come up fairly quickly with a serialization scheme that encompasses the global community.

RFID. The time line laid out by the FDA is actually very good. Why don't we have 2D bar codes when we start the pedigrees in December, RFID on cases and pallets by June, I'm sorry, January of next year. Why don't we do that? We can have item levels as we move further beyond.

And, of course, for pedigree time line, we're already working towards that. A lot of implementation, a lot of issues to deal with. If you're running the full-blown system, you need to start somewhere and you don't have to have the full system in place. With that, thank you.

CO-CHAIR GLAVIN: Thank you.

(Applause)

CO-CHAIR GLAVIN: Our second speaker is Krish Mantripragada from SAP.

DR. MANTRIPRAGADA: While he is loading the presentation, first of all, we would like to thank FDA. First of all, we would like to thank FDA for organizing this workshop and we are very grateful to be part of this discussion. And there was a lot of talk this morning around the importance of data management and the use of data and business applications and solutions.

Well, that is the business we are in. For those of you who don't know about SAP, we are in the business of data management and enterprise applications and, well, while it comes up -- and we have a very active program on trying to make sense out of the data that is being used in RFID in a variety of industries.

And we are in a fairly unique position to take some of the lessons and experiences from one industry and apply it across others. And we heard some of that experiences shared this morning from speakers of Wal-Mart and others and DoD. So it looks like we're having some technical problems.

CO-CHAIR GLAVIN: Just pause.

DR. MANTRIPRAGADA: Okay. So we're not biting into my time, right?

CO-CHAIR GLAVIN: No. Oh, goodness. Can we put this on hold?

DR. MANTRIPRAGADA: Just checking.

CO-CHAIR GLAVIN: We'll give you an extra minute. How's that?

DR. MANTRIPRAGADA: Great.

CO-CHAIR GLAVIN: We'll start it back at six, okay, when he gets going, because he's really good at his work.

DR. MANTRIPRAGADA: Of course, one of the themes is the reliability of technology that we're worried about today and this has many manifestations at different levels, and we appreciate your indulgence with this one. All right. It looks like we have done that.

So talking specifically about RFID. RFID is among one of several Auto-ID technologies that is fairly important for SAP. We have been one of the founding members of the Auto-ID Center and continue to invest heavily. Over the years what started out as a

research project was commercialized about two years ago and now we have solutions in over 15 industries in 15 countries and the list just grows. And so we are very happy with the way things are going.

Now, why is SAP interested in RFID and why is it important? If you'll recall, the last decade of solutions focused on the plan, execute, monitor loop and we foresee that the next decade of solutions are going to supplement that with the whole sense and respond. What are you sensing for, counterfeit products in the supply chain, or you are sensing for certain variations in demand or things like that, and that needs to be supplemented with the traditional business applications in order to be able to, you know, adhere to some of the evolving requirements.

We heard a lot about, you know, how supply chain and the pharmaceutical supply chain is exposed to an increasing number of risks and safety and security is becoming a prime concern, and there are a lot of these laws around establishing a chain of custody and so on.

But the way we look at it is that there

are really three things to ascertain the safety and security. You have got the product, you have got the transaction and then you have got the party dealing with it and they all have to come together in order to be able to truly address the problem of safety and security.

So, you know, we looked at mass serialization and other techniques where it's a layered approach where, you know, mass serialization is one aspect where now that you can uniquely identify every product, but you can tie that together with some of the existing technologies, so that a unique serial number on every product can be correlated with all the overt/covert, you know, security markings.

And you can also keep track of the various product hierarchies, things like what item went into what case, what case went into what pallet and so on, and that data is also valuable. Every time, you know, the product exchanges hands, you can also check for not only the authenticity of every number, but also the consistency of the hierarchy.

And the other aspect is that transaction

that controls the movement. Every legitimate, you know, good movement, whether internally or externally in the supply chain, has a business process and a transaction behind it and the ability or the key is to be able to, you know, every time there is a moment of truth where, you know, products move from Point A to Point B in the supply chain, weave in.

So security, authentication, traceability should not be an afterthought. It should be something that is weaved into the business process itself, things like, you know, every time there is a transport or every time goods move from Point A to Point B, and that's one of the views we're taking where all the security features are on identifying products, making all the checks and balances and the data that is both captured in the RFID tag and the logic required to ascertain whether it's in the right place at the right time, associating that with the business process that controls the movement of these products to begin with.

Now, from our products point of view, again, you know, I won't go too much into our products, but essentially we have developed both

platform and solutions to enable companies to manage this volume of serialized data, whether it's encoding different types of naming schemes, if you will, because, you know, we have to support both the DoD's constructs and, you know, the EPC constructs for, you know, consumer products and whatever scheme that pharmaceutical industry finally settles down to. We will support that construct as well and integrate that into our business solutions.

So just to give you an idea, I don't expect you to go through all of this in detail, but we have solutions today where we have worked with leading companies worldwide and have mapped out the whole process, what it takes to tag down to an item level, construct all the hierarchies, perform the validations and integrate it into your manufacturing and packaging process.

Similarly, same as the case in distributional logistics, and we're also working actively with our partner base to not only capture all this data, but make it available in the formats that are required to adhere to specific pedigree law

requirements, if you will. So even though data management does appear as one of the biggest challenges, solutions are in place today to at least enable you to get through the first step or the hurdle and, as we go along, there will be more and more solutions coming out.

The other thing that we have also actively done is one is to track-and-trace the product as it moves down the supply chain with things like electronic pedigree, monitoring all the events and status, but the other is also to enable the authentication of just the product itself anywhere. And we worked with companies like Nokia where they have an RFID-enabled cell phone.

And so now you can use existing technologies such as, you know, SMS, GPRS over your telephone networks and authenticate any product anywhere anytime. This technology exists today and we have successfully tested it in our labs. And the back end system is fully aware of who is authenticating the product, where did the event come from and things like that.

And all of this can also be progressive if you just -- you know, looking at the serial number could be one step but, you know, there might be concerns that serial numbers can be copied and all that, but there are various other things with all the technology improvements coming up with the Gen2 tags. There are things that can be done using a layered approach where it's almost foolproof.

So safety and security is the first step, but our goal is eventually -- as you can see, the value of mass serialization is if it gets used and absorbed in everyday business processes, and we are gradually one-by-one identifying the various business processes that drive today's business and infuse serialized RFID data checks and balances into these processes.

And there is a whole road map, you know, especially if you look at it from a life sciences point of view, ranging from, you know, logistics to transportation to even moving up to clinical trials and sample management where we try building this road map working with companies.

So in a nutshell, as Dan was alluding to before, a lot of the technology exists in some shape or form and we would encourage the industry to start adopting this, if not already, to take advantage of it.

CO-CHAIR GLAVIN: Thank you very much.

DR. MANTRIPRAGADA: Thank you.

(Applause)

CO-CHAIR GLAVIN: Our next presenter is Laura Osburnsen from Unisys.

MS. OSBURNSEN: Thank you. Good afternoon. Unisys appreciates the opportunity to share our perspective on the healthcare and life sciences track-and-trace adoption curve with the FDA and this very impressive group of participants. Now, we only have seven minutes, so I'm going to go ahead and just get right into it in the absence of the slides.

What we want to do is really spend the majority of our time sharing our take or perspective, once again, on the industry adoption, the pace and the curve that we foresee, and then specifically share

several provocations or big "what if" questions about what might change the rate of adoption in the industry, whether it's changing the shape of the curve and/or shifting the curve entirely, so big "what if" questions.

Let me start by sharing some good news. Unisys has seen significant progress in the adoption of track-and-trace technology since the FDA's 2004 report. In 2005 Unisys saw spending two to three times the level that it was in 2004 across the industry. In 2006 we anticipate that that spending will continue to increase as piloting continues to gain momentum, although it is still for a very, very limited number of SKUs.

And, therefore, at that rate of adoption, again pace is very gradual, so we do think that it will take well beyond 2007 before the industry is fully enabled with track-and-trace. Can I help you? All right. Well, it's okay. It's all right. We'll just -- if you can get the full screen. If not, that's all right. We'll just keep going. Okay.

In terms of the industry adoption curve,

first of all, we based our perspective on the adoption in two time dimensions. The first is what we call inside the planning horizon, and this is really representing only about 18 months to 24 months.

And then the second time dimension is what we call outside the planning horizon, and this is because beyond 24 months we just feel that the ability to predict what will truly happen, given the number of issues, the complexities and the obstacles that we have been talking about, we think that ability to predict greatly decreases.

So two time dimensions and within those time dimensions we see two primary tipping points. Okay. Can I just keep paging down? Then you need to escape. Well, I mean, there. Really escape, right? I think we got it. Is that good enough? Okay. It's not paging down, but that's okay. We have been going for it. All right.

Let's go back. So inside the planning horizon, again, 24 months. The first tipping point, widespread adoption, widespread requirements and, therefore, adoption around electronic pedigree.

That's tipping point number one that we anticipate and we foresee that within the next several years really or, excuse me, 18 to 24 months. This is based on the assumption that the state's activity will continue and that also there will be a drive toward universal pedigree requirements.

How are we doing? Okay. The second tipping point is what we call RFID equilibrium and this falls in right at the start of what we're considering to be that second time dimension outside the planning horizon, so beyond 2008, somewhere in the time frame of 2009, the next several years.

And RFID equilibrium tipping point number two is really based on an assumption that from what we're seeing in industry, from what we're seeing, the technology providers and advances and so forth in the capabilities, that a number of those obstacles will, in fact, be addressed, therefore driving a second tipping point.

We do also though, however, predict that potentially -- aha, there we go, a second path. I know that is really meaningful for the people way back

there, that we finally got the slides working.

The second path though in the second tipping point is actually a reduced rate of adoption around RFID equilibrium and that is because many of the obstacles or could be because many of the obstacles may, in fact, only be addressed to a limited extent because these are very complex, challenging issues.

Okay. Now, this actually looks a bit like a sixth grade science project. I'm not going to spend a whole lot of time on it. The whole purpose here though is really just to talk a little bit about the DNA and provide some context. I think we all have a unified focus around patient safety. We have heard that and there are various responses, I think, by industry, by standards groups and so forth, and so this is just meant to try to put some context to the various dimensions and what we consider to be a very complex DNA that is involved in this.

Let me just quickly try to share a couple of variables that we think are impacting the current rate of adoption. Obviously, I don't have the

opportunity to go through all of these. I will just point out a couple.

The first one is agreement around the "form factor" for track-and-trace and this I think is really exemplified or represented by a number of the activities we have heard already today from the trade associations, pulsing the member organizations and working very collaboratively to try to reach agreement around practices, industry models and ways for implementing track-and-trace. In terms of the regulators and policy decisions, certainly the open question at hand around the status of the PDMA and, again, we do fully expect that state mandates will continue as well as the universal pedigree.

I think I'm going to have to just jump ahead a little bit. Let's go into the big "what ifs." The first big "what if" that could dramatically increase the rate of adoption or dramatically shift the curve is if FDA removes the stay. This would require all trading partners collaboratively across the chain to identify issues, resolve issues and to invest in the infrastructure.

The second big "what if" is what if standards were widely adopted in a relatively short period of time, within a year, to say a year and a half? Obviously, this would help resolve a number of the issues around frequency, schema and other things that we have talked about, and the standards would facilitate trading partner collaboration.

The third big "what if" or provocation, this is what Ian Morrison the futurist I think would call a jump to the second curve, and this is where we're looking at a dramatic increase in adoption because we see value chain incentives aligned and this drives increased data sharing across the industry, thereby facilitating trade, facilitating trading partner collaboration and opens up great efficiencies all across the chain.

Okay. So key take-aways. Let me summarize. Track-and-trace is a complex domain. We have talked about that, obviously many, many issues and dimensions. The variables that we believe have the greatest impact or potential to impact the pace of adoption are really around process impact and trading

partner relations.

And then we think that a key success factor for policy makers is that when considering policy changes, you have to make sure that you're not implementing policies that have unintended consequences that, essentially, negatively impact cost or quality for the industry. Thank you very much.

(Applause)

UNIDENTIFIED SPEAKER: This one should be much quicker.

CO-CHAIR GLAVIN: Okay. Okay. I'm going to ask you just to hold a minute while we get the presentation up, so that you can -- people are being great sports about this, but it's really -- you know, these are important presentations and we don't want them interrupted. So if we can't get it right away, we'll do some questioning of the panel members who have already spoken. Ah, you got that one. Great. Thank you. That was the magic touch.

Our next speaker is Milind Mehere from OAT. Is it O-A-T or OAT?

MR. MEHERE: OAT Systems.

CO-CHAIR GLAVIN: OAT Systems. Thank you.

MR. MEHERE: Thanks a lot. Hopefully, this is the right presentation.

CO-CHAIR GLAVIN: Well, I wouldn't guarantee it.

MR. MEHERE: So first of all, I want to thank FDA for providing us the opportunity to speak here, very grateful and delighted to be here in front of a very wide, you know, array of end-users and as well as policy makers who will have a chance to speak.

So just a couple of lines on OAT Systems. OAT Systems was founded out of the Auto-ID Center at MIT and our founder of OAT Systems, Dr. Sanjay Sarma, was also the founder of Auto-ID Center at MIT. So really what I thought I will do today is talk briefly about -- we have obviously seen a lot of opportunity for discussion since the morning.

I thought I will take a view of what needs to be done in the next 12 to 18 months to really execute on those opportunities and where are we seeing a lot of investments being made from a technology and research standpoint, because that is really the panel

discussion.

So really, when I put up this slide, right, I'm really preaching to the choir here. The ultimate goal, of course, is to enable safe and secure supply chain and to prevent counterfeiting, right? And all of these buckets are absolutely instrumental in getting us there, right?

The key question or the message I want to take out of this slide is how can RFID help us get there or can RFID help us get there and, if so, in what time frame, right? So that's really the key that all of us should be thinking about. And to facilitate that discussion, what I thought I will do is just kind of lay out in four buckets what are the typical initiatives that will drive a technology innovation in the next, you know, 12 to 18 months.

What I also thought I will do is, you know, kind of give you a perspective of what is less likely to what is the most common one that will be adopted in industry depending upon, you know, what's your business problem you are trying to solve. Okay?

So the first one, of course, is

authentication and really what is really prevalent today is self-authentication. You can put a tag and, you know, the technology exists there, as Dan also pointed out, whereby you will be confident that your downstream supply chain partners will be able to, you know, read that tag.

Network EPC authentication, that is the key question that was raised in the earlier panel around centralized or decentralized data management. So that is something that is coming but, you know, it's probably not going to happen in the near future.

That kind of takes us from having a tag on the product and authenticating that tag to the next level, which is really E-Pedigree. This is kind of a very key, you know, business process because that is really driving a lot of technology innovation in the RFID space in the last 12 to 18 months and we continue to see that going forward as well.

So what will happen right now? Right now we are seeing several successful pilots where partners one-on-one are sharing pedigrees. Okay? Whether network pedigree will happen, again, that goes back to

the centralized versus decentralized question.

We also are very encouraged by the whole serialized ASNRx initiatives that some of the wholesalers and the retailers are requesting in support of the state laws, and I think that will really provide us a very good platform to expand that infrastructure to an RFID infrastructure and tremendous efficiencies we will see once we kind of move from a document serialized ASN process to an RFID-enabled, you know, ASN process, which is kind of the starting point for a pedigree type of application.

Of course, the next bucket is very key and dear to everybody's heart from an operations standpoint, which is supply chain. What we are seeing here is, at this point, you are tagging certain products, right, and I want to kind of go back to that earlier panel which spoke about NDC. What you can always do today is that you have an EPC code on a tag. You could always associate that EPC code with an NDC and that way track an NDC. So even if you don't have NDC as a part of the EPC construct itself, there are ways by which you could track NDC.

And similar to that, you could track code number, lot number, expiration date and really start identifying low-hanging fruit in terms of FIFO analysis or FIFO management, first expired, first out type of management in supply chains. From there on, obviously, you can go and build, as Dan said, all the way to, you know, charge-backs and some complex supply chain processes.

