additional information on this evolution. Uniform Code Council is committed to help the FDA and the health care industry in this important initiative. Our solutions are global, proven and available today to identify, deter and combat counterfeiting.

Thank you again for this opportunity to speak.

[Applause.]

MS. LULAY: Good afternoon. My name is Dicki Lulay. I am President of EPCglobal U.S., which is a joint venture between the Uniform Code Council and EAN International.

I would like to thank the Food and Drug Administration for the opportunity to speak about the electronic product code and how this new technology will provide the health care industry with a powerful supply chain identification tool to fight counterfeit drugs.

First I would like to provide a little bit of background on the electronic product code. In 1999 the Massachusetts Institute of Technology formed MIT Auto-ID Center. Its charter was to research and develop a next-generation solution for automatic identification and data capture for the global supply chain. For the last 30 years the

most well-known standard for automatic identification and data capture has been the UPC barcode.

The Auto-ID Center wanted to work with industry to develop a complementary next-generation solution that could provide even greater supply chain capabilities. With the active support of over 100 user companies representing a broad range of industries, research was conducted on five continents. The best and brightest minds in academia, business and technology community worked on this research. The Uniform Code Council was a founding sponsor of the Auto-ID Center and an active participant and supporter of the research.

The product of this research was electronic product code or EPC. The Auto-ID Center and its participating sponsor companies conducted extensive pilots on EPC technology to test its performance in real world supply chain applications. Since MIT and Auto-ID Center are research institutions, they wanted to license this technology to an organization that could commercialize the EPC for worldwide use.

Since the Uniform Code Council was a founding sponsor and had a 30-year track record in

standards, it was a natural next step that the UCC take a leading role in bringing the EPC to market. In May of this year MIT finalized an agreement with the UCC and its global partner, EAN International, to standardize this emerging technology on a worldwide basis.

In order to support this effort, the UCC and EAN formed a joint venture called EPCglobal to drive the commercialization of the EPC. In order to move this technology from the research phase to the real world of business, the EPCglobal organization is focused on working with industry users to develop the necessary standards to drive broad adoption. It is a multi-industry focus and the standards will be developed in a user-drive consensus-based process.

Our strategy to standardize EPC technology is built on the following key components. Standards must be open and global so that all industries can adapt this technology. Our focus is on helping users apply this technology to solve practical business problems and address realistic supply chain opportunities. We will provide implementation support, education and training so that users can implement EPC technology quickly and

correctly. There will be certification and compliance testing for EPC solutions so that users will have access to multiple suppliers and can make investments with confidence.

The EPC is still in its infancy and we are committed to continued support of the basis research so that technology can be enhanced to provide even greater value and utility to the global business community.

Open global consensus-based standards will provide the foundation on which the EPC network will be built. There are obviously tremendous business benefits. The EPC will enable immediate, automatic and accurate identification across the global supply chain. The potential to improve the efficiency of business practices is enormous. Equally important is the benefit to consumers. EPC technology will allow the health care industry to improve the quality of care for patients and consumers alike.

The EPC is uniquely positioned to address issues like counterfeiting and product tampering, and conserve, as an important tool, to improve consumer safety.

There are strong business cases for

implementing the EPC network in the heart of supply chains and industry today. Greater efficiency, accuracy, automation and supply chain visibility are just a few of these benefits. This technology can and will create real value for businesses and consumers.

What do we need to be able to deliver on the potential of the EPC network? We need a systematic approach to Radio Frequency Identification--or RFID for short--that is based on standards.

This is a view of the EPC network components. Starting with Electronic Product Code or EPC, the EPC uniquely identifies the item. The tag is a small RFID chip with an antenna. In the EPC network, these tags can be as small as a dime and can be made to fit within the lid of a vial. Tags are excited by and broadcast their EPC information back to the reader.

Savant is a set of functionality that serves as the real-time event manager or traffic cop in a reader network. Savant can be implemented in software or as a combination of software and firmware in the reader itself.

ONS, the Object Name Service, provides a

simple directory that can tell Savant where in the network information related to a particular EPC number can be found. ONS is very much like DNS, the Domain Name Service, that's part of the Internet. ONS and DNS share many of the same characteristics.