Last, but not the least, all of this adoption will be, you know, definitely driven by what the regulatory and the policy makers advise us and guide us, right? So, basically, the key take-away from this slide is really to figure out a roadway for you and what we recommend is to, you know, begin some item level tagging projects in your manufacturing plant or in your distribution center to help you do this.

So quickly talking about a manufacturing scenario. I hope all of you can see this, but really here is where you kind of start putting the EPC or the tags. So this is where the life cycle of RFID begins on the product. And here is where you create the

manifest, meaning what is the saleable unit or item and to which case it belongs and then to which pallet it belongs.

And once you have done that and it goes to your distribution center, here is where it gets complex because now you have a full pallet that gets broken into a mixed pallet. And what really happens here is you need to have an ability to capture those associations, meaning did I create three old packs from these two cases? Where do those old packs go? What is the association of an old pack with the order that I sent out and create, if you will, a delivery manifest that basically tells you that, okay, here is what I am shipping out to my downstream trading partner. Okay?

This is very important because this is kind of where you lay the foundation for the data and this is the data that you are going to use to address any business problems that you might have leading up to safe and secure supply chain. Okay?

So once you do that, right, how do you take raw data? Okay. What does the tag tell you? It

just tells you a number. How do you take that number and it basically goes through your supply chain. It will go through different read points.

That data is almost meaningless until and unless you put a context to it, right? So you need to have an ability where you take that data, and these are unstructured reads from within your supply chain and also from your partners, and take that data and have an ability to build a supply chain model.

What I mean by that is can you put these reads together, okay, and basically determine how long did a product spend in your facility or what is the transit time between your facility and your downstream trading partner's facility? You know, are they following the FIFO rules that you have set for them? Are they following the set of rules that you have set for them?

If you have this type of a data model, that will really help you put a platform that can help you solve the business problems, right? And so the point that I'm raising here is that data is extremely important. The value of data will only be possible if

there is correlation between the trading partners and, you know, mutually identifiable low-hanging fruits that all the parties can go after.

So with that, the last slide. Of course, the key points that have been raised since the morning, I agree with them. Standards is extremely important. There has to be a cohesive pact where every partner in the supply chain is moving towards and that is really why CPG has been successful, because even though everybody are going after different business problems, the baseline pact is very clear to them.

The second thing, of course, is regulation. It will be immensely helpful if we would have a coherent set of laws that can guide us in moving forward. And then last but not the least, reiterating again, data sharing is very key. You know, we have to identify mutually low-hanging fruit from a business value perspective and go after that.

And, of course, we thank the FDA. You know, they are in the perfect position to help us guide in this endeavor. Okay? Thank you very much.

(Applause)

CO-CHAIR GLAVIN: While we get the next set of slides up, our next presenter is Narendra Srivatsa from NJ Packaging?

DR. SRIVATSA: New Jersey Packaging.

CO-CHAIR GLAVIN: New Jersey Packaging, oh, hey.

DR. SRIVATSA: Well, we would like to thank the FDA and the audience here for this opportunity to present to you. As a brief on who is New Jersey Packaging, we are the leading pharmaceutical packaging company and supplier. We have been in business for over 40 years and the only work that we focus on is pharmaceuticals. So we are CGMP-governed and that's the way we run our business.

We are part of a parent national corporation which is incidentally the third oldest privately held manufacturing company in the U.S. So we are here for the long run for pharmaceuticals. So having said that, we are looking at a very significant patient safety issue here, but we have several solutions available out here. The question that

remains is are we doing enough?

I think we have heard differing viewpoints, some believing that we are moving as fast as we can and clearly the FDA would not have held this if they thought that we were not moving fast. And so the FDA objective, I want to track it in two different ways. You can get to patient safety in a number of different ways and we are looking at here a lot of the discussion that has been around track-and-trace requirements, traceability of drug product.

But then, there's also the anti-counterfeiting elements, because there's drug products that enter the supply chain through other means like Internet pharmacies and if you were to read the press, I mean, you would say that a large chunk of it comes from these illegal supply chain elements. So there's different objectives, cost and outcomes.

The other way to look at it is, I mean, both of these get to the ultimate objective, which is patient safety. And clearly, we need to do both. And while we are talking about track-and-trace, we have heard the better part of this morning and this

afternoon that the data infrastructure that you need is not ready. I mean, it's not there across the supply chain. And if you will look at the track-and-trace, where the bulk of your expenses are, that's where it is.

And the going business routes, that is what is going to determine your ROI. So it's not going to be whether your tag is reading or your bar code is reading or what have you, but because it's different elements by which you can provide the data to this infrastructure and I'll go through that.

What if you would add the counterfeiting, I mean, you do the layering of the different options that's available out there and you're creating additional barriers for the counterfeiters, especially those who sell through Internet pharmacies would not be affected by E-Pedigree, would not be affected by data infrastructure who really don't care about any of these things, who are just out there to make quick money.

So we have to look at both the pieces and because our primary objective here is really patient

safety. And what we have happening here without mentioning all the trade associations that spoke this morning, you have different authorities coming up with different standards. I mean, the ISO standards which was already in place for RFID tags, there's four different ISO standards. And clearly, the industry has adopted one ISO, which is 15693, which has a security chip encrypted in it. So those pieces are in place.

I mean, you see a lot of the pharmaceutical companies that's the direction that they're going. EPC, we have heard that the EPC is pretty close to defining what the codes are going to be. E-Pedigree, there's different states that are already legislated and there's many more on the horizon. And while overarching all of this is the FDA, which can, very clearly with a mandate driven program, force a lot of these authorities to go at a higher pace, because now we are putting it in as not as a cost, but we are doing it as the cost of doing business and focusing on patient safety.

So there's so many, many different drivers

that come at it. Now, if you were to look at how do you feed data in? I mean, you could do it with a bar code, just simple bar code. I mean, if you look at UPS and FedEx, well, they deliver billions of packages and they all get there safely enough. They do it with simple bar codes.

So you have to ask the question, is it the data that's being tracked is the issue or is it the data infrastructure not being there the issue? And clearly the answer is the data infrastructure not being there is part of the bigger issue, because UPS and FedEx they manage their own supply chain and they can create the business routes easy enough. While the pharmaceutical manufacturer, they don't manage their own supply chain, even though we have three wholesalers who admittedly supply 90 percent of the drugs in the U.S., you'll still have other issues because of the convoluted nature of our supply chain.

So serialization is another thing that we have heard about plenty and it's another encryption, so that's easy enough to do. Again, it's printed, I mean, the costs are very minimal. Then there's also

the chemical tags which you can apply to get at item load, track-and-trace. All of these can be fed electronically into the data infrastructure that we create.

So that's not the -- that's clearly not an issue here, because we can provide that. We can provide 100 percent reliability with those things. Then the electronic option, RFID. Clearly, the advantage is pretty significant, because you have non-line-of-sight. You don't have to open the cases, unless you are repacking it and sending it in a different way.

So the advantages are very significant. And there is many success stories. If you look at pallets, I mean, when we take drugs, I mean, we're looking at so many different side effects that's listed there, okay? So we have to look at this whole RFID in the same way, because we have to look at where the successes are and there's many and we heard from the world's largest company this morning, Wal-Mart, which is down with the phase program, and they have many, many cases where people are able to read 99

percent plus.

So the readability of RFID is not really at question. It's more a matter of how we implement it. What type of readers we use, what is the environment that we use? We can't expect to have 172 bottles in a case. We may have to rearrange the number of bottles we put in a case. It might be coming down to the levels where it is manageable. And we build it as the technology builds up.

So this is a very naive way to show the supply chain for the pharmaceutical industry, because clearly it's not such a straightforward chain. And looking at this, if you have something simple like this, you will be moving quite fast. But then it's not that simple. Then you have all these different legislations coming from E-Pedigree.

So looking again at RFID, tagging items with RFID is not new. RFID has been in use since World War II, okay? The initial quality issues have been overcome. There has been a specification created. We started off with 16 bits, 8 bits. The Auto-ID was started seven years ago and I was involved

with it.

Now, it's at 96 bits. Now, the next level is going to be -- we can put it at temperature sensitive. We can put a humidity sensor there. Let's wait for that to be 100 percent right. So we can -- there's enough reasons for us to put this off, but there's more important reasons to do it today in terms of patient safety.

So clearly, we need to understand what the business rules are, because this is really a business problem that we are trying to solve and patient safety is what we are all about here, okay, and I think nothing less. I mean, patient safety is our existence. If any of our brands get affected, we know what the implications are, okay. The price to be paid is pretty significant.

There is high initial investment costs. There is tag performance issues that are being talked about, but then you can manage that with staged implementation, which is what Wal-Mart has done. The bigger question is can it be compromised? So that's what we need to look at. That will be more a longer-

term solution.

So in terms of trends, I mean, FDA focus is great. Already PhRMA has announced that they have good reliability in their RFID Program. Merck in Germany is investing $1.2 million at University of Darmstadt for printable RFID. That's probably going to be at least five years away.

Now, there's tremendous resources being applied and as we heard from Unisys and others, there's two companies which have approved budgets, so it's just meaning that the wave has begun to move, but is it moving fast enough? Not yet, okay. So the opportunities clearly are if an RFID tag was available for a cent, I mean, that cost issue will be gone out and we will be looking at different things. So you have to look at robust tags. You have to look at printable tags. You have to look at the alternatives to RFID.

So again, going back to patient safety is what this is about. I mean, the Commissioner has stated that and we all know that and that's what we focus on. We have to look at two different approaches

to track-and-trace and the counterfeiting. What the FDA could do to accelerate this whole development is to set a date saying end of 2007 all tags, all products maybe perhaps in solid dose form will be the first element that would have RFID tags.

I mean, if not at the case load, at least at the item level, would be even better. And then documentation of the product, that really is all about creating the standards to make this adoption go faster. And thank you for your time.

CO-CHAIR GLAVIN: Thank you.

DR. SRIVATSA: Okay.

(Applause)

CO-CHAIR GLAVIN: Our next presenter is Randy Stigall of UPM Rafsec.

MR. STIGALL: Well, I'm Randy Stigall and UPM Rafsec makes tags, so I'm the lowest level on the chain there is. So just keep that in mind. And so I'm looking up and these are my views from looking up. We make both HF and UHF tags. What I want to talk about today is I believe and people before me have indicated that technology suppliers are ready for

2007. I think the issues are mostly non-technical and they need some resolution and I have some suggestions for the FDA.

Why are we ready? Well, we're ready because there are a variety of protocols in place, primarily out of ISO and EPCglobal, that will work and will work for pharmaceuticals. So there are reasonable choices and I believe the activity of EPCglobal will ferret those out here in the next few months.

Unfortunately for us and fortunate for you, there's lots of capacity to make tags in the system, because we have been a bit disappointed by the fast moving consumer goods business. So we have the capacity to make tags. There are a variety of the reader manufacturers that have been put in place because of the fast moving consumer goods activity in the UHF side and there has been significant HF activity in Europe for many years. So that supply base is in place.

And then you heard several people speak here of the middle-ware that's in place, that

architecture I think has been well-established because of the fast moving consumer goods and all is required are pilots and actually the short time period to refine the applications. And you have powerhouses, absolute powerhouses available to do the enterprise level. And they are ready to go. They have the body count and whatever.

I do believe there is some question about the communication infrastructure and the data management that goes along there. I suspect and I think Steve referred to that this morning. Perhaps the pharmacies aren't quite wired fast enough or prepared and the fragmented databases given that communication infrastructure calls to question could you use just a license plate?

I'll run through these really quick, so that just to give examples of how ready the industry is and this is just a group of names. We have a lot of small tags. We have competitors who have a lot of small tags. There are lots of reader manufacturers. I think the SupplyScape story about down the chain authentication being possible that they put together

for Pfizer is a good example of an application that shows that this is in place.

And as I said, the enterprise folks have the talented people available to do the work. So what is the issue? Well, I think the issue is data ownership. Who owns this immense amount of new data that's coming forward? Who gets access to that data and who has to pay for that access? That's the underlying questions that I think really keep us from moving forward aggressively.

Kind of stated simply, manufacturers want some return, data ROI, for source tagging. They don't want to make that investment without some return. The retailers demand that they cannot allow reduction in the data they sell that they create today, and so you have manufacturers saying I deserve more data for less and you have the retailers saying I can't afford to give up that part of my revenue stream. So there's a little conflict, I believe, there.

And then there is also the fact that every entity, and we talked about the trading partner sharing data, that claims ownership to the data they

create while the drug or pharmaceutical is in their custody. And then I think the most imposing thing in the short-term is accessing fragmented data through multiple firewalls. It seems like to me as a simple tag guide that that's a tough proposition today.

And then also from the privacy point of view is how do you allow different levels of access to individual's data based on their personal preference? Some people will want you to have a lot of access, because you'll give them a lot of benefit and there will be other individuals who will say I don't even want you to know I'm taking this drug. And so given those different levels of personal access, I do believe is imposing. So those are issues to be resolved.

So what are things that the FDA can do? Well, I think the FDA can sponsor not only discussions, but demos, plugfests where at major meetings like the HDMA meeting, I think is in June, there are a variety of meetings coming down the pipe where you could ask the technology suppliers to show more end-to-end solutions than just their isolated

solution.

I think another activity that could be done is bringing the business managers that own the data together and say let's work out the financial details relative to the data, because it is a business manager not a technology manager issue of who owns the data, who has access to it.

I believe there are opportunities to have this technology pulled through by consumers and patients. I believe Krish showed the Nokia phone and being able to use technology like that with the consumer so that they follow their drug regimen and you get the benefits that you all know exist when people take their medicine every time on time is a great benefit that this technology can support. They can also, as he said, do authentication.

And then finding the -- I think the real secret here is how do you find the equivalent of the DoD phased implementation in this business? I don't know the answer to that, but I think that is a necessity. One way to do that perhaps is tags can carry more data at the beginning and less at the end.

There are a variety of technologies that allow you to carry more than 96 bits, many more bits, and security techniques such as PKI that allow that to be protected and then transition that to more license plate oriented approach when the data infrastructure and the communication infrastructure is in place.

And then I think it's easy to say that there won't be a stay for part of this business in 2000 -- after 2006. So thank you.

CO-CHAIR GLAVIN: Thank you very much.

(Applause)

CO-CHAIR GLAVIN: The last panelist on this panel is, the last presenter on this panel, Siamak Zadeh from Oracle.

DR. ZADEH: Thank you and thank you. Not having had the benefit of seeing some of the presentations this morning, so I may address some of those issues and challenges, there will be some repetitive items there too. But I thought what I heard today was that from many representatives of the industry as well as people from various associations that for wide adoption of either RFID or pedigree, any

process, any new process needs to eventually become part of the normal business process.

So for any wide option of E-Pedigree, we need to really start looking at the entire current business processes and the disruption that this may introduce and how this could be adopted to the advantage of the changes that it needs to bring thereto. So E-Pedigree whether it is from manufacturer, distributor or repackager or retailer or any of these trading partners on any business transactions they do among each other, needs to incorporate this new -- a part of the current business processes if it's in stand alone and remains in stand alone, it would never really be widely accepted.

So if you look at some of the requirements, especially from the data perspective, a lot of my colleagues earlier have addressed the RFID. The physical layer tacts. I'm going to really be looking at the layers above that, mostly when that identity data information needs to be collected, captured, managed, queried thereto.

Now, if you look at this process, there's

really three major categories. One is the capture of data, the collection of data. And I think many of my colleagues have addressed that. It's not really technological issues remains. There may be still some, you know, pending technology, but primarily is business issues and identification of what data needs to be captured and collected.

And from our perspective really, it's -- we're agnostic toward what technologies to use as a carrier of that information, whether it's bar code or whether it's RFID. Then after that information is captured and collected, then the process of managing data and sharing data comes and that's where we get into some of the business issues as we have heard today is how that information is transmitted, whether it should be as one speaker this morning suggested a peer-to-peer or whether it should be a centralized repository or a collection of decentralized repositories with an ability to provide a very secure access to them by doing federated queries.

And at the end of the day, even if you access that data, what will you do with that data?