Once we know where to find information about a particular EPC, we need a common language for expressing that information and that brings us to PML, the Physical Mark-Up Language for describing physical objects and their location in the supply chain.

Lastly, users will need some common web-based services for building up PML information and querying the information in the network. That set of services is what we call EPC Information Services. This is a snapshot of the EPC Network. Our focus is to work with users to develop open, global standards and technical specifications to make this technology come to life and work in the global supply chain.

While the EPC Network is the next step in the evolution of the supply chain, it is equally important to remember where we are coming from. The EPC Network builds upon 30 years of heritage,

in which the uniform co-counsel and EAN International have partnered with industry to create a global system of efficient, standard-base commerce.

The EAN.UCC System can be used by the health care industry today as a foundation for accurate and automatic item identification, inventory management and asset tracking. EAN.UCC data structures will work in the EPC Network, and using the EAN.UCC system now will pay dividends well into the future.

The EPC and EPC Network technology have the potential to bring profound benefits to the health care and pharmaceutical industries beyond what we are concerned with today, which is bringing forward the best solutions to combat counterfeit drugs.

In the shorter term, I believe EPC technologies can help to reduce warehousing costs, aid in the returns process between trading partners, reduce pilferage and reduce security costs, reduce diversion, aid recalls, highlight short-dated product, reduce the costs of trials, improve speed to market of new drugs, and enable more concise prescription fills.

The Auto ID Center commissioned Cap Gemini Ernst & Young to research the financial benefits so pharmaceutical manufacturers, distributors and hospitals could achieve with a fully functioning EPC Network. The results of their investigation are astounding.

Pharmaceutical manufacturers, for example, could realize a full spectrum of benefits across their supply chains. Cap Gemini estimates that with EPC Network technology, 40 days could be reduced in clinical trials, thus, allowing for improved speed to market of new drugs. If we use a $500-million drug as an example, a manufacturer could realize an additional $55 million in Year One sales if it were able to launch a new drug 40 days earlier.

Additionally, EPC Network technology can aid a manufacturers ability to source materials, manufacture products, warehouse and ship, all of the while reducing gray-market goods.

Cap Gemini estimates that a manufacturer, with a $15 billion sales, could realize $68 million in net present value in implementing EPC Network technologies for its internal supply chain.

The potential benefits to distributors are

also tremendous. The Cap Gemini investigation estimates that a wholesaler could improve its distribution center processes, improve inbound and outbound logistics, reduce lost and stolen products, and improve its expiration processes. Using a $50-billion distributor as an example, Cap Gemini estimates that a project to implement the EPC Network could realize over $180 million in net present value.

The potential benefits to hospitals should also be noted. Using the automatic identification and tracking capabilities of the EPC Network, hospitals can significantly reduce adverse drug events due to wrong dose, wrong person, wrong time, as well as improve inbound logistics, improve central pharmacy operations, and improve the quality of health care.

Cap Gemini estimates that a 400-bed hospital could achieve a 5-year net present value of $3 million by implementing EPC. With thousands of hospitals this size, that's a number not to be ignored.

The EPC network also has the potential to bring longer-term patient and consumer safety benefits to the industry. At the top of the list,

of course, is the ability of the technology to enable track and trace functions, as well as item identification to help reduce the problem of counterfeit drugs. The Electronic Product Code can uniquely identify each item, providing a pedigree for each unit of product, tracking the unit as it moves from the point of manufacture through the supply chain, making counterfeiting virtually impossible.

Robin Koh of the Auto ID Center will explain how this would work immediately following my presentation.

I also believe EPC Network technology can enable drug compatibility monitoring either in a pharmacy or at home, monitor whether drugs have been taken in-home by consumers, reduce inaccurate prescriptions and adverse drug events, promote greater accuracy so that drugs are provided to the right person in the right dose and at the right time and aid compliance to FDA guidelines.