What type of information you need to gain from that data? And what type of knowledge you need to gain to start making business decisions, whether it is a flag raised for a counterfeit that's been observed or overall in terms of same patterns in terms of distribution?

Now, if you look at some of the current challenges at these different layers and some possible solutions, by no means these are meant to be, you know, a solution or any silver bullets. But, please, we all heard today a very polarized presentation about what type of technology needs to be used. And in the short-term our view is that no matter whether bar code or RFID is used, any solutions needs to support any data carrier identity technology.

At the end of the day, identity, as I said earlier, is just the data. So instead of trying to, you know, dig down on these polarized perspectives of whether which technology support the other one, I believe both technologies are probably providing the foundation for, you know, identity management or identity data. And the idea was that solution was to

capture that.

We already heard about different mandates and regulation of states and already there is a call for a uniformity and creation of a uniformity E-Pedigree wall. This is something that probably regular, you know, entities, you know, can deal with it, especially FDA have more of a national mandate versus multi-state mandates, thereto. But again, in the short and interim period with a State of Florida mandate going into effect starting this year, the California Electronic Pedigree going into effect next year, again a solution needs to handle a super set of all this information, these data, whether it states various specification of state mandates or what is national into a single.

Again, by centralized way, not necessarily centralized repository, but rather a central way of accessing management, especially in entities such as FDA. In terms of different data collection points, and you have seen that, this is probably one supply chain that you have multiple touch points, multiple points of entry for that. And again, an approach

needs to be a solution needs to handle both the centralized data capture with a centralized data management capabilities.

This is probably some sort of a hybrid type capability that if and while we are trying to figure out whether a centralized repository or centralized product approach, we should be able to provide some sort of a federated queries over, you know, the data that may be even collected or reposited a centralized way.

And again, in terms of the different data sources for chain of custody and data sharing across supply chain, we are looking at a variety of, you know, players in this space and we need to be able to solution that does cover this multiplicity of the players and parties involved as well as the multiplicity of the technology network.

I want to spend briefly a little bit of time on this emerging EPC Information System architecture, because our view is that, and I guess Bob in the next panel is going to talk a little bit more about it, he and I haven't talked too much, I

don't really know whether he will or not, but I want to mention that EPCIS has the promise of potential to provide in terms of information management some of the capabilities both at the physical layer capturing data as well as the ability to transmit data from the physical layer information is captured at ages to the applications and back and forth.

And that needs to happen if this is going to be uniformity of the data, too. And as we heard today that eventually we need to have a long-term view of that. This needs to have more network oriented VIPPS service or service oriented architecture network on that.

And finally, since I'm at the end of my time, the E-Pedigree to be widely adopted needs to be part of a larger enterprise solution. This application of E-Pedigree needs to be integrated into their existing applications that they already have whatever is house management system, whether it's the purchasing order, whether it's in terms of any type of manufacturing processes, any types of procurement shipping and eventually part of all the forward

logistics as well as reverse logistics to be able to be effective and introduces not only a benefit to all the players in that as well as optimizes the existent supply chain.

So in summary, as option wide, an option of E-Pedigree, it needs to be part of uniformity. E-Pedigree needs to be a part of normal business processes. There needs to be an infrastructure for information management, which provides a uniform data capture, uniform data access, uniform data management and information analysis. And finally, the E-Pedigree solution needs to be part of a larger enterprise solutions. Thank you.

CO-CHAIR GLAVIN: Thank you very much.

(Applause)

CO-CHAIR GLAVIN: Before we start questions, I want to thank the whole panel for both some very interesting information that you shared and some interesting perspectives on the issues we're facing and also for your good humor and solidness in working through our technical problems earlier in the panel. So thank you. Randy?

CO-CHAIR LUTTER: One housekeeping note, as I mentioned earlier, I see people standing in the very back. We have four empty chairs to my left. In the interest of

CO-CHAIR GLAVIN: Not at the table.

CO-CHAIR LUTTER: Not at the table, to my extreme left, but there is a view. So anybody who wishes to have a seat, please, feel free to come forward and take those. You'll be more comfortable than if you stand.

I have one question. We have probably maybe 10 minutes of questions before the next panel. I have one question that I would like to ask to Randy Stigall and this pertains to on your comment earlier that the primary issues to resolve are who owns the data, who gets access and who has to pay. And these are not primarily the technical issues in which, I think, this panel has a forte, but I'm going to pick on these questions because of their clarity.

And my question to you is, and perhaps their ease of understanding for those of us who don't specialize in this, what can FDA do to promote

agreement on these issues? And I think I have heard several suggestions. One is set a date, earlier today. Another one is schedule conferences and, of course, we're doing exemplary at that. And I wanted to solicit your views on those two suggestions or alternative third or fourth ones that you might wish to propose to remedy those three issues.

MR. STIGALL: Well, I think, the point I made to really close on that, because those have to do with companies= money, how much they make, how much they pay, and so I think those are very business oriented. And finding a forum in which trading partners begin to negotiate out those details is very important.

And I know the sensitivity of that makes it not necessarily conducive to a public forum, but some expectation that those discussions occur and the balance -- the burden be balanced across the participants. Because if you make any one participant carry too large a load, they will falter, they will fight.

CO-CHAIR LUTTER: Any other response to

that question from the other panel participants? Questions from the FDA Task Force?

MR. McCONAGHA: Is this on? Yes. I have a question actually on the technology issues and I would address this to Mr. Stigall and Mr. Engels and any others, I guess, who have a view on it. We have heard anecdotally largely different things about the read rates with respect to the current technology tags and we understand that in an ideal environment in kind of very successful pilots, the read rates can be as high as 99 percent.

It's also our sense that there are kind of real-world conditions that might interfere with that on a case-by-case basis. And so my question is how real a concern is that? And, Mr. Engels, if the industry were to begin to use RFID in kind of a widespread way in the very near term, what would be a kind of a realistic sense of what the read rate might be? And to what extent is the read rate or its limitations a barrier to moving forward in this area as a technological matter?

DR. ENGELS: I would answer your question

actually with a question, define read rate.

MR. McCONAGHA: You're tripping me up on technology, which is very effective and very easy to do as it turns out. What I'm getting at with the read rate is the idea that -- and I think we heard reference to it earlier this morning, the idea that there can be other things in the environment, be they metals, et cetera, that surround the packaging or the shelving that it's on that interfere with the ability of an RFID reader to accurately read a tag and give the information to the reader that's intended.

And I'm just wondering if there are real concerns there and to what degree that they frustrate the implementation of RFID?

DR. ENGELS: Yes, unfortunately, when you are talking about using RFID, really RF communication fo any communication, you have the issues associated with I've got metal in the environment. I've got liquids in the environment. I've got other RF interference in the environment, potentially coming from other readers, all of which will degrade my ability to communicate with the tags.

Now, when I'm talking about passive devices, we're always trying to operate those devices beyond their actual limits. We always want just another inch or just another half an inch. Well, we're trying to do that and really if you're trying to read 200 case tags on a pallet of products as it runs through your dock door at six miles per hour, you are going to have difficulty reading all of those case tags all of those times for all products.

Tags that are buried between lots of metal, you're going to have a very, very hard time reading at UHF frequency or really any other frequencies if you're using a passive tag. You use an active tag, use a semi-passive tag, you can improve your chances. So there will always be scenarios where I will not be able to read tags. The real question is why am I trying to do verification as I'm running through a dock door?

If I need to do verification, I go through a verification tunnel for that. So there are business scenarios that have been put forth as this is the way we have to do our business, even though we don't do it

this way today. But I have to be able to do that in order to verify or be able to use RFID in any meaningful ROI type of sense.

I reject those types of scenarios because they just don't make sense on the face of them. So in terms of being able to use RFID, you are always going to have interference. In all scenarios, you are going to have random noise that's going to cause you issues and you're going to fall below that 100 percent. The goal is to be at 99.999 for those tags that you need to be able to read.

Can I read a tag on a pallet load of product as it goes through a dock door at six miles per hour with an accuracy of 99.999 percent using UHF frequencies? The answer is yes. Can I read every tag on a case in every pallet that runs through that dock door at 99.999 percent? The answer is no.

CO-CHAIR LUTTER: Thank you. Steve?

MR. SILVERMAN: I would like to address my question to the panel generally and I would like to confirm a perception that I took away based on the panel's general comments, which seems to be the

suggestion that at least currently the technology exists now to implement a meaningful RFID system, but for certain business decisions that need to be made by the companies that would use those systems.

And I would like to ask the panel if that's an accurate perception and in responding, I would appreciate feedback in terms of whether the statement of currently available technology considers the cost to businesses of implementing that technology and making the technology widely available down to the retail pharmacy level.

DR. SRIVATSA: Well, I guess the panel in general was presenting that. Your perception is right. I mean, what you took away is right, that the technology is there to do at least a limited phased-in RFID implementation. Now, as far as the costs and the ROI trade-off, it really depends on what the business rules engagement is going to be and simplification of the supply chain that really happens is going to be a big advantage in terms of seeing the ROI really quickly.

So you saw numbers in Milind's

presentation where I think he had something like $3 billion available out there by efficiencies, I mean, that's looking at it at a global mapping level. But clearly, the ROI is there depending on what cases you look at. It's not going to be a widespread implementation ROI. We heard this morning what are you going to do about generics, okay, it has to be a phased-in approach.

MR. MEHERE: Just to add to that, right, to be kind of precise, I think where the technology is today, you can very comfortably do case and pallet level tagging and also go down to item level. I think the key question is what are those low-hanging fruits from a business ROI perspective that you can enable? And you can enable those only by the point that Randy leads which is how can trading partners share the data?

Because if you don't share the data, then your ROI case becomes extremely weak, because then you are looking for internal supply chain efficiencies, which are there, but those will come with scale. And right now you don't have scale, you're just tagging a

partial number of SKUs on very less number of products out of the total product mix that you have.

So that's kind of the Catch-22 here. If you want to go after low-hanging fruits, then you have to be able to do data sharing between trading partners. And that's how you will get to ROI.

CO-CHAIR LUTTER: We have time for one more question. Thank you.

MR. VERMILLION: Okay. My question I'm going to address to maybe Mr. Stigall here or Mr. Engels and then if there's others that should answer it, I'll be glad to hear you. Normally as the criminal mind starts looking at an opportunity, they start inventing ways to interrupt the security that are surrounded with whatever we put in place of a nation's currency, safeguards for counterfeiting and others.

I'm wondering what is your opinion on the ability for exploitation of the RFID tags, either to be counterfeited or to be altered? Do you have any thoughts on that?

MR. STIGALL: Well, it takes a significant

amount of capital to be in the silicone-making business, so in the tag side, the first deterrent to counterfeiting is that you have to have about $2 billion for your own fab. Now, there may be entities in this world who have access to that. You probably know that better than I do.

But there is a significant cost of entry to be able to begin at the silicone level, which is the base of our RFID tags. But in conjunction with other data that you will have, which is this tag which has a silicone serial number as well as this grub which has a serial number and where it is at, those three pieces of data are difficult to replicate around the world.

If the right numbers are in the wrong place, it's still the wrong numbers. So I believe -- and I will mention this. That one of the uniquenesses and one of the benefits that RFID will bring will be able to individualize the other security marks that can be placed on packages, such that each package will have its own unique set of colormarks, watermarks or whatever.

And you'll look up and you say with this number what features am I looking for? So I think it aids that. But from my previous history at Procter & Gamble, I do know that counterfeiters are incredibly, incredibly talented and they only have to work on breaking your security piece. They don't have to develop the product. So they have an advantage. They are unfair competitors.

DR. ENGELS: Yes, the issue when you think about security is you have to think about it as a layered approach. By having a unique identifier for a particular product, that's one level of security. You have a wrong product identifier on a particular product, clearly, it's a wrong product. Counterfeiters get over that fairly quickly.

When I go to serialization, well, now, I need to worry about what is the status of that serialization? So if I'm just looking at the manufacturer issuing numbers, counterfeiters can potentially identify what numbers have been issued previously and start using those numbers on their counterfeit product.

If the manufacturer is now operating an authentication service for those that wish to authenticate that this particular number has actually been issued and has not been closed out, then you've got an actual status associated with that particular number. Has it been issued? Is it in process? Where is it? When was the last time it was seen? Has it already been used? And you can then associate that information with the product itself. So I can potentially know where it is.

Now, when I think about other security features, on tag you've got a unique tag, a unique silicone ID associated with it, that's why you need the fab. That's the number that's written in the fab. It is not written anywhere else in the world. So I laser etch it in the fab. If I've got access to a fab, I can potentially create my own design, so I can replicate those in the field. That's a lot of expense, but there are organizations out there that may have access to be able to design that type of silicone or have access to those fabs.

But I still have effectively a product

number, a unique serial number that I then have to match with effectively a random number. That is actually an interesting and very difficult thing to do. Either I'm sitting there reading all those numbers as they come out of the factory, I've actually physically read those numbers or I'm tapping into databases, hacking into databases and pulling those numbers out.

In addition, you can use RFID to have additional security features on it. No one says this has to be promiscuous tags only. We may, in fact, have secured data either encrypted in the memory or have encryption capabilities for the memory, so that I have one time use. These types of systems already exist, have been implemented in TI and your mobile Speedpass uses a form of encryption for the numbers that it stores.

So there's many additional layers that you could put on here. The first step, just having a unique serial number on the product is going to take the counterfeiters a little while to get over that hump. Then you start adding additional layers,

additional layers, additional layers. There are many, many layers that we can add to this that will help to keep the counterfeiters at bay for at least a little while.

I think with silicone, particularly with an RFID system, we can -- if we're willing to spend enough money, we can put a super computer on there, but absent that, we can put lots of layers of security there that are fairly inexpensive that will thwart, at least in the short-term, nothing is ever permanent, in the race with the criminals, but at least have a leg up, at least very much in the short-term.

CO-CHAIR LUTTER: Thank you very much. Please, join me in thanking our distinguished panel for this excellent presentation.

(Applause)

CO-CHAIR LUTTER: We have about a break of two minutes while we change panels. So take advantage of it to stand up and we'll start very shortly.

(Whereupon, at 2:54 p.m. a recess until 2:58 p.m.)

CO-CHAIR GLAVIN: Thank you. All right.

We're going to start. We have two panels who are going to address the subjects of standards, E-Pedigree, and data access issues. I apologize. Over the last several months we have been approached by several stakeholders seek our advice and thoughts on various issues that have surfaced as a result of standards development, pilot studies and E-Pedigree implementation.

Such issues include mass serialization and numbering schemes and data access and security. The next two panels will discuss these issues. The first panel will focus standards and the second on general issues, and I'll let you introduce the panels.

CO-CHAIR LUTTER: Bob Celeste of EPCglobal will speak first and after that there will be a 15 minute combined presentation.

CO-CHAIR GLAVIN: No, no.

CO-CHAIR LUTTER: Oh, I'm sorry. You're doing one combined.

CO-CHAIR GLAVIN: Okay. Just keep going.

CO-CHAIR LUTTER: Welcome, and please, proceed.

CO-CHAIR GLAVIN: Whatever you want to do.

MR. CELESTE: Great. Thank you. Actually, I'm from EPCglobal standpoint, and our entire panel we're really appreciative of the FDA in all their efforts and how they have worked with us to develop standards. Much like the supply chain, our panel, the first panel has collaborated on our presentation, and so you will see two of us deliver the presentation, but all five us are very welcome and open for questions.

What I would like to do is just introduce our speakers, myself, Bob Celeste, Lucy Deus, and then we will have our other panelists Verun, Bruce and Piers, who will actually answer a lot of the questions for us. And I will talk a little bit later about why this group was put together and the importance of them.

What we would like to do is talk a little bit about some of the standards that have been developed within EPCglobal that relate to healthcare. Now, we have developed a number of standards around hardware and software for the implementation of

EPC/RFID, but today we'll just focus on ones that are particular to healthcare and then have an in depth discussion about the E-Pedigree standards.

So a lot of information on the slide, but I just want to talk to you about when this supply chain came together, an entire supply chain coming together of trading partners and competitors, the first thing that we tackled was the pedigree management itself, the processes, the use cases that were developed, how to process information through a supply chain such as this. That information has been completed. It resulted in about 21 use cases and 224 requirements that will go on to our standards development areas.

The pedigree messaging standard was next and as far as standards go, it's probably a record for us. Within about 12 weeks, a little over two months, we developed a draft pedigree messaging standard that has gone now to the unified coalition, pedigree coalition that involves the FDA, states and a number of trade organizations.

Item level tagging. We have a group now

that has gone into the standards development part of that dealing with issues around serialization, decommissioning of tags, what kind of information would go on a tag, those type of things. The item level tagging one is now in standards development within our Hardware Action Group.

Serialization, the number on the tag. You heard a number of talks today about whether the number should include an NDC or whether it should include an entire serialized number, and those are issues that we're working through now.

Decommissioning. Also, we're working on how to make sure that tags do not reenter the supply chain. And in 2006 we're actually going after the true track-and-trace. So the industry will start talking about what do the read events mean to the industry? How do you interpret them in a business?

Along all of this, security and privacy are part of our discussions and part of our concerns with each and every standard that we build. Along the bottom you see sort of what happens after standards are done. So now, the industry needs to implement

this through capital spending, process re-engineering, systems integration, line retrofit, as we heard from Pfizer, and then scale-up. So those are the things that have to happen after standards are actually in place.

So I would like to bring Lucy up and we can take a deep dive into the pedigree area and then answer some questions.

MS. DEUS: What I would like to start off by doing is distinguishing the specific standards that we did focus on because you hear about two different things. Really, you hear about E-Pedigree and you hear about drug product.

CO-CHAIR GLAVIN: Can you hold the mike?

MS. DEUS: Sure. Thank you. And you hear about drug product identification and these really are two different things. The serialization and the RFID that we have been talking about, that enables the drug product identification and additional applications beyond that.

When we talk about electronic pedigree or pedigree itself, what we're talking about there is

ensuring a legitimate chain of custody for products as they move through the supply chain, and this is independent of whether or not those products are serialized or they are not serialized. And so when we talk about creating standards for pedigree and moving into the world of electronic pedigree, what do we need to do that?

And so there's a number of different standards and technologies that underlie that, which include the electronic pedigree format and exchange format, digital signatures, as you have heard talked about earlier today, electronic records and business-to-business exchange mechanisms.

And for those latter, those few latter, there are standards that exist already. They are in use in industry in different ways, but the gap that we have is what is that E-Pedigree exchange format, what does an electronic pedigree look like, how does it relate to these other technologies and standards that exist, and then how do I tie those things together, and what is the standard for tying these things together so that we can enable electronic pedigree in

the industry? And that is really what the working group focused on.

So as part of that, we looked at two key challenges that the pharmaceutical industry faces, having a universal interchange format for the pedigree data elements that meets the varied state pedigree requirements because they are a little different sometimes when you go from one state to another, and also a standard in formats for enabling trading partners to send and receive pedigrees in a secure and interoperable manner.

The pedigree format was driven not only by the pedigree data elements, but also by the pedigree process requirements that you see in the different regulations that are out there. And so this involves providing a pedigree as part of wholesale distribution. It involves certification via signature of those pedigrees, and it involves authentication of those pedigrees that you received for the validity of the pedigrees and also against your products.

So when we look at the E-Pedigree format in the standards that we have created in the EPCglobal

group, we have created an E-Pedigree interchange format that satisfies the following requirements. It has all of the data elements. Think of it as a superset of all the data elements that are required that were listed in the PDMA, as well as all the different state regulations that are currently available, and even including some draft and pending legislation that is out there.

Also, it includes support for both non-serialized as well as serialized products. This is particularly important, that we have one pedigree format that will enable electronic pedigree for both non-serialized and serialized products because our reality, and as many people have talked about throughout today, is that, well, today products are really -- they are not serialized yet. It's going to be quite some time before you see mass serialization of all products in the supply chain.

So the reality of our world is that we're going to be living in a mixed world for quite some time as we get to that endpoint that we're all looking to get to. And so the standards group, as we looked

at this, is how do we create a format that handles the future requirements, the today requirements and then that interim time frame.

In addition, it needs to -- the format supports repackaged products, the different types of exchange transactions of sale transfer and returns, the ability to take paper pedigrees and convert them into electronic pedigrees, the digital signature requirement, the electronic authentication of pedigrees.

It needs to be in a common portable format, and it needs to leverage and work with existing business data transfer mechanisms when people exchange pedigrees with each other. We don't want to have to invent new technology just for sending pedigrees around.

And the format that we have defined includes -- this is a summary of the pedigree data elements that are there. It includes all the product information. This is things like the NDC, the drug name, the dosage, foreign strength, etcetera, the item information that is the subject of that chain of

custody exchange transaction, so lot number and expiration date, how many quantities of unit and if those products are serialized, what is the serial number of those individual products?

The specific transaction information, so that this is tied back to the purchase order or invoice that this exchange transaction is about, the information that identifies the trading partners, who are the two parties that are the subject of this transaction, and the information about those companies, and finally, the signatures that are required to be on the pedigree.

The standard that we have defined actually is composed of two parts. One is the actual electronic pedigree format that contains all the different data elements. And so this is what the electronic pedigree would look like in your computer system and how all those data elements are expressed in a standard way in which you express those. And the key there is so that when one company receives pedigrees from another company, that their technology is able to interpret and understand that pedigree and

the information that's inside of it and act on it.

The second part is the electronic pedigree envelope. And really, this is nothing more than a mechanism that allows us to wrap up pedigrees together and send them electronically from one company to another in a portable format. And this is a bit of a technology facilitator, basically, for exchanging pedigrees in an interoperable manner.

The next component in the standard are, we talked about earlier, the signatures and the authentication. So the electronic pedigrees use digital signatures so that you can electronically sign or certify the pedigrees.

This gives us document integrity, the ability to do authentication and it's an extremely secure signature, and it allows us to ensure as we're signing each step of the way, as the pedigree moves from one supply chain to a partner to another and they add information and then they sign it, it allows us to verify that the information in the pedigree was not altered since the time that it was signed, so that it helps to secure that content.

So this is the result of the activity of the working group. We finalized the pedigree format, so we have got the technical specifications in terms of what is called a schema and those have been created.

We have got a document that is a specification that actually identifies all of the different data elements, the different ways that this gets used, how it ties to the other relating technologies, different use cases and scenarios for how you use it, and all the steps that you work through, so that the different companies who will use the pedigree format to send electronic pedigrees back and forth can all use it in the same way and understand how to use the format.

The pedigree, you know, the working group, as Bruce talked about, has worked really hard over the last, you know, couple of months. And when we say a couple of months, it's actually -- you might have a worry, gosh, is this mature if you have only spent a couple of months on it?

But the reality is is everybody here

sitting at this table and others, this was the result of many, many more months, and in some cases, years of work that those companies were already doing in this area and it was really bringing all of that knowledge to bear and all that experience to bear in bringing this together into a standard format. So it actually has a lot more time behind it than the couple of months that was really the process of merging and melding it together.

But the format that we have created is a common format that meets the PDMA and the state needs, and it's extensible to support future requirements. It addresses both the regulatory and the business requirements, again, for non-serialized as well as serialized items, the digital signatures, that electronic authentication process, and it enables the interoperability among trading partners with that common portable format to exchange pedigree data.

What you will see in terms of the formalization process, that's the part that we're moving into now, is in formalizing the standard and we're moving into that process within EPCglobal. And

what you will also see is once it gets to this stage is when vendors actually start implementing against this. That would typically happen simultaneously in a standards process.

And so this is the version that the vendors are implementing their products against. And actually, what you will see is real-world implementations with wholesalers and retailers actually starting to exchange pedigrees in the coming weeks and months, very soon, in support of meeting the regulatory requirements in the State of Florida for a pedigree. And so you will actually see this standard in action for meeting the Florida requirements with many companies in the supply chain.

Again, we thank the FDA for the opportunity to share the progress that we have made with the pedigree standards with you.

(Applause)

CO-CHAIR GLAVIN: Thank you very much. So that I understand, are there other presentations from Panel 1?

MR. CELESTE: No.

CO-CHAIR GLAVIN: Okay. Would you like us to go to Panel 2?

MS. DEUS: No, let's ask questions.

CO-CHAIR GLAVIN: Questions? Okay. All right. We have a time for questions for Panel 1, and I have a question, and it has to do with the fact that we have heard a number of times today reference to states beginning to set standards in this area of pedigrees, etcetera, and your sense of whether a federal standard would help that or make it -- would it make it easier or more difficult for companies to comply with the standards, the pedigree requirements imposed by individual states, if there were a federal standard? And I will let anyone who --

MR. HARDER: I'll take that. I'll take that one because that's a fairly straightforward one. This is Bruce Harder from VeriSign. From a technology standpoint, and I will articulate the technology aspect of this, and I can only address the technology piece because the industry is owned and operated by the regulators, the wholesalers, the manufacturers and the pharmacies and dispensers. They

have got to speak to the overall issues.

But on a technical standpoint, if you're building a solution, whether that is an interior organization solution or a solution inside an organization, building to one known spec is a heck of a lot easier and is a heck of a lot more likely to be workable and be automatable than if you're working off of, you know, two, three, four, 50 different specs.

So, clearly, from a technology standpoint, I think it would be more straightforward, more economical to address a single spec than multiple specs.

CO-CHAIR GLAVIN: Other contributions to this?

MR. LINGLE: This is Piers Lingle from Cyclone. I just want to add one more point. It's more of an example.

One of the questions that is being raised by the companies that we work with from a software solution perspective is what do we start doing about cross-state deliveries of product and if each state has its own standards, there are different

requirements between those states.

So a very concrete example is, if we have one standard, a federal standard, then those questions can be put to bed and we can actually work on the business process to actually make that come to fruition versus trying to figure out now or divine, you know, what did each, you know, legislator intend, you know, for their respective state.

CO-CHAIR GLAVIN: Okay.

MS. DEUS: Yes, and just to add one more piece to that. A pedigree, again, is not just about the data elements. It's also about that pedigree process and so technology can really handle the issue of the data elements and making sure that you have all the data elements required to move pedigree from one state to another.

But many of the companies that have to implement pedigree exist in different, multiple states, and for them to have different processes in different facilities that they have in different states, that can be challenging for them.

And so what you do see a lot of companies

doing -- because Florida is getting up and running just in, you know, the next few months and having pedigree required in July and then, you know, you have got California six months after that. A lot of companies are, you know, gearing up their processes, their systems and moving forward with a particular pedigree implementation. That's the first one to hit.

And I don't want to speak for them, but, you know, I can say if it was me, I would find that if there was -- the thing that I'm implementing to now, that level of standard that I have to implement to now, if that was sort of the common bar, you know, that I had to meet in the other states, that would probably make a much more repeatable process that I would have to go forth and implement, and that would, you know, save on my cost in terms of rolling pedigree out through all of my different facilities in all the different states.

So, you know, people are already meeting sort of this certain, you know, Florida/California bar. And so, again, I think having, you know, sort of a level playing field there would probably be helpful.

But I would encourage you to ask that of, you know, the actual industry themselves.

CO-CHAIR GLAVIN: Right. And we also have a panel of states tomorrow, I believe, so thank you. Ilisa?

DR. BERNSTEIN: Hi. Thank you all for coming, and I appreciate all the work that you did getting these standards done in such a quick time.

I have a question. Going through in the other room, you all have examples of how you have actually kind of implemented some of these standards and they all are very impressive. However, there are a lot of pharmacies and smaller wholesalers that say, you know, I just can't afford to do some of these things.

The technology or the standards that you have developed, can those be transformed into kind of off-the-shelf type software programs that someone can just go and buy at their local place wherever you buy that stuff and plug it in? And while you answer that, I have another question if that's okay after that.

MS. DEUS: Okay. I can take that. So

there are -- you can tell by the vendors that are on this panel, and there are more out there, that there are a number of vendors that offer pedigree solutions.

The standard that we also develop is documented in terms of a specification, which enables-- you will see some companies building their own in their own internal IT departments, if they have the resources to do that, and that capability is there by the specification. All the information is there to know how to build out a pedigree in this format and exchange it.

So there are numerous vendors and also, vendors are offering numerous types of solutions. So you will see solutions that companies who can afford and have the staff, you know, to operate software internally and have computer systems internally that they can run this on, those types of solutions are available.

There are also vendors that are offering subscription-based services of offering pedigree solutions so that for some of the smaller companies that don't have the ability or don't have the computer

systems in-house, they can take advantage of the subscription-based services. So I think you do have a spectrum of capability that is out there for the spectrum of the more sophisticated to less sophisticated technology bars that are out there in the companies.

DR. BERNSTEIN: The second question is you have put up there that this will work in a paper and in an electronic environment, and we have heard this morning people saying we should take a phase-in approach, and I can see that in some situations paper just may be really the only option.

Can you explain, it's hard to visualize, in an easy way to understand how you would live in a paper and in an electronic world and make sure that that paper itself is secure, too?

CO-CHAIR LUTTER: Let me just refine that a little bit. We heard very strong comments earlier that the paper is not worth anything. So if you had a hybrid system with paper and RFID, wouldn't the contaminated paper contaminate and pollute the entire system?

MS. DEUS: Do you want to go first?

MR. HARDER: No. In looking at the, you know, how to meet the regulations that are out there today and, again, a lot of our work focuses around the states that have enacted laws and also put together rules associated with those laws, but when you look at, I think, for example, Florida, Florida does not have a requirement that a pedigree, one, is electronic or, two, that it has an electronic signature.

Basically, the level of rules and the level of processes basically says that you have to have a pedigree, and you have to have a pedigree that you have authenticated and that you have certified. So if you're in a situation where, let's say, an electronic pedigree is received, but you don't want to -- but you can't authenticate it electronically, there is a list of other mechanisms that you can use, other actions you can take, to authenticate that.

And some of that includes, you know, telephone calls and emails and things like that, but there's also mechanisms in there that say, you know, if the previous owner has included an image or a copy

of the previous pedigree, that is also an acceptable form.

So it's not -- the process wouldn't run as smoothly if one of those steps along the way was a non-electronic step, but the solution is set up in a fashion that can accommodate that. Now, again, I think, leave it up to the industry to say, can a paper pedigree en masse work? You know, that's up to the industry to say, but what we have had to do from a standards group is recognize that there will be both paper and electronic and they will have to work together.

CO-CHAIR GLAVIN: I think we can do two more questions. Do you want to go next? Yes.

MS. STEFANO: Again, we heard this morning, we heard earlier, about the importance of having to communicate each person's sharing data and so on and the possibility of breaching privacy and the like.

Is it more of a concern that there are security issues such that, you know, hackers are everywhere and they could break into these data

systems or is it more just from a business process? You know, have you looked into -- I guess the question is, the bottom question is, have you looked into the security of the systems? Is there apprehension because of the potential security breaches?

MR. LINGLE: I think we see pedigree really as more evolutionary than revolutionary and that, you know, industry has been for, you know, some years connecting electronically, exchanging electronic information and doing it in a secure way.

And so what we have done is we have brought to bear sort of those years of experience of trial and error, you know, and trying to get a bunch of smart people in a room, get a whole bunch of operational people in a room and try to figure it all out and are just basically using standards and using technologies that have already been used and are tried and trusted. And what we're really trying to do is secure that supply chain piece.

Now, pedigree is, you know, different than, say, RFID. You know, they are sort of different topics and RFID can be a lot more pervasive than

pedigree. Pedigree is really about the transfer of items among sort of the supply chain. So I think some of the privacy concerns aren't as great when you're talking about pure E-Pedigree between sort of a manufacturer, a wholesaler and a retailer.

MS. STEFANO: Yes, and what I was talking more, if the two are paired to each other, then I know that complicates the matter.

MS. DEUS: To be clear though, the pedigree is about the chain of custody in a supply chain.

MS. STEFANO: Right.

MS. DEUS: So there is no patient data in the pedigree itself. There is currently no regulatory requirement that exists that has you include any kind of patient data in the pedigree itself. It is really movement of companies in the supply chain. It's that information that gets recorded in the pedigree.