Counterfeit drugs are a direct threat to a patient's safety and present an enormous cost to the entire health care industry. In closing, I would encourage the FDA and the leaders of the health care industry to support the EPC Network as

a solution that will increase patient and consumer safety, improve supply chain efficiency and reduce costs. It is backed by the Uniform Co-Council, and EAN International recognizes the leading organization in global standards.

Health care companies can begin using barcode standards of the EAN.UCC system today in combatting counterfeiting. Because EPC Global is a joint venture between the UCC and EAN, there will be an orderly migration path between current barcode standards and the new EPC. And as EPC matures, EPC will be able to provide even greater effectiveness of identifying and removing counterfeit pharmaceuticals.

Thank you for your time.

[Applause.]

MS. KOH: Good afternoon. My name is Robin Koh, and I am the director of Applications at the MIT Auto-ID Center. We have had plenty of time to actually think about this technology that we're about to release and exactly how it could potentially play into the anti-counterfeit arena.

First, let me reiterate what this EPC system is all about. I think pictures speak a thousand words. I don't know how clearly you'll be

able to see it, but essentially the Electronic Product Code is a 96-byte number, which is actually a very, very large number, which gives us the capability to uniquely identify every discrete product.

So what that means is that every single vial essentially has its own license plate. So it's like a vehicle identification number. Everything is different. So one vial can tell a very different story from another vial, and that is a very, very important characteristic of which this technology is about to release.

There are the radio frequency identification tags and readers, and that's what you've been hearing a lot about today. But the important thing to note on here is that the EPC Network is considerably more than just a radio frequency identification. There's mass serialization, there's tags and readers, and then there's this entire back-end network, which actually links the physical object to the information about the object, which is essentially where the EPC Network derives a lot of value.

The thing is, is that the system is designed so that an object can tell a story about

itself, which is a very, very major, important characteristic of the technology.

Targeting counterfeit. This afternoon, in the interest of time, I'm just going to pick up one application, the counterfeit application, and show you how we're going to actually try to address it.

There's something called EPC authentication. I'm going to differentiate between track and trace.

What is EPC authentication? EPC authentication is just bouncing the EPC back through the system to the manufacturer's database to make sure that the manufacturer actually made it. Remember, the EPC is a unique serialization number. So, if I want to know whether this vial was ever made by the manufacturer, it just bounces back to the manufacturer's database and says, did you ever make this item?

So not only is it able to address EPC authenticity, but the fact is that it will be able to tell you the status of the product because you will also know whether it's out of date, whether it's been recalled and issues like that. So we consider this Step No. 1. It is the most elementary step which we would implement if the EPC

system is used to address counterfeit.

Step No. 2 is what we call track. Now, today, you've heard a lot about track and trace, but in our minds, we actually separate them considerably. Tracking is the maintenance of control of the goods going forward in time, and that is very important to actually differentiate because what happens is, as the product moves from company-to-company, from Company A to Company Bank, we can essentially say, all right, you're going to receive these very specific Electronic Product Codes. If you don't get them, tell me about it. So I am maintaining control of that object going forward in time in the supply chain.

There is what we call shipment receiving and verification, which is one of the processes which we engage to actually execute the tracking function. So, essentially, what we are shipping to you, you should be able to verify at your position and send me back a message if you didn't get anything. And this happens from company-to-company.

Tracing is a little bit more complex. Tracing is when we build a history behind the object. So it's no longer going forward. This is

when we are trying to build a history behind the object, and each company essentially writes its own data to its own databases, and what we are going to try to do is that we are going to try to archive the EPC, the time, and the custodian or the product going in and the product coming out from each organization. So that in case we ever needed to develop the history on the object, we actually have a registry at which we are able to develop the trace.

That's all we have. This is a simple three-step process, at which we think a logical roll-out of the EPC system could potentially aid the battle against counterfeit on the technology.

I would like to thank the FDA for this opportunity to highlight this project.

Thank you.

[Applause.]

MR. SANNA: Thanks. My name is Alberto Sanna. I come from Milan, Italy. I am the director of the DRIVE Program.

First of all, thanks to FDA for inviting me here to share with you the experience that we have done on DRIVE.