MS. STEFANO: I understand that, but I'm just talking about the, I guess, cracking what is being transmitted from Point A to Point B in tracking a product in the system.

MR. HARDER: I think it might be a good idea to kind of defer the answer to that, because we as a group focused on this format of data.

MS. STEFANO: Okay.

MR. HARDER: And I think we have got other groups that will talk about security and privacy.

MS. DEUS: Yes. And if this helps, one of the things that was a key design point for this when I talked about that common portable format to leverage the existing business data transfer mechanisms, many companies use already secure business data transfer mechanisms --

MS. STEFANO: Okay.

MS. DEUS: -- to exchange data very securely from one company to another.

MS. STEFANO: Okay.

MS. DEUS: This was designed in such a way that it can leverage those existing transfer mechanisms and be just as secure as the other data.

MS. STEFANO: Thank you. That's --

MS. DEUS: That's what you were looking for.

MS. STEFANO: Yes.

MS. DEUS: Okay.

CO-CHAIR GLAVIN: Jeff?

DR. SHUREN: Bruce, you had mentioned that it is easier to develop a technological solution if you have specific specs. And then, Lucy, you said one issue you're encountering is that you have got 50 states and potentially, I know you're already seeing, you can have a lot of different data requirements and that makes it a little bit more difficult. And to the extent you can get some uniformity and maybe some federal involvement, that would be helpful.

Are there other areas where either from a federal level or from the business end, from industry, that there are things you need to hear that would make it easier for you in developing technological solutions?

MR. DILLON: I'll speak to that.

DR. SHUREN: Okay.

MR. DILLON: I'll speak to that when I present. There are more things.

CO-CHAIR GLAVIN: Okay.

MR. DILLON: Readability.

MS. DEUS: Yes.

CO-CHAIR GLAVIN: Are you willing to wait to hear the next presentation?

MR. DILLON: That's fine.

DR. SHUREN: I will exercise my option to ask the question later.

CO-CHAIR GLAVIN: Okay. Okay. I would like to thank Panel 1 and ask Panel 2, are you the third member of Panel 2, if you would come up to the table, and thank you. And you have individual presentations is my understanding.

DR. RUDOLF: Yes.

CO-CHAIR GLAVIN: That's right? All right. Then we will start with -- and you were supposed to be the first, Paul, I gather. Yes. Okay. Because you said there is an order issue, and I didn't want to B since you had -- is that okay?

DR. RUDOLF: It's fine.

CO-CHAIR GLAVIN: Okay. Good. Thank you.

Paul Rudolf. Yes, I did, too. I thought you -- this is an update to your slides?

DR. RUDOLF: Yes, I had to change it. I wrote it on this morning, but I guess --

CO-CHAIR GLAVIN: Yes, right.

DR. RUDOLF: I can do it without the slides.

CO-CHAIR GLAVIN: Are you willing to do that? Why don't you just tell him to forget it?

UNIDENTIFIED SPEAKER: But that was the version that was up. Why doesn't he use the old version?

CO-CHAIR GLAVIN: Because he doesn't want to use the old version. He would rather go without.

DR. RUDOLF: Thanks. Thanks for being so patient. What I will do here is since the original slides I had submitted have changed somewhat, I will just go ahead and give the presentation without slides. I think I can make the same points without any visual aids and we can find a way to make it available to the panel.

First, I would like to thank the FDA and the Task Force for allowing me to speak. And having been at the FDA and as a former Member of the Task

Force, I certainly agree that combatting counterfeit drugs is very, very important. However, there are other important things also that may be helped with the use of electronic track-and-trace technology that I do want to discuss.

Recent reports about disparate supplies of flu vaccines indicating that some areas have major shortages and others have major surpluses, along with reports of difficulties of getting medications and other supplies to victims of large scale natural catastrophes like Hurricane Katrina highlight some of the other potential uses of electronic track-and-trace.

What if there is a serious outbreak of flu, a pandemic, avian flu, serious terrorist attack using biological weapons? Is the Government prepared to make sure that all life-saving medications can reach victims in time to save their lives?

This potential problem became more evident, at least to me, this fall when U.S. public health authorities admitted they couldn't locate large amounts of flu vaccine and with the additional reports

of the introduction of counterfeit Tamiflu and counterfeit flu vaccine into the supply chain as avian flu became more prevalent this fall.

It may be that the Government can do more to speed the adoption of electronic track-and-trace technology generally through its purchasing power for stockpiles and its authority to require tracking of medications in times of a public health emergency, which it has under the Project Bioshield Act, which was enacted in 2004, that that type of mechanism may be more effective than some of the other mechanisms that the Government has to speed RFID that have been discussed this morning.

There are two key things that electronic track-and-trace can provide in the time of a public health emergency: visibility and preparedness. Now, I have heard that many people think that visibility and preparedness come automatically with RFID, pedigree, and authentication.

However, visibility is really a little different. It does build on and it results from pedigree and authentication track-and-trace solutions,

but it is not an obvious, immediate outgrowth of those. Visibility in an emergency is the ability to know in real-time the location of every medication needed to combat that crisis no matter if the medication is in a Government stockpile or a private distribution center, in a hospital, potentially even in a doctor's office.

Authentication and pedigree systems are set up to track-and-trace and authenticate one item at a time. Visibility is the ability to see all items at the same time. Preparedness is the ability to distribute needed medications and supplies to areas affected by a public health emergency. In other words, getting the right medication to victims in time to save lives.

In an emergency the Government must not only locate and ship product immediately, but it has to deliver those medications to victims, not just shipping them from one city to another, but actually getting them to the particular location, street corner, where there are victims waiting and to be able to do that efficiently and effectively.

In fact, not only is efficiency and effectiveness an issue, but other factors will come into play also in a time of an emergency. I just mentioned counterfeits. I think other behaviors will include things like theft, diversion and hoarding. In fact, hoarding is a potentially significant factor in the time of an emergency. Why would a doctor's office or a hospital or any other entity be willing just to give up all of their stockpiles of medications?

Electronic track-and-trace does have the ability to address all of these issues. It provides visibility. It facilitates preparedness and it can identify hoarding, diversion, theft and improve efficiency and delivery of medication.

However, developing visibility and preparedness systems can take time. When an emergency exists, the information provided by track-and-trace is priceless. I think the Government and a lot of others of us would pay anything to know where every vaccine is and where every last bit of medication is, but that information won't be available at any price when the emergency actually hits.

Government officials should take advantage of existing technology and new technologies for pedigree and authentication to assure widespread visibility and preparedness and should start doing that now. The FDA, other HHS agencies, the Department of Defense, Department of Homeland Security, the states, others should begin now to take steps that will allow the building of an infrastructure that is needed to ensure that the country is prepared to deal with a public health emergency that might occur two or three years from now.

The procurement power of the Government, along with the authority of FDA to require tracking of medicines needed in an emergency, can be an extremely powerful force for speeding the adoption of mass serialization and RFID in the pharmaceutical supply chain in general. Requiring electronic track-and-trace in an emergency should immediately facilitate other implementations and be a catalyst for developing existing infrastructure.

In fact, by protecting the public in the event of a crisis, the FDA would be addressing

counterfeiting and would inspire industry into faster adoption of electronic track-and-trace for all products, such as the phase-in approach that we have heard about earlier today. In any crisis, there will be a mismatch between the location of victims and the location of life saving medicines, as I pointed out, and it's very important for the Government to know where everything is.

So what can the FDA actually do? There are a large number of potential actions, and I can just mention one step that does seem feasible to me at least, is to start meeting with federal and state departments and agencies to start planning for this and determine what each agency's role and responsibility might be in a procurement environment and in a regulatory oversight environment to make sure that there is coordination between all entities and that, in fact, an RFID tag case will actually be visible at every different point in the supply chain, and to begin to facilitate initial implementations of such a system.

Without planning, the chances of a public

health emergency in two or three years becoming catastrophic, I think, are greatly enhanced. The slides are a little out of order. I did want to make one comment about the timeline.

From what I have heard today and from what I have been hearing since I have left the FDA in the last year, I do believe that widespread mass serialization and RFID tagging of cases and pallets is feasible in the next two years, by the end of 2007. However, I do agree that widespread tagging of RFID tagging at the item level does face very significant business and implementation challenges.

Although in large measure the technology is available, I would agree that a lot of the business and operational issues are going to be difficult to overcome and meet the original timeline for all drugs. However, I think if industry is committed, and I think that's a key point, that industry needs to be committed, I do think that the critically important drugs, those most likely to be counterfeited and those needed in a public health emergency, could be tagged by the end of 2007.

And then I had a couple of recommendations on the slide that point to requiring RFID at a case level for it to address public health emergencies, 2D bar codes initially at an item level in order to get this done in the next couple of years, and then the development through the Government auspices of E-Pedigree and e-authentication systems to provide visibility, and then to assure through the state and federal regulatory framework that appropriate oversight is provided. Thank you.

(Applause)

CO-CHAIR GLAVIN: Thank you very much. Jim Rittenburg from Authentix.

DR. RITTENBURG: Thank you. I would like to thank the FDA and the Task Force for their leadership in bringing these issues to the forefront and for providing this public forum to talk about these issues.

The drug supply chain is at risk today. I think everybody realizes that. Counterfeits are on the increase in the U.S. and globally. Unauthorized distribution and diversion is increasing, and the

supply chain is vulnerable to terrorist attack, which I think is one of the more scary aspects of our supply chain at the moment.

Technology does exist today that would allow us to take steps to improve the security of the supply chain, and I believe there are things that can be done today that aren't being done in the time where RFID technology is being expanded.

RFID technology holds much promise for the future, and many of you know that it has been in use for decades in a number of different types of applications. However, for this application and for securing the drug supply chain, there are significant barriers that must be overcome to apply this technology to that application.

We have technological issues around read rates, interferences, and standards to address. There are economical issues around costs and there are political issues around privacy, data ownership, and things like that. All of these still put the widespread use of this technology out a number of years and I think you have heard today different

forecasts on when that might be, but I believe widespread use down to the unit level is well out in the 5 to 10 year range at best.

So the question is, do we have the proper focus in what is being done today? I believe that RFID technology is being pushed into the pharma industry in a manner that isn't necessarily the most conducive to getting its acceptance in that area. Much of the agenda today for using RFID is being promoted by the retail industry, which has a different objective than what is being looked at in the pharma area and securing the drug supply chain.

The retail industry is interested in improving the supply chain efficiency and getting benefits from that and that is a very different application than ensuring the security of the supply chain. I think there are important differences there, and I think there are costs that are associated with the pharmaceutical industry applying these tags under this situation where the benefit does not come back to that industry. So again, are the priorities and the focus at the current time being put in the right

areas?

There are a number of things that I believe could tighten the supply chain very quickly, and some of these are being done, but perhaps they could be done quicker, and that is one area where I think the FDA could have an impact. Strengthening penalties for counterfeiting and unauthorized distribution would have a huge effect.

Countries that have put the death penalty in for drugs of abuse don't have a very big drug abuse problem, and counterfeit drugs is a problem in this country that is a life-threatening problem, and the penalties should be in that same realm. They should be extremely severe, and I think that in itself would cut the problem down substantially.

I know the industry has started to go down this track. Establishing strong distribution agreements with wholesalers will have a big impact on the supply chain and employing authentication technologies on products and packaging throughout the supply chain also enables quick checks to be done, and also would enable an ongoing field audit process to be

undertaken both by the manufacturers themselves and perhaps by the FDA and other agencies to look at both the physical product, the agreements that are in place through audits, and electronic information around the supply of the drugs.

Also, strengthening licensing and oversight requirements for wholesalers is another very important thing that could be accelerated and would help tighten up the supply chain. I believe the PDMA pedigree provisions should be implemented without further extensions at the end of this year. They won't be perfect, but I think they will be better than what we have right now.

And to get to the point of this conference, I believe initiation of mass serialization of product to the unit level would have a big impact on helping to control the supply chain, and I believe we should be prioritizing bar code technology to do this, which is available today. It's economic, and it's being used for other applications in reducing medical error in hospitals.

And there are approaches where bar coding

and RFID can be used in a hybrid fashion, to use bar codes at the unit level and, where applicable and where it makes sense, at higher packaging levels RFID can also be used in conjunction with bar code. And I also believe that even when RFID becomes adopted, there will be a need at least for the foreseeable future to use bar codes in conjunction with RFID tags so that you have got duplication of information on readable tags.

And by creating parent-child relationships when products are bar coded and packaged, we can avoid having to scan every single item in a box, and it doesn't need to be as difficult as it was shown earlier where you could scan a pallet code or you could scan a case code and capture all the information of the items that are in that.

I think if we leverage existing technology and do that in a way where we build forward compatibility into what we're doing, we can move toward RFID, but with a system that can be implemented today and can help protect the supply chain.

Mass serialization with bar code systems,

such as a data matrix at the unit level and bar code and RFID at higher levels, would allow the mass serialization to be accomplished. With that in place, we can build out the data management infrastructure.

The numbering system can be standardized around bar codes but also be formatted to be EPC compatible, and the various data fields can be agreed, the standards can be put in place, so that whatever is put in there initially with bar codes could be followed up with RFID information, and we wouldn't need to rebuild the system.

Manufacturers I think, initially, could manage and own the data for their products. They could be responsible for serializing the products that they produce in initially a bookend type strategy where the serialization at the front end with manufacturers serializing their products and, at point of sale or at point of dispensing, reading of those codes and comparing it to a database that would contain the valid codes would provide at least a relatively quick way to get some aspect of control over the supply chain.

I think in this way we could establish mass serialization, establish a database and at least initially have a system which could provide an early warning of problems in the supply chain, because multiple hits off the same code would indicate you had a problem with that product. You wouldn't know necessarily which one was fake, but you would know there was a problem out there to investigate.

So I think we should look at a phased approach which now would involve serialization of products with bar code technology, establishing a data management infrastructure, and utilizing a bookend approach, but doing it in a forward compatible manner so RFID could phase in afterwards.

The next phase would be to add the pages between the bookends and involve the third party distributors to achieve full traceability with bar code technology. And then Phase 3, which would be five years plus out, would be to phase in RFID at the unit level at the point in time where it became economical and the technology issues were addressed and build out the RFID infrastructure for widespread

use of the technology. Thank you.

CO-CHAIR GLAVIN: Thank you very much for that.

(Applause)

CO-CHAIR GLAVIN: The third presenter on this panel is David Dillon of Verify Brand, and I remind you that Dr. Shuren will not forget his question.

MR. DILLON: My slides are here. Thank you very much. Thank you for inviting us. Everyone has thanked the FDA so far. Let me do that, but let me also add why. For a lot of organizations, it's a very daunting thing to wonder how will we approach the FDA? To whom will we speak? How much time will go into this? For you to gather here, for us to be able to talk to you all at one time is greatly appreciated.

You know, whoever has set this up for me, I see that this is the one that came in before. I wonder if there is a moment. I guess I won't take the time. I will go through the old presentation. I truncated this in order for those of you at the back to have a chance to read, but clearly this is the

finer version.

Just a moment to talk about Verify Brand background. We're probably unknown to most people in the room. We have actually been at serialization for 25 years, started a long time ago with Cure 81 hams and expanded out through Hewlett-Packard and significantly verification, serialization for verification with Microsoft. Also, probably I should say as a matter of disclosure, our parent company does make RFID tags and we have validated and deployed a serialization and authentication system.

That said, I am here to talk about numeric codes and web authentication, to make a distinction between authentication and supply chain tracking, a distinction I think that is not made often enough, to talk about human readability, to talk about random and sequential serialization, bar codes and RFID for machine-readability, alphanumeric versus simple numeric and precision and error in dealing with very large numbers.

Authentication or track-and-trace? The answer is both, and we encourage the FDA to focus on

authentication, and a couple times in the 10 minutes I have I would like to recommend that the FDA look at the work of Los Alamos National Laboratories and the work their Vulnerability Assessment Team did and their approach to authentication and the use of random numbers. If one is going to do track-and-trace, there is a logic to authenticate first and then track-and-trace only authenticated product.

Human readability. That has come up actually today a couple times. If this is about protecting the consumer, then why not give the consumer tools they can use? There's many benefits to human readability. One is the number of potential authenticators. There is obviously a shortage of RFID readers. There aren't all that many bar code readers. Sometimes those readers don't work. If there is a human readability opportunity to authenticate, it's advantageous.

There is an opportunity for communication. If a human authenticates a code, there is a possibility for a brand owner to give a message to such a person. There is an opportunity to get

information back. Timeliness of getting information back with respect to catching counterfeiters is a huge issue. Today it's often six months late before somebody knows that it's, in fact, a counterfeit medicine.

It's also the ultimate backup. Destroyed RFID tags, miserably scratched bar codes, human readable stuff is decipherable even when it's quite injured, but it also includes the notion of the universal revelation of your code, a factor that needs to be taken into account.

Random versus serialized. Well, random versus sequential, I'm sorry. Sequential, if you find two, you know the pattern. From the standpoint of making the bar high for a counterfeiter, it has really not been done. One of the points about random is that there is no information content in the number. You can guess, but you won't be right.

In other words, if you take a 12 digit alphanumeric number, it's really not possible for humans to imagine how many combinations are inside there. If you pull out 50 million and I say I have

all 50 million here that are all winners, just guess one, your chance of guessing one of those 50 million is less than one in 80 million, less than winning the lottery. It is a minute, minute, minute subset of the total.

It represents a significant barrier for somebody who is trying to guess one, but for the counterfeiter trying to guess thousands it represents an impossibility. And that was with the 12 digit alphanumeric. Here's a formula for the mathematically inclined I had deleted before.

2D bar codes in RFID. We have heard a lot about that today. 2D bar codes, small, available, inexpensive. They are accepted for serialization. We have clients who are using them as a part of their thought process and on-ramp to RFID. If you are going to put a unique number, so many snowflakes, so many fingerprints on everything you own, that has a significant daunting task from a business process standpoint without necessarily having to engage in RFID frequency battles, that kind of thing.

Clearly, RFID is the future. There are

issues of tag economics. There's issues of global standards. We have heard a lot about that, so I'm going to move on.

Alphanumeric versus simple numeric. It comes down to being nice to the humans. If your intention is to cut the humans out and not have them have an opportunity to be able to authenticate, this isn't as significant. But if you do intend to have human readable, if you look at the difference between Base 2, Base 10 and alphanumeric, there is a whole lot less real estate used if you're dealing in alphanumeric representations.

There's three numbers up on the screen. The top one is an alphanumeric. The next one down is Base 10 and then, finally, the same amount of number space would be 57 spaces in binary.

The ASCII trap. Before I say that, an announcement that we have, we came to a decision at Verify Brand. Our board concluded that it would be best for us to release our intellectual property through EPCglobal, which is what we're intending to do in the near future with respect to these issues to

help move the ball in terms of standards setting and that kind of thing.

There was a question about the FDA role, and we think it's important and useful for the FDA to participate in what's going on at EPCglobal. It may be needed to settle differences in the future, but that's where we're going to seek to share our approaches.

A final point would be to ask the FDA to consider including certain six sigma processes in their CGMPs. When you're going to make huge volumes of individual numbers, error rate starts to matter. If you take a look at a 10^{th} of a percent of an error rate in 50 million numbers, you have thousands and thousands and thousands of bad numbers.

So you do need to get to extraordinarily high process controls, and it can be done, but the usefulness of failure mode analysis and cause and effect and those kinds of approaches to be certain that you're at better than 99.99966 percent is needed. Thanks.

CO-CHAIR GLAVIN: Thank you very much.

(Applause)

CO-CHAIR GLAVIN: Well, thank you because you also allowed us a little more time for questions, and I know, besides Jeff's, there are some questions for this group. And you should also feel free to address them to the earlier group, and the earlier group should also feel free to chime in if anyone feels they have something to add to the discussion. So we'll start with Jeff.

MR. DILLON: Did I answer your question?

DR. SHUREN: Not exactly.

MR. DILLON: Okay.

DR. SHUREN: A little bit. But it kind of goes to in developing technology. We keep hearing about the more narrow the specs, the better. One issue had been raised about the states and their varying data requirements, and that there may be a need for or there may be value from the Federal Government providing some uniformity.

Again, are there different things, answers, you would need either from the federal level or from the business side that would make it easier in

developing technological solutions?

MR. DILLON: I think I would be the fourth person on this panel to endorse the idea of federal involvement on the pedigree standards. I don't think there is anybody who is going to argue for the House of Babble. So I would endorse that.

We would also ask the FDA to endorse the idea of human readable in codes and to follow in the footprint or the tracks of EPCglobal. Rather than trying to set standards, participate with them in those standards settings. We would also encourage the focus on authentication as a different notion from track-and-trace.

CO-CHAIR GLAVIN: Can you talk a little bit more about that?

MR. DILLON: The idea of authentic is that I know specifically that this is exactly mine and no one else's like fingerprints or snowflakes. In the implementation that I was talking about, if you take a tremendously minute subset of the available pool of numbers as a random set, each of those are truly unique and not guessable. If you apply those to a

product and then provide a web authentication service, you can go and find out whether or not those are yours.

CO-CHAIR GLAVIN: Okay.

MR. DILLON: Like so many snowflakes and so many fingerprints put on a package. From those of us from the geek perspective, those would be so much digital payload in an XML wrapper that could be shipped around to whom, you know, they are needed by.

CO-CHAIR GLAVIN: Thank you. Other questions?

MR. McCONAGHA: I would just like to explore the track-and-trace capability of the RFID as you see it implemented, and I would address this to all eight of you, to both panels if I may, because I think, Lucy, you had mentioned in your remarks that the EPCglobal schema anticipated using kind of existing modes of communication to transfer a kind of E-Pedigree information through the chain of custody.

And I inferred from that that what you were talking about was basically a situation in which one wholesaler would deliver a product to the other

wholesaler, that they would obviously exchange their own information and then whatever information that had gotten already down the line. And what that suggests to me is a decentralized database and we have heard a lot today about kind of decentralized versus centralized databases.

If we have a decentralized database and the model is one wholesaler passing the drug to another or to a retail pharmacy, if the E-Pedigree is passed that way, how is it that that is really any better than the current paper pedigree, and how is it that -- and I realize this is a very basic question, so pardon the ignorance, but I'm very interested in your thoughts on this.

How is it that the individual receiving that pedigree is in any better position to authenticate the accuracy of the history on that past the person they are receiving it from than would be somebody today getting a paper pedigree, you know, in the normal course?

MS. DEUS: Part of that, the authentication requirements are actually addressed in

the implementation that we followed and the standards, was following the Florida rules for electronic pedigree.

And the model that they establish there is if you are purely just putting a bunch of data together in an electronic document and sending it around then, yes, you can say, well, what if I change the data that you sent to me, alter that, change quantities, lot numbers, and then I pass that on to somebody else? That would be no different than forging, you know, information on a piece of paper.

However, what Florida had implemented, and this was leveraging work that had been done in the DEA CSOS, Controlled Substance Ordering System, and in other prior work, which is basically when you apply the data, you use the digital signature. And what it is is I add data to the pedigree. I digitally sign the data on the pedigree.

When I digitally sign the data, without going too deep into the digital signature technology, basically what it does is it is using standards that allow me -- that when I apply my digital signature to

the document, it is not just a signature that says Lucy Deus signed this document. What it is also doing is it's creating a digital fingerprint in a way of the data that I signed and that is unique to my certificate that I use to sign that data, as well as the data that I'm signing.

Later, when you go to -- when you receive the pedigree and you authenticate or verify the pedigree, there is a mechanism that is part of the digital signature technology that allows you to verify that that signature really is mine and it came from an authorized certificate authority and that the content that I signed was not altered after I signed it.

So for example, if I digitally sign something and then we even change one space in that document and add a space character to it, when we go to recompute those digital signatures and I create another digital fingerprint and compare it to the other one, those two digital fingerprints won't match up anymore because even one character was changed. And so that is how you can verify that the integrity of the document was not altered since it was signed.

So this was part of the regulatory framework, you know, a requirement that was already established to ensure the integrity of the document and the integrity of the signatures on that pedigree document.

And that is what is embodied in the standard that we created, again because we looked across all the regulations as the requirements base for the work that we did to create something that was not only interoperable from a technology point of view, but also was compliant with the different regulatory requirements that all the different states have been working on to date. So I hope that helps to --

MR. McCONAGHA: It does. And just to be clear then, my understanding is the technology that I would have as a wholesaler would allow me to verify your signature even if you were three or four persons up the chain?

MS. DEUS: Yes, that's right.

MR. McCONAGHA: Okay.

MS. DEUS: And there is a mechanism that

we employed that basically I add some content, I sign it. Then you get the document from me. You're going to add some content. You don't just sign your content. You sign your content plus all of my content.

MR. McCONAGHA: Okay.

MS. DEUS: So it all gets nested and you have to, like, peel back the onion and verify each step of the way.

MR. McCONAGHA: Okay. Very helpful. Thank you.

MR. DILLON: Just to add to that, your question, though, underscores a point. The electronic -- the comments before were absolutely right that an electronic document is extremely secure as a document. But if you're talking about so much counterfeit Lipitor, does that document prove that that Lipitor is not counterfeit? No, it's not what it shows.

It shows that you know for sure where that document came from. If you want to know if that counterfeit Lipitor really is counterfeit, somebody must have taped some digital fingerprint, some digital

snowflake onto it, so you can authenticate that.

MR. McCONAGHA: Okay.

MS. DEUS: Right, and again when --

CO-CHAIR GLAVIN: That helps. Thank you. That answered my earlier question. I finally --

MR. DILLON: Okay. It's about uniqueness.

CO-CHAIR GLAVIN: The penny dropped.

MR. DILLON: It's about uniqueness that allows you to authenticate.

MS. DEUS: Yes. And authenticate is an overloaded word. It applies in many different -- so we have that form of authentication where you're physically authenticating the product. When we use authenticate in the pedigree context -- and the reason I use that word there is because it's in the regulatory language, but there think of it as the word verify.

You're verifying the integrity of the signatures and the integrity of the content of the document. So it's that type of a verification that applies to the chain of custody information. And I apologize because we both used the same word, but they

were meaning two very different things.

CO-CHAIR GLAVIN: Yes, okay, because you're talking about the product, authenticating the product. You're talking about authenticating the process and the pedigree.

MS. DEUS: Yes, firmly verifying that transaction, who applied that transaction in the pedigree, which is what the pedigree regulatory requirements ask for with respect to the pedigree part.

MR. DILLON: Microsoft faced this exact same issue years ago. Their biggest competitor by far, their only real competitor, is counterfeiters and they weren't so concerned with tracking the movement of their software as knowing whether or not the software that somebody brought up and was wondering whether it was genuine was authentic or not.

CO-CHAIR GLAVIN: Okay.

DR. BERNSTEIN: I have a question for Paul. For the public health use that you described, do you see the Government creating the infrastructure that is needed to do this or layering it on top of

existing efforts?

DR. RUDOLF: Well, no, I don't see the Government creating the infrastructure. I see that the Government would work with all the entities who would be involved with making, manufacturing, shipping, and I wouldn't call it selling but putting the drugs in a stockpile or somewhere else, working together.

In fact, the Government would actually have a greater responsibility and be able to have a bigger seat, if you will, at the table in developing standards because, clearly, the Government would have to play by the same standards that everyone else is playing by. And right now as EPCglobal and industry develop standards, the FDA certainly, when I was there, certainly participates, but it's a different kind of participation if the Government is actively involved.

I think that the Department of Defense has been very actively involved in EPCglobal for that reason, and they have been a big player in a terms of developing the standards. So it does put the health

part of the Government, if you will, in a much different position, but it clearly is completely a joint effort.

CO-CHAIR GLAVIN: All right. Thank you very much this panel, these two panels. Yes, Jeff?

DR. SHUREN: In response, I have two quick just general statements that I'll throw out there. One is just a follow-up to what Paul was talking about.

We had signaled in our Federal Register notice interest in the use of RFID if it provided any additional benefits in the setting of a public health emergency and particularly in this area of re-deployment, that rather than moving a product sort of through the chain to an individual and it goes through that route, that there may be a need to pull back that product as it's on route and move it elsewhere because we may be faced with shortages in the setting of a public health emergency and need to redeploy.

We would be very interested to hear from companies who currently make medical countermeasures, whether they be for a terrorism event or they be for

an infectious disease or some other public health emergency. If you actually have any pilot studies underway or are planning to tag any of those products, we would be very interested.

And if there are any pilots underway that might address this re-deployment issue and may well not be, and it certainly may be something that the Government would need to do, and we would be interested to hear from other manufacturers who might be interested in such a pilot.

The second thing we would be interested to hear about, I think it was Jim who had mentioned it, about the business models, that currently the driver, the big push for RFID technology is coming from the major retailers and that this mode -- if it's a little bit different than what we may be interested in and that we may be looking for different priorities.

We didn't hear this from PhRMA or some of the pharma companies this morning, but we would be interested to actually get some feedback from those folks in terms of the current drivers and whether or not there need to be different drivers. And this gets

back to the issue of incentives being put into the system, getting ROI and appropriate business plans.

So, again, if we could get those comments submitted to the docket, that would be very helpful.

CO-CHAIR GLAVIN: Thank you, Jeff. That was a good contribution. Thank you to this panel for drilling down into yet another aspect of this set of issues and on this topic. So thank you very much. It has been very helpful.

(Applause)

CO-CHAIR LUTTER: If the panelists would take their places, we will start.

(Whereupon, at 4:11 p.m. a recess until 4:14 p.m.)

CO-CHAIR LUTTER: Hello? The most memorable fine meals often end with a treat, a dessert, at the end, and this is like a fine meal, is a long day and there is a treat also at the end. I'm delighted to have an opportunity to introduce a distinguished panel on a very important topic, privacy.

We have been talking about RFID and

electronic track-and-trace technologies and how they might help address the problem of counterfeiting by accumulating and compiling and sharing vast amounts of information. Information issues related to the use of RFID need to be better understood. The protection of patient privacy is a concern that has been raised by RFID advocates and critics alike.

We would like to use this opportunity to raise the awareness of these issues and discuss possible measures that would address privacy concerns. We're also interested in hearing about the need for consumer education to further inform consumers about RFID and its use.

I would like to remind everybody that the slides for these presentations and the final versions of them, not necessarily those that may have been shared with you in paper format, which as we know isn't always reliable, those final versions will be posted on FDA's Counterfeit Drug Initiative website on Friday and the URL for that website is on a one page document at the registration table.

The participants in this last panel are

Julie Mayer from the FTC, the Federal Trade Commission, who will speak first, Paula Bruening from the Center for Democracy and Technology, Elliot Maxwell, a consultant with Johns Hopkins University, Steve Casey of SureID and Joe Pearson of Texas Instruments.

We have just 28 minutes to remain on schedule, so I will give everyone -- I think I have scheduled you for seven. And to avoid an autocratic decision that you might only have six, I will instead adopt a different approach that we will schedule you for seven, but presume a certain professional self-regulation on your part.

And I think you have seen the benefits of Qs and As and we would like very much to reserve time to do that today. So without further ado, please.

MS. MAYER: Okay. No pressure. Okay. So I have already been introduced. Here is my disclaimer, my views and big picture. The Federal Trade Commission is the nation's consumer protection agency and we're delighted to be here, to be invited to consult with one of our sister agencies.

We do a lot of work more and more recently in the area of privacy and information security, although that effort has been going on since the '90s with the advent of Internet and online commerce. Here are some of our key statutory tools that we use related to consumer privacy and security, and just pointing out that generally under the FTC Act we regulate for-profit commercial entities so not other, you know, Government agencies and their conduct.

Some of the recent work we have done relates to financial privacy and also general information security practices of companies. A good for instance is a very recent case we announced just two weeks ago against ChoicePoint, when we announced a settlement with ChoicePoint I should say, relating to their disclosure and practices in securing credit histories and other information about personally identifiable information about consumers. So that shows you a little bit of, you know, the kind of work that we do.