DRIVE is a European project that has been

funded by the European Commission. We started in '99. It was a project of 4.2 million euro. It is a project that was involving several stakeholders in the pharmaceutical arena all around Europe, starting from two major pharmaceutical manufacturers--AstraZeneca and GSK--two major European IT industries--Atos Origin and Bull--and the European Commission Joint Research Center, which is the specific center of European Commission dedicated to research in the specific area of protection and security of their citizens, and a lot of other research institutions all around Europe. We also involved the other 40 stakeholders from East Europe, West Europe and Israel to validate the DRIVE System.

So before telling you the system, I would like to share with you why we wanted to make this project and why the European Commission founded it, by the way.

This is basically a very basic value chain. We have manufacturers and distributors. In this case, we have hospital, which is added value; we have pharmacy, which is working toward the back end, and the ward, which is working toward the front end, so the patient and the bedside.

Basically, we were aware of huge waste of money in the logistics, so, in the area of the back end, between the manufacturers and hospitals, as well as we are aware of huge patient safety issues, either coming from the area of medical errors, and here I am quoting the U.S. study on To Err is Human, as well as also the counterfeit problem that is worldwide, and I am quoting World Health Organization figures.

So our challenge was to try to address all of those three elements all together. So I think, at the end of the day, it is safer, smarter and trusted health care system at least within the scope of the project.

And basically what you see here is what we have made. We have made an integration of entities like Public Health Authority, we have drug registration, drug surveillance, we have supplier and including the distribution and the hospital where you can identify here the in-bound logistics, so the pure aspects related to administration logistics, and the clinical process. So therapy, validation, preparation, administration, monitoring and feedback.

Basically, this is the project we have

done. We have done a pilot on this, and I will make some comments that are relevant for this audience on that. So we have made all of those functions, integrating all of those activities together, but one of the most important parts of the project was to identify the trust model because we have made the clinical functions and the logistic functions, and they are quite easy once you are able to model the system, but the trust model is much more critical.

Because what we have done is we have identified the process models, we have identified the assets in the process, and then we have analyzed all of the threats to safety, creating what we call the safety models, and all of the threats to security that include confidentiality, privacy, integrity, accountability, availability, and we have created the security model.

We have combined all together, and we have made the trust functions, which are real-time validation and verification, authenticity and traceability, identity protector, authorization and role-based access control, and we have used this as trust layers of the entire system, otherwise you can make a perfect clinical system, a perfect

logistic system, but you have no trust between the stakeholders. This is a major point of concern.

And here it's in a very simplified way is the system how it links the supply and distribution to the pharmacy, the world, and the point of care because this is an integral part of the process. Obviously, I only want to focus on those major tokens, digital tokens, that are in place to enable all of these aspects. It is marked out for the decision of the operator. Otherwise it is not possible to track humans operating into a system, a wristband, digital wristband to track the patient, whether it is in relation with the operator or with the drug, and the digital label where we have included the market number, the lot, the expire date, a serial number to uniquely identify the product, basically for counterfeit reasons.

Obviously, we have made this with a dimensional code, but we also made some experimental activities on target, and that will come at the end of the slide on this.

These are some results to share with you. The digital wristband was in favor by more than 90 percent of the patients. We wanted to ask the patient if they liked to be scanned like a product

in a supermarket because their dignity is part of the project. We are doing this for defending them, not for giving problems to them.

And when they understood all of the chain, what we do with the digital label, they were in favor of this because it's easy for the patient to understand the barcode or whatever complexity is arising from that because they go to the market and buy food and things.

We had a significant improvement in patient safety. To give a number, as an average, I can offer an increase in patient safety on the order of 70 percent, 7-0 percent. We have significantly increased the trust infrastructure through digital signature and role-based access control, either in patient privacy, in the care operator accountability, which is very important in the health care process, and business-to-business confidentiality, another key issue.

And then with the digital label, we completed a real-time traceability of drug life cycle in the production, logistics, and clinical phases, and significant improvement in fraud prevention because we had real-time control against a possible blacklist of drugs at risk. We achieved

this reducing the operating costs of logistics of 30 percent.