In addition to enforcement, we also do public education and policy, hence we're here, and we

also hold our own workshops in the RFID arena. We held one in June of 2004, which we followed up with with a staff report, and that report summarizing the testimony at the workshop, as well as comments that were submitted and presentations from the workshops, are still available on our website.

We have also done others in a host of related privacy and technology areas, and we also develop education materials relating to regulatory requirements for businesses as well as best practices for businesses, especially in the information and privacy arena, and also for consumers about how to protect themselves.

At the workshop that we held on RFID, like the FDA's effort today, we made a concerted effort to hear from as many different constituencies implicated in the consumer privacy area of RFID use. In many ways we were dealing with the potential, but there is still a lot to say, and we heard, of course, from retailers, from folks working in healthcare applications, transportation, consumer products and Government applications, be it on the federal level

with, you know, Homeland Security down to library books.

We also, of course, heard from consumer and privacy advocates and academics and folks who kind of analyze the market trends and did some surveys of consumers, so we could really find out, at this point, two years ago, you know, may be a big difference from even now, but what do consumers know about RFID and what applications and protections would they value if RFID was introduced in the consumer space. So those are important not just for us to understand, but of course for industry to understand as they deploy it.

Based on what we heard at the workshop and comments and other work we have done in the privacy and security arena, we made some -- well, we drew some conclusions that are about RFID.

Some seemed to be in terms of privacy issues specific to the technology, as alluded to earlier today, with the ability potentially to surreptitiously scan tags and glean information, the fact that these things are just small and people can't see them and necessarily on a label which is part of

its, you know, benefits in many ways, but also makes some people and consumers nervous, particularly in the absence of any explicit notice about the use of RFID devices.

And also, of course, as we have heard a lot about, the bit capacity of chips, the ability, which is also its benefit, to uniquely identify the object to which it is affixed. We also then made some recommendations, the staff of the FTC did, and we also said that basically even though they were specific to the technology, there were concerns. A lot of what we heard, and a lot of agreement even from sort of the extremes of who was at the table, was a lot of these concerns are about database security. Again, you know, absolutely confirmed by what I have been hearing today.

Every, you know, data was mentioned, you know, several times a minute it seemed like. And so RFID use is obviously facilitating the collection of data and more precise data and, therefore, more valuable data. So considerations for users of the technology are what information really needs to be

collected, just if you can do it, should you do it?

And obviously, there is a business, you know, return on investment consideration there, too. But once that data -- if that data is collected and also if it's associated with other data about consumers, particularly personally identifiable data, that should be appropriately safeguarded and that implicates security as well as, you know, access considerations.

And I think the baseline standard that we're applying in this arena, not just in RFID but with other technologies and with ChoicePoint, as I mentioned, is the use of reasonable and appropriate measures to secure personally identifiable information about consumers. So this is not a one-size-fits-all approach, but what is the data, who is using it, what is the need for it?

Other recommendations that are definitely related and part and parcel of deploying an RFID system would be consumer education. Again, there is a lot of business justification for doing this because if there are benefits, as we have heard today, for

consumers, those should be made clear to them, especially where there might be a tradeoff with consumer privacy, and also dispelling myths to the extent that they are being perpetuated. That would go a long way.

Supporting that is consumer notice. That should be clear, conspicuous and, of course, accurate. And we also believe, as evidenced again by what we're hearing today, that self-regulatory efforts are an important part of this process and they should be encouraged and they should also, when they are being developed, include accountability mechanisms for members of that self-regulatory program so if compliance is not met, that there are some consequences.

So in sum, what we're doing now on the RFID front, as in the information security arena, is monitoring the use of the technology and self-regulatory initiatives regarding privacy and security, tracking developments, which events like this are helpful for us to see firsthand how the technology is being used, working with our sister agencies, okay,

and participating in international forums that address privacy and security issues around RFID. Thank you.

(Applause)

CO-CHAIR LUTTER: Our next speaker is Paula Bruening from the Center for Democracy and Technology.

MS. BRUENING: Thank you. Thank you very much for the opportunity to be here this afternoon. This is my first experience speaking before the FDA and I am very grateful for the opportunity. I would first just -- okay, this is how it works.

I first just wanted to say that the Center for Democracy and Technology is an independent nonprofit public interest organization, and we advocate for civil liberties in the digital environment, and we are privacy advocates.

We have been working in the RFID space for about two years now, but the way that we do our work is very much consensus-based. We try and bring stakeholders together who have concerns about an emerging technology and try to address the privacy issues that are a result of the technology early on,

so that privacy protections can be deployed early and effectively.

We feel optimistic about the potential for RFID to secure the drug supply and we feel as though, for the most part, RFID technology in this space does not raise major privacy concerns as long as you're talking about the supply chain and perhaps the pedigree.

But the fact that this is a technology that the consumer will take home with him or her and the fact that there may be after purchase applications for RFID implicates personally identifiable information. And when information about individuals is involved in this kind of a technology, that is when the privacy concerns arise.

The first thing that I would just like to say as a starting point is that when it comes to privacy, whether you're talking about privacy as a civil liberty or as a business application, it's really privacy is about creating trust. If you want really robust acceptance of a technology, if you want consumers to engage, it's important that they

understand that their personally identifiable information is being protected and secured and that they have choices about the collection of that information.

And I think it's also important to recognize that right now, as this technology is rolling out, we're looking at a really challenging environment for privacy. There are several things going on right now. There is heightened public concern about data security and data breach.

Last year, we saw several instances of data spills. There was a lot of press around this. There was state level response. There was Federal Congressional response, and obviously, the Federal Trade Commission, as Julie just said, was also involved in trying to address the concerns about the security of databases.

At the same time there is a heightened awareness on the part of the public about Government surveillance and the proliferation of data collection and use and Government access to data. And I think if we have been, you know, reading the papers in the last

couple of weeks in particular, you know, there is really not much that one needs to add to that comment.

And then there have been many instances in the last year in particular where there has been a failure to address the privacy concerns in RFID technologies prior to that technology being rolled out. And as a result, I think, when that happens, when there hasn't been the proper amount of public debate about the privacy concerns, that's when you end up with some kind of public backlash and a bad reaction and public relations problems.

So what is it that is different about RFID? What is it about this technology that raises concerns? I think it's pretty well-accepted now and I think we have seen over the last 10 to 15 years that as new technologies that are involved in data collection, data exchange, emerge, there tends to be a revisiting of the question of privacy.

But there are some things about RFID that are different, and Julie alluded to some of those. This is almost an invisible technology. In some cases, if you don't know to look for it, you don't

know that it's there, or it may be there and you don't recognize it for what it is.

There is potentially a collection of information that is passive to the individual. You know, you're not turning over a credit card. You're not engaging in an EZ Pass/Speedpass kind of program. This information collection, potentially, is happening without your necessarily knowing about it. And I think that because these tags are attached to products that people are taking home, RFID raises concerns about tracking of individuals.

The title of this workshop, RFID track-and-trace, I know that we're talking about this with respect to drugs and to pharmaceuticals. I think what concerns individuals is that they are also going to be tracked and traced and it raises the concern about surreptitious surveillance. And of course, because we're talking about pharmaceuticals, we're talking about sensitive information.

So what is our framework? How do we go about approaching questions of privacy for this kind of technology? We have in this country, we have

internationally, well-established principles of fair information practices. They provide guidance for responsible data collection and they form the basis for state and federal regulations, for business best practices and they are intended to give individuals some control over the collection and use of their information to limit data collection and then to place responsibilities on data collectors.

Let's see. Now, I have heard today many people referring to notice and choice as being fair information practices. I think that's true as far as it goes, but it really is a much more comprehensive list of practices. But I will say that in the case of RFID, what is peculiar to RFID are these questions of notice. Are we telling people that this collection is happening, that this technology is in use, what kinds of choice are available to them, can you build that choice into the technology, can you offer that choice at different points, how do you offer that choice, and then I think also security.

There is the question of the security of the information that is being collected in the

databases, but then also there is the peculiar concern about the security of the information in the tag itself and that is very specific RFID.

I think that RFID technology presents challenges to how you apply these fair information practices. We have had experience in different environments, but when you're talking about this kind of technology that is so small and difficult to see, oh, wow, what did I say, and that is, you know, in this kind of environment where there is this passive collection -- thank you, there is -- it is more difficult to perhaps put in place some of these fair information practices.

Industry needs to work with stakeholders to figure out how best to apply these fair information practices, but central to the question is figuring out what is the application, where is the real privacy risk and then how do you go about protecting against that privacy risk and applying fair information practices?

It's important to build all of this in at the beginning. You end up with better privacy

protection. You end up with more streamlined systems. You end up with better acceptance, and you can fold in a lot of the policy questions that are being debated, once they are decided, right into the applications themselves. And again, you end up with better acceptance and, you know, less controversy in the public.

And this conclusion is really just a recap. Again, I appreciate the opportunity to be here and I will stick to my six or seven minutes. Thank you very much.

(Applause)

MR. MAXWELL: At the end of a meal comes either dessert or potentially the bill and maybe privacy is the bill in this or sort of creme brulee.

Let me just talk a little bit about what you care about it, building on what has been said before. This is going to get into the hands of consumers. If you think about this or plan about track-and-trace simply as a supply chain or anti-counterfeiting or diversion, you are going to make a mistake because eventually you need to think about

this holistically.

And one of the things that is going to be important to do is to think about it to the extent possible in conjunction with other people who are trying to do the same things in different domains so that inconsistent and more costly remedies don't work.

So why care about it? Privacy issues are unavoidable. We see that. If you want to Google privacy in RFID, you will find that this is not something that you get two or three hits about. The privacy community is engaged. There are lot of forums for discussing these things. And, in fact, poor implementations have caused more and more problems.

And, to wit, think about the passport issue and think about the kinds of controversy about Government mandates of use of this particular technology and the concerns that it brought out. So you really need to think about it carefully and, even more importantly, the Government mandate requires more thought about it because it means there is not choice and that is one of the important things about thinking about privacy, to ensure consumer choice.

Privacy and security, as was said just before, are intimately intertwined and one can't think about this technology and the questions about privacy without thinking about these two things together. It's not as if there is a blank slate because not only do you have HIPPA, you have state consumer laws, you have labor laws and health impacts that people need to be thinking about at the same time.

We're seeing this in the consumer space, but it's also going to be true with respect to this technology in regard to the FDA and whatever mandates come out for anti-counterfeiting purposes. So we need to think about it in the context of sets of rules that already exist to, again, try to avoid inconsistent rules, inconsistent applications.

What we have learned so far? There is a threat that consumers feel about information being gathered about them without their consent and linked to their personally identifiable information. There is a concern about post-sale. What happens? Can they be targeted or traced or profiled because of the presence of this technology?

There is the same kind of background about a growth of surveillance infrastructure and, in particular, of Government access to the data because, again, this can be done for good purposes, but extended to other purposes that people are not comfortable with. So one has to think about that from the beginning. How does one control for that? How does one deal with the possibility of access by people other than the purposes that were originally thought to call into use the technology?

New issues because radio is involved and radio can be intercepted and radio can be used to have unauthorized reads and so it's a different thing than just the regular 2D bar codes. Employees= concerns about job loss and particular concerns about health impacts that have been raised in the settings of what happens when there are more and more radio emitters in an environment or, as the FDA is addressing, the health implications of use of the technology with respect to the drugs themselves.

Other things. Most of the issues that we come across in the privacy space have really good

precedents. We have seen it in fair information practices. We see it in the FTC's work now on best security practices. We see it in the planning for deactivation from the beginning at the Auto-ID Center because they thought from the beginning that there needed to be some way of deactivating it to give consumers more control.

On the other hand, there are lots and lots of potential and existing benefits that might come into play if the tags are active. So we need to think carefully about post-sale benefits and giving people choices about disabling or deactivating the chips. Clear notices, no hidden tags, because the last thing one wants in thinking about a new technology is to have a tag spring at someone and say I didn't know this was going on, and that is the way to cause an absence of trust.

Straightforward consumer education is needed, clearly. We have also learned that the real differences in this technology with respect to other technologies is the post-sale issues, and in fact, there are a number of technological fixes that are

being looked at and a number of post-sale benefits, returns, recalls, warranties, increases in the efficacy of recycling, support for the disabled. There's lots of research going on in terms of home healthcare monitoring right now.

All of these things may, in fact, rest on people choosing to let the tags remain active after sale, but it will take time and effort to build this infrastructure. Lots of solutions that people have come across, kill commands, partial kills, making the chips switch on and off, encryption, authentication, blocker chips so that someone can't be scanned without their knowing of it, database controls, anonymous data mining, but they are all tradeoffs about this in cost, in process efficiency, in who bears the burden and the impact on these post-sale benefits we were just talking about.

So recommendations, privacy and security by design from the beginning, recognize what is the same, the update of security issues, data minimization issues. Decentralization of databases is generally more preferable for privacy purposes than

centralization of databases. Recognize what is different. The radio waves, there is the possibility of unauthorized reading and interception.

Use what we know already and has been developed over the last 25 years, the principles underlying fair information practices, clear and understandable notices. Again, seeking consistency changes the economics of this for the people who have to be involved in it. If there are lots of different ways of doing it and lots of different requirements, it raises the cost on the complexity. And choices for consumers in regard to information collected and giving them more means of controlling it.

Support the development of technical solutions, involve the FDA. Clearly, as the FTC has done in security, it has been very important and can potentially play a major role in consumer education.

Industry codes and self regulation. The Government can actively stimulate these post-sale benefits and coordinate Governmental requirements and show preferences for open and global standards and to take the fruits of this so they can be applied more

globally, and that is going to change the economics and the efficacy of the use of the technology in general.

Once again, my thanks to the FDA for allowing me to speak and for making us dessert.

(Applause)

CO-CHAIR LUTTER: Thank you very much for that enlightening presentation. Our next speaker is Steve Casey from SureID.

MR. CASEY: Hello. I would like to thank the FDA Task Force for allowing me to speak today and thank you, attendees, for staying so late in a very long day.

Privacy is an important topic, though. As with any new technology, privacy concerns must be discussed, understood, and addressed. As with these concerns, the benefits must be understood as well. By weighing the benefits against the concerns, individuals can make a choice as to whether to use the technology or to not use the technology.

As we already heard today, there are many techniques for protecting privacy: encryption. You

can use PINs. You can disassociate the personal information from the RFID tag or you can turn it off, but then you would lose downstream benefits.

Let me give you some examples of where consumers en masse have made a choice to tradeoff privacy concerns for significant benefits. When we look at credit cards, very commonly used today, the safety, the convenience, access to emergency funds all have outweighed the concerns. If you look at e-commerce and Internet shopping, the convenience, ease of comparative shopping, access to hard-to-find goods, lower cost all outweigh the concerns.

In libraries where items are tagged on an individual basis, speedy and automated returns, actually the privacy of a self-checkout, freeing up of librarians to help other patrons and also lowering of local and regional budgets all have outweighed the concerns. So I would like to propose that when the benefits significantly outweigh the concerns, the actual technology enabler of those benefits become irrelevant and of no great concern.

There is an issue facing most individuals

today, and that is the cost of healthcare. By the way, hard copies of the slides will be outside on the table where the handouts are, if I'm going too fast for you here.

RFID could help reduce the cost of healthcare by as much as $300 billion annually. That is if you look at the downstream benefits of using this technology. And the costs that are related to that would be related to medication counterfeiting, supply chain productivity and shrink medication hours, poor patient compliance and persistence and unknown treatment outcomes.

If we extend the use of RFID tagging beyond cases and pallets and use intelligent tags at an item level, significant benefits emerge. You could provide the right amount of the right medication to the right person at the right time. You could also maintain and monitor environmentally sensitive medications, such as the biologics. You could ease patient access to critical medical information. And, lastly, you could provide personalized and professional assistance to maintain an individualized

medication regimen.

As we heard, RFID can benefit many stakeholders, including the patients and the consumer by lowering their cost, providing greater access, to care givers to easing the care burden, and to provide ease of mind, to the care providers for measured and improved outcomes and increase in sales, and to the payers by addressing healthcare costs and shifting high costs, emergency and hospitalization costs, to preventative measures with medications and medication therapy, which is one of the cornerstones of the Medicare Modernization Act.