We also made, I am responsible for standards at the European level in the health infomatics, the name being Safety Procedures for Identification of Patient and Related Objects, in which those aspects will be implemented as a standard in health infomatic system in Europe.

The main issue missing now, after this experience, is that we need drugs based on real-time track and trace. Track and trace is necessary, but is much more necessary to have real-time track and trace.

And the supply chain efficiency and real-time track and trace, to scale up the system, like DRIVE, such an integrated business model, we need large-scale sustainability in the reading cluster of products. We cannot have the burden of line of sight in scanning each single product at every checkpoint. So we need something which is very close to RFID, obviously.

Then, we need the reliability of the distributor system architecture. So we need scale of architecture, which is something very close to Savant, ONS, PML.

Then, we need synergy with other nonhealth care market. Otherwise the burden of the cost will be too heavy for health care markets alone, and this is another matter that is close to the issue of EPC.

And then we need a standardization of the universal identifiers at the item level, global. Otherwise we are not able to trace and track counterfeit because counterfeit comes from this distributed sources and origin.

Obviously, there are other issues, but one I want to mention that we need also to extend the issue to medical devices for exactly the same reason.

Last week in Milan, we initiated the process for what we call that DRIVE 2, which is exporting this pilot that has been deployed in Milan rapidly to being an EPC label process. And we were in Milan with MIT and the colleagues of JSC, the European Commission Joint Research Center, to address or start this initiative.

So my thanks for having me here and sharing with you our experience. And on my side, all of the best for possible cooperation because this is something that we can address at national

or even continental level in my experience.

Thanks so much.

[Applause.]

MR. TAYLOR: All right. Any questions from task force for the panel members?

As we reiterated, this technology has been discussed all day, and we are excited about its use, as well as the cooperative work with yourself.

MR. RUDOLPH: Paul Rudolph, from the Office of Policy.

I ask the question for the whole panel. We had heard from the previous panel some of the issues about costs, and in all of these presentations, it seems like there are significant benefits. Has there been any practical experience with pharmaceutical companies doing business cases or any adoption yet by pharmaceutical or nonpharmaceutical companies to show actually when the investment is recouped or whether the costs really outweigh the benefits, as was mentioned in the previous panel?

MR. SCHAA: I will start because cost is a major concern for my CEO. We have demonstrated with the pilot very close to break-even, but the real point is that the complexity of addressing

this issue, and other related issues, in such an environment needs to raise rapidly a pilot because metrics is the most important thing.

What we are speaking about is like using the clinical trial concept to the system. So whatever can be the business case, if we don't have the pilot, if we do not have a real system running in a real environment, if we don't share the vision, and if we don't share the metrics, all of these others can be addressed only in terms of esteem.

But what we want to address, we try to, is exactly to understand the return on investment, which is, by the way, I would like to highlight our focus is not really track and trace. We are doing this for better patient outcomes, for better care of the patient in the hospital. To use and to save money from the wasted part of the hospital, to invest this in better care. So track and trade, for us, the infrastructure is not the goal. It is an infrastructure to build upon this, the real value, which is patient outcome for us.

MR. TAYLOR: The point I was going to make is similar to the question that Paul just asked, which is we've heard a lot about the technology and

its benefits, and we also realize that it's moving in that direction, but we haven't really heard much about the cost-benefit analysis. But, you're right, as it's piloted and as it's explored, that will obviously become a little more clear, and we continue to make those decisions and factor that in later on down the road, and keeping with the fact that we do not recognize this as something that will be coming, but it's not quite here yet.

Thank you very much. I really appreciate it.

Now, the next panel is Panel 6, which has a number of people on it. This is the portion that really deals with the manufacturers anti-counterfeiting technologies. How much time is allotted? You were provided your time allotment when you were contacted originally. We have an enormous number here, so we really need to keep on schedule.

Paul Schaa of AC Compacting is scheduled to speak first. Actually, it's David Schoneker.

[Pause.]

MR. TAYLOR: To make it simpler, the people who are scheduled to speak, who are second and third in the queue, why don't you start moving

up to the two white tables. Then, once you're done, move back to the audience and so forth, and that way we'll have people moving forward, and it will just help move things along a little more efficiently.

Thank you.

MR. SCHONEKER: I'd like to thank the panel for having me here to speak today. I'm Dave Schoneker from Colorcon. I'm the director of Global Regulatory Affairs, and I'd like to talk a little bit about some very interesting tablet authentication technology today.

We've heard a lot so far, and we'll hear a lot more this afternoon, about packaging solutions to anti-counterfeiting, and that's the most common thing everybody is talking about. What I'd like to talk about is actually some on-tablet technologies, both covert and overt, that actually can get a product identification down to the tablet level, since tablets usually get removed from packages at some point in the process, whether it be in pre-packaging or at the patient level.

We offer, along with a number of partners, a suite of technologies that can make drug tablets extremely difficult to fake, but very easy to

identify. That's what I'm going to try to go through here.

This technology is really a five-dimensional approach to the utilization of both overt and covert technologies for solid oral dosage forms. It includes a visual component, which is the use of very unique colors and logos for easy visual identification by patients, care-givers and pharmacists. It includes an electronic element, which is overt, again, and incorporates actual barcodes on the tablets themselves, using two-dimensional barcode technology that I'll get into in a minute.

The third dimension of identification we talk about is chemical identification, using covert markers in the film-coding system on the tablets.

And then the fourth and fifth are two different type of sensory profile-type technologies using very specific flavor and aroma profiles.

Now, if I get into visual identification, it's extremely important that this whole issue of counterfeiting and medical errors get down to the patient level, the consumer level, where they can easily identify something in the kitchen or the bathroom and the bedside, not only with specific

equipment that might be necessary or use of covert-type techniques.

So it's important that there's easy identification from a visual standpoint. We saw earlier some of the tablets were, in fact, counterfeits that you could not easily see any differences, and part of the reason for that was they were little white, round tablets with very little identification on them whatsoever, other than maybe an embossed number--very easy to produce, very easy to simulate and fake.

We now have some very unique pearlescent colors with high-definition logos that can be used to design the product with characteristics that are extremely difficult to fake, yet produce a very unique image for easy visual identification. These technologies are currently commercially available using pigments that are all FDA, meet FDA guidelines, and we're not talking about any new chemistry here. We're talking about a unique way of using various colorants and printing technologies.

Now, just to give you an idea, these particular tablets are qualitatively and quantitatively chemically identical. They contain

the exact same chemicals. There is no different pigments or no different colors involved in those tablets. However, it's a combination of both processing, as well as knowing some very specific grades that are used here, and without the right combination, you could use the same materials and come up with a completely different color.

So it's very hard for somebody to simulate this color unless you know exactly how the drug manufacturer is producing the product, exactly what their conditions are in their process and some very specific information about a particular grade of pearlescent pigments.

In addition, from a counterfeiting perspective, this type of technology makes things very easy to identify, and grandma is not going to mix up one tablet with another tablet when they're supposed to take it after dinner or before they go to bed.

Now, that said, in addition to pearlescent colors and various types of colorant technologies, you can also take a look at very high-definition logos. Like, for instance, I happen to be an eagles fan, and we have a very high-definition eagle here, but we can also put an entire human

body with every organ, and if you look at it under a magnifying glass, you would be able to determine where the intestines are, and the heart, and you name it, on a very small tablet.

So it's very high-definition printing that can be achieved, which of course can be used for logos or pictures. In fact, you can put a picture of a human face on a tablet, but you can also use it for identifying marks, whether it be numbers or logos, a company logo, et cetera.

Now, this high-definition printing can not only get at logos, but we can also put two-dimensional DataMatrix barcodes down to the tablet level, down to the very small tablet level. We can actually print these things down to 2.5 millimeters on a tablet and read them with a standard barcode reader, image-type reader that handles two-dimensional-type technologies.

We are currently working with the Uniform Code Council to make sure that the DataMatrix symbology is incorporated in the EAN.UCC standards so that this technology can be used. Now, it's very important that this technology is allowed because, to be able to get the size limitations that we need, to put a full NDC code number on a

tablet, we need to have DataMatrix-type technology.