But most importantly, we could save lives, live healthier, provide greater access and lower cost to society. With RFID we could collaboratively address one of the most serious issues facing our nation, and that is the cost of healthcare. I want to thank you for your time today.

(Applause)

CO-CHAIR LUTTER: Our final speaker is Joe Pearson from Texas Instruments.

MR. PEARSON: Good afternoon and, as was

just stated and with the risk of getting my applause now instead of after my presentation, I am pleased to be the last presenter.

(Applause)

MR. PEARSON: And appreciate the energy that has been in this room today. I think it has been a very enlightening day and a full, good discussion. So Texas Instruments is the fourth largest semiconductor manufacturer in the world. We have been in the RFID business for about 16 years. We have created a lot of RFID technologies, and we have produced over a half a billion RFID tags in those 16 years.

So this issue has kind of come up today and the question, "Can you read what I have when I leave a pharmacy or any other type of medical facility?" One could say, well, maybe it would be difficult. Maybe, you know, it would be really hard to do, figure it out. But I think from a privacy perspective, the question "Can you read what I have?" will be there for sure, and we have to address that head-on, and the answer for certain has to be, we

can't let that be possible.

So we have talked a lot about whether NDC information should or should not be in a part of the tag data. Let me take just a few seconds to talk about what would be on the tag data and what are some of the options.

Of course, you would have some kind of header data fields that would tell you who was the authority providing the RFID tag information. You would have the manufacturer identification, who was the manufacturer. Was it a Merck, was it a Pfizer, was it an Abbott? You would have a serial number. We know this is critical. We have talked about it today. A unique number for that product is important and, obviously, managed by the pharmaceutical manufacturers. And, of course, product class.

Again, this has been a discussion of whether we should or should not include the product class information. One could imagine a scenario where you have RFID tag data that does not include product class and you could imagine it with product class information.

The benefits, the deliverables of RFID with a serial number only, is that it will deliver an E-Pedigree solution. With a serial number you can deliver E-Pedigree. There is the participation, of course, that is required by all the members in the supply chain in order to deliver the information with that serial number.

And so what I have heard a lot from the people in the industry, the members in the industry, the various sectors, is that in order to participate, in order to be able to afford to provide the infrastructure to support that serial number and allow that electronic pedigree, the product information is necessary in order for me to have those applications, that Steve Perlowski talked about and others have talked about, that provide ROI, return on investment, whether that be inventory tracking or what have you.

So assuming that we go forward with some tag data structure that includes product information, how can we protect that scenario where it's not possible for someone with a rogue reader when I come outside or you come outside of a pharmacy or a health

facility and not to be able to read that data?

Well, there's two basic ways. The first way is read protect, to protect that data from being read. Now, you can make an expensive chip on an RFID tag that has a microprocessor that would authenticate a reader to see whether it's a rogue reader or an authorized reader. Costly, probably a time-consuming process that wouldn't be very efficient.

Another methodology is to have a password mode in order to read a tag. In other words, the reader, whichever reader in the supply chain, would have to provide a password that has been actually programmed on during the initial manufacturing of the product where the tag was applied, and you would have -- throughout the supply chain people would have to access that tag using that password.

Now, there is an inherent risk in that in the sense that whatever it takes to make it easy for people to have access to the correct password for a particular tag is the very thing that may make that vulnerable to people finding out what that password or that password protocol would be in order to determine

what the password would be for a particular tag. And, of course, at the end of the day when the consumer has left that pharmacy, that product information is still on the tag and any technology, any security, as you know, can probably be broken.

Another approach is to decommission the data off the tag. It's not, you know, a rocket science approach, but basically an individual tag would only be able to be decommissioned, the product class information to be decommissioned, when it was presented with the correct password. This requires a limited distribution of the password in the supply chain, as opposed to the read mode where everybody has to have that password just to use it in the supply chain.

In the decommissioning mode where you have a password write scenario, only the end of the supply chain is really the one who needs access to that password. And, again, when that tag leaves the pharmacy with that patron, the data is removed. There is nothing to break. So the risk of figuring out what John Jones has in his bag or in his office is removed,

because the data is simply eliminated and not present.

So our opinion is that decommissioning is a recommended approach to protect privacy. We think that a simple 32 bit password programmed onto the tag during the manufacturing process would be sufficient.

And in fact, it really becomes less of a security mechanism, as opposed to an administrative mechanism, because in the supply chain you want people to be able to read that tag. And simply when that tag leaves the supply chain and goes with the consumer, the administrative task of me as a pharmacist or a pharmacy being able to remove that product class information is more administrative than as a security officer.

Additionally, not only when you remove the product class information, you also have the other elements of the data still on the tag. You would have the serial number. So if the tag or if the product had to come back and you had access, you were authorized to have access to the network, you would be able to understand again what that product is.

And if it was a real important product,

maybe an aged product where you really didn't want someone to be able to read that it was even an RFID tag, you could use a total disabling function with the kill function with the same password scheme. Thank you.

(Applause)

CO-CHAIR LUTTER: Thank you very much. I'm delighted with people's respect for the clock, even without my not taking any autocratic decisions. I'll try and -- I would like to exercise my prerogative as Chair to ask three questions that actually have yes or no answers. So I'm going to ask them of everybody. And I think you can maybe offer a maybe or a no comment, but it's probably very, very short. And these are really to interpret, if you will, the broad privacy issues that you have raised to our narrower perspective at FDA with RFID for pharmaceutical products.

And maybe I'll just do these three in a row and then we can do each one with answers. The first question is, should disclosure of the existence of the RFID be on the drug label, meaning either the

bottle or the insert into the box or the box itself, given that this real estate is really valuable and the costs of lousy risk communication are so high?

MS. MAYER: That's for me to start?

CO-CHAIR LUTTER: Because of the time, I'm really looking for something really short.

MS. MAYER: Right. So that's always a challenge.

CO-CHAIR LUTTER: We can start at the other end.

MS. MAYER: Yes, if you wouldn't mind. Okay. Sure. I would say that our position, at this point, is without knowing exactly the specifics of the needs of industry and labeling requirements from your end, that we would say if there's going to be a disclosure, as I said in my presentation, it would need to be clearer and conspicuous and recognizable, some other folks have pointed out, so it needs something meaningful to consumers.

MS. BRUENING: Yes, this is Washington. There are no yes or no answers. But, you know, I think that really what you would need to do is

probably study, you know, how to communicate this information effectively. If there is a way to do it effectively and economically on the label, you know, some research may bring that out. Maybe it isn't, maybe there is another better way to do it. But I just couldn't sit here and give you a yes or no answer without more information from or feedback from consumers.

MR. MAXWELL: Yes, I think these guys are both right. You have to figure out what communicates this to the public. You are asking us to make a judgment on that when you should be getting feedback from the people who will be putting it on the packaging or on the label as to whether that's the most effective way. But it is to be conspicuous. It is to be meaningful, and that's your task. And it's the task of those people who are commenting to say what's the most effective, cost effective way of doing it if you have to make it clear and conspicuous and understandable?

CO-CHAIR LUTTER: Let me just clarify my question. There is only a finite amount of space on

the label broadly defined. And we have a key role to communicate the risks associated with medication, the use of the medication as prescribed and that's our -- that's probably one of our first and foremost functions. And given that, you know, enlarging the boxes is itself expensive, the question is how to communicate that, given that there's limitations to attention. But I respect very much the advice that you are providing.

MR. MAXWELL: Well, in 10 seconds more, in the best of all possible worlds you'll have a symbol that will eventually become as understandable as a UL mark or a kosher for Passover marker or what have you. That's the aim and that way it doesn't take up much space and communicates. But it is the effectiveness of the communication that's important.

CO-CHAIR LUTTER: That's clear. Thank you.

MR. CASEY: I guess from a personal perspective, if RFID was used everywhere ubiquitously and there was the potential that could be on any of the medications, then the notice, which is absolutely

important, could be done elsewhere, as opposed to taking up important real estate for communicating other warnings and other information. Maybe it could just be within the stores where the medication is picked up that RFID is potentially being used for that medication.

MR. PEARSON: Besides being woefully unqualified to answer the question, as a marketing background, sometimes going through the process of branding a symbol is very beneficial in terms of education of what you're trying to communicate what that symbol means. So to that point, having an EPC code or some kind of RFID indicating code is actually a great mechanism in which you are really forced to communicate what you're doing and what it is and what it represents.

CO-CHAIR LUTTER: So I'm going to interpret these suggestions, if you will, as the use of a symbol may end up being an effective economical way of communicating the presence of a chip at the level of a package. Let me take turns with the panel. Yes, Steve?

MR. SILVERMAN: Let me direct my question to Mr. Maxwell. In the interest of the late hour, I'll try to be concise, which for me is novel. To what extent do we have to engage in this conversation about robust privacy protection and consumer education, if we have an RFID system that doesn't capture personal information? When we talk about using it as a proxy for the drug pedigree in the paper environment, there is no collection of personal information and there wasn't corresponding consumer privacy protection and consumer education.

If we have chips that are disabled when they leave the pharmacy, do we need to be worried about what symbols we put on the box, what message we convey to consumers and what privacy protection for manufacturers or distributors are building into the process?

MR. MAXWELL: I don't have much of a reputation for conciseness, but let me try to make it quick. One is that I don't believe that you can think about this simply as a supply chain issue and say that it stops at the point where it gets sold. You could,

in fact, take it and disable it, but there's so rich an array of benefits that we can see post-sale, even furthering the aims of FDA, for instance, for home healthcare monitoring where you don't want to say it is by definition turned off.

And if that's the case, then there are lots of ways in which that information will be matched with personally identifiable information. So you need to think about it, I think, (A) in an environment where it's ubiquitous, (B) in an environment in which it has post-sale applications and, (C) in which those applications and the threats are taken seriously by consumers. So it's trying to think about from the beginning to have privacy by design with those conditions.

CO-CHAIR LUTTER: Let me ask a follow-up to that, and I'm going to adopt my earlier format and solicit yes or nos, which I may not get. And this is, let's suppose that there is a default procedure adopted, which is for retail pharmacists to turn off the tags, unless directed otherwise. And in this instance, would legitimate significant privacy

concerns persist?

MS. MAYER: Well, first, I'm just going to exercise prerogative by going first and just supplement my first answer. I just wanted to say I hope if a label is the, you know, selected outcome that it's, you know, not provided in a vacuum and it's part of, you know, a larger consumer education effort by the FDA and the, you know, technology developers and users, so it's more meaningful and also maybe something that is used across different industries so a consumer would see the same label at Wal-Mart as at Walgreens, you know, so there's some consistency.

As far as the is that a kill option in providing some -- it sort of goes to the consumer choice issue and is it removing that choice and is it removing any privacy concerns? I guess it could be seen as that, but as Elliot has pointed out, you know, pretty directly there it's also cutting off potential benefits.

CO-CHAIR LUTTER: No, no, but my --

MS. MAYER: No.

CO-CHAIR LUTTER: -- question is, it's a

default procedure.

MS. MAYER: Oh, okay, yes.

CO-CHAIR LUTTER: So I go to a pharmacist. I say I would like to pick up my prescription, and unless I ask that it not be killed, it would be killed.

MS. MAYER: I think that generally opt-in or opt-out, I guess, that would be for consumers would be --

CO-CHAIR LUTTER: It's an opt-in.

MS. MAYER: Oh, I mean, is opt-in, yes. It would be, you know, less burdensome for consumers. So I think that seems to make sense.

MS. BRUENING: Yes, I think that if you are -- if the default is that the tag is killed at the point of purchase, I think you probably have addressed a lot of the privacy concerns, assuming that there has been no linkage of information via that RFID tag to the person identifiable information prior to that. I mean, which I'm assuming is the case.

So I think, yes, it would take care of a lot of it, but I would be concerned about possibly,

you know, cutting off benefits to consumers. I think that that, you know -- I think that the choice needs to be robust.

MR. MAXWELL: Yes, I used to think that the kill function, when I first started thinking about this problem, was very attractive. And a default might solve some of the problems. It solves most of the post-sale problems. It doesn't solve the problems of data security with respect to the sale and the linking of the in the retail environment purchase data with the data about the object.

I have been spending most of my time thinking about openness over the last while and what the Internet is meant for openness and innovation. And the one thing that comes clear to me is that this technology is an infrastructural technology that is going to result in lots of benefits that we don't even think about now, and in lots of applications that we can't even think about now.

So I'm hesitant to say yes, it solves most of the problems, because I don't know what that would do to post-sale applications that I might find

terrifically interesting and which require a critical mass of on-chips. So I'm hesitant.

CO-CHAIR LUTTER: Okay. Thank you. Mr. Casey?

MR. CASEY: Yes. I'd like to say if the privacy concern is specifically unintended monitoring of what someone may have in their purse and if you kill it, it does address that specific concern. But I think there are other privacy concerns and other issues that are at a higher level than just the unintended monitoring of the RFID device itself.

CO-CHAIR LUTTER: Thank you. Mr. Pearson?

MR. PEARSON: Well, as my presentation outlined, decommissioning the product information, I think, goes a long way in addressing the privacy concerns. And a serial number that has no meaning to anybody that doesn't have access to a secure network to understand what that means, you know, certainly would prevent people from being able to understand what that product is.

CO-CHAIR LUTTER: Thank you. Let's take one more question, two questions. Two questions and

then two quick answers, please. Toni?

MS. STEFANO: Mine relates more to the consumer outreach and education component of it. You know, we're talking about a whole host of things that are technologically, you know, difficult for a lot of people to understand, given the fact that the literacy level of the bulk of the population is pretty abysmal, below the sixth grade level or right around the sixth grade level, and even the most educated of people can be health illiterate, if you would.

How would you propose that we do an outreach program? From whom do you think that would be best received by consumers? Would it be FDA? Would it be the industry? Is there anything that you can give us that can give us help in terms of how we would do an outreach program, given the fact that this is a difficult concept to get your arms around?

CO-CHAIR LUTTER: One answer, I'm sorry, Toni, who did you mean to ask the question to?

MS. STEFANO: I guess the FTC or is the -- you seem to have the most resources.

MS. MAYER: Well, I mean, we haven't --

the FTC itself has an office, and I don't know how your, you know, department works, but, you know, dedicated to consumer education and we could, obviously, have conversations to, you know, work through how. I don't know how they always do the magic that they do, but they have worked with -- conducted surveys and worked with third parties, particularly around identity theft, which is an, you know, obviously, huge issue.

MS. STEFANO: Okay.

MS. MAYER: So there might be something we could provide some consulting advice on. But definitely using quantifiable evidence about what consumers understand is helpful and who they understand it from.

CO-CHAIR LUTTER: One final question.

MR. McCONAGHA: This is very quick and intended for Mr. Pearson. I assume that you recommend decommissioning the tags or killing the tags. I assume that in order to do that on the retail pharmacy level, the pharmacists would have to have some kind of machine? And if so, how expensive are those types of

machines?

MR. PEARSON: Well, in terms of answering the question directly, yes, the pharmacists would have to have some kind of a machine. And you could -- an analogy, of course, is you go to Home Depot and as products are checked out, their EAS tag is decommissioned fairly widespread. And I'm not saying that it necessarily has to be at the point of sale. Decommissioning could actually happen at the distribution center in bulk and it doesn't have to happen one at a time. It really is dependent upon the scheme.

In terms of integrating that into a post or a widespread solution, you're talking maybe hundreds of dollars type thing, not something that is too extensive, I believe.

MR. McCONAGHA: Okay. Thank you.

CO-CHAIR LUTTER: The patience of the audience in staying 15 minutes after our scheduled time is a testimony to the quality of the panel and the quality of this discussion and the answers. And I would like to thank the panel and all of the

participants today for what I have found to be a remarkably educational and informative session.

So, please, join me in thanking everybody here.

(Applause)

CO-CHAIR LUTTER: Tomorrow the session begins again. There will be a walkthrough with the Assistant Secretary of Health at the vendor display at 8:30.

(Whereupon, the workshop was adjourned at 5:10 p.m. to reconvene the next day at 8:30 a.m.)