Other technologies are too large to fit on these small tablets, but all of the codes that you're looking at up here do contain the full NDC number for a given drug, and this can be put on various types of shapes. And one of the very interesting things about the DataMatrix technology is that up to 50 percent of that logo or that barcode could be missing, and it still would read the right number. It also can be read on concave and convex surfaces, which we need for various tablet shapes.

I'll just try to finish up because I see my time is coming up here. This is done on high-definition printing equipment that is commercially available and can be explained by our partners back in the other room.

That finishes my discussion. Thank you very much.

[Applause.]

MR. TAYLOR: Avi Vyas from AMCO, and then after that we have Denise Banks, and then Toni Petrucci, Joe Pleshek, and then Julia Hunter. Maybe you could all start making your way forward so we can have a rapid transition.

When the little red light starts blinking, that means your time is up. We have a timer here that we're setting, just so everyone realizes that. When it starts blinking, if you all will sum up and finish your talks, that would be great. Otherwise, I think we may be here until 7:00 or 8:00.

MR. VYAS: Good afternoon. This is Avi Vyas from AMCO Plastic Materials.

Successful product innovation is our goal since 1955. Our objective today is to initiate some product authentication and eventually improve your business model.

Of the three anti-counterfeiting initiatives, we have chosen forensic. The four ways that AMCO proposes forensic is spectral, elemental, taggant and optical.

In our spectral method, we basically want to put a traceable micro-taggant, a resin, and use a photometric footprint to actually identify it.

In a taggant method, our Microtrace partners, we actually implant the taggant into a plastic material and detect it using UV.

Elemental method, we can put in up to six different codes, and we use an X-ray-type spectrophotometer to detect it.

Optical, again, we can put in three codes and determine the process with a laser.

Essentially, AMCO features are easy detection, low maintenance, confidentiality, enhanced product integrity, and increased security, and ultimately deter counterfeiters.

Our strengths are in distribution, design and development and support service.

Key benefits with AMCO plastic materials are focus, multiple applications success, customer service, dedicated team of technical and professional partners and add value to your business.

The next steps, we suggest that you visit our website at www.amco.ws or visit our customer service. By all means, come to our display booth.

Thank you very much.

[Applause.]

MR. SHEAR: I am Adam Shear. I'm replacing Denise Banks for this presentation. I'm with American Bank Note Holographics. I'm our company's Vice President of Corporate Development and New Business Development.

Our company's roots in security go back 200 years. We were among the original printers of

U.S. currency, and we developed holograms as a security solution in response to a threat facing financial documents with the advent of the color copier. Holograms are highly reflective. They are not printed. They involve 25,000 lines of resolution per inch. So essentially what we do is we scratch in 25,000 lines per inch, and that allows for us to incorporate depth, motion, color change and also forensic tools that can be verified by field investigators and more sophisticated investigators alike.

If you take a look at this chart, what you will see is that we offer, within a hologram, three levels of verification, for the general public, for the document issuer, and for law enforcement. You can take a look in your wallet, you'll probably have a Mastercard or Visa hologram that we made, and there are also physical characteristics. If you feel across that hologram, the surface is perfectly smooth. We feel that that adds another dimension of security that's often overlooked with our own version of holography.

For the pharmaceutical market, we have taken this core competence that we developed in the financial world and applied it toward packaging

elements that are already in use by most pharmaceutical companies. We have developed holographic, tamper-apparent seals, cap seals, and shrink sleeves, which you can see in our booth next door. Each of these are ready for implementation right now, and most of them are already in use by major pharmaceutical companies.

Thank you.

[Applause.]

MR. TAYLOR: Everyone should have the agenda, so I won't keep calling the names. Just please keep coming up.

MR. PETRUCCI: I'm going to try and go fast because I have a lot of slides, but I'll try and cover it. My name is Toni Petrucci, and I'm with Angstrom Technologies.

We have security verification solutions that I'd like to discuss. We have scanners that can review the security toner, security taggant and UV and invisible UV security inkjet. And I urge those of you at the end of this session, if you'd like to see our booth, please come by, and we'll give you more detail.

Basically, it's authentication and verification of various luminescent taggants,

various fluorescent detection devices. We started out with document security, but it's also item security, the security toner. We have a device that can read this information. Security inks are applied, as well as various security taggants.

Potential applications, you can identify the pallets, the cartons, the item identification. It can be packing slips. It can even be physician reports. The types of technology that we have can go across the board.

Security protection elements. This is a taggant that's actually printed into a document. It can be in a label. It's also an area where it can be reviewed with sensitive data and areas susceptible to tampering, and we also have the secure invisible UV image of ink, which can be an inkjet logo or product information.

Here's an example of what I'm trying to describe here. If you're looking at a label, at a pharmacy label, let's say, this is in nonvisible fluorescent ink, and what you see, these little areas that are rectangles, will show the areas that would be printed within that area. That would be a taggant area. And what would happen, as an example, would be you could have a logo, just as

we're trying to show here in the UV light in a passport.

Variable data is also imaged in these areas, and it would show up in black ink, just as you're looking at it in this area, also where the taggant had already been applied. If you look under normal light, this is what you would see. If you look under it with variable data printed in the security toner, in those areas, you'll see a different color. I'm showing them in red. It would actually be in blue or green or yellow, but that's an area that, in other words, that toner that I showed you initially that was in black ink, when you put it under the black light, it will now turn into a different color, and that's variable information.

Moving right along. Here's the forensic version of this security toner under black light. If you look at this area, it says "USA Taylor" on your left. If you look at this area right here, you cannot see it under normal light, under normal ambient light. However, if you look at it under forensic, you can tell that somebody removed it. That is our taggant, our toner taggant, that you would be able to see.

So, basically, this is also another image. This is the inkjet image. If you notice, this is a regular color photo. The blank that you see under normal light, this is exactly what you would see. This is what you would see under black light, so we can reproduce that image under inkjet.

And seeing that this flashing light is going on here, I will tell you just come and greet me in the back at the conference room, and as soon as we get through this, we'll provide this information to you in greater detail. And Dr. Coil is back there. You can also meet and discuss this with him.

Thank you very much.

[Applause.]

MR. PLESHEK: Thank you. Good afternoon. My name is Joe Pleshek. I'm with Appleton Security Products. Appleton is a security substrate manufacturer. We have been manufacturing security substrates since 1993 for the commercial check, security document and label and packaging markets.

Our business model is to take innovative security technologies and imbed them or coat them onto paper, films, nonwoven subtrates for the security labels and packaging that allow companies

to authenticate and track their products throughout the world.

Recently, Appleton conducted one-on-one interviews with leading brand companies in the pharmaceutical, spirits, automotive, electronic, and computer component markets. The purpose of these interviews was to identify current and emerging needs for anti-counterfeit technologies. Many of the key themes we heard from brand owners in these interviews, within these segments, align very closely with the FDA's Counterfeit Drug Task Force interim report, including the need for cost-effective solutions, a layered technology approach, and the need for a solid technology migration path to stay ahead of the criminal element.

Additional technology requirements include that the technologies need to be easy to authenticate, reliable and difficult to replicate. They must integrate seamlessly into the manufacturing process, especially the packaging process. They must be verifiable throughout the supply chain. They should prevent remarking or be tamper evident. They should also be globally feasible to implement, and also be located as close to the product as possible. And, finally, they

should not impact the product or product packaging appearance.

Appleton has utilized this research and these requirements to develop a broad portfolio of substrates that can be applied to labels and packaging. They include anti-counterfeiting solutions, such as the AssurMark security label, the TechMark taggant, which offers machine-readable verification, as well as track and trace solutions, such as the TechMark thread.

I would stress that these products are commercialized and are in use today to help authenticate and track products.

To integrate our solutions Appleton works with leading label and packaging converters, including New Jersey Packaging, who delivers labeling solutions to the pharmaceutical market, and Zebra Technologies for on-demand labeling applications. These partners take our substrates and convert them into a finished security label or security package.

In working with our suppliers and partners, we maintain strict chain-of-custody policies to ensure the integrity of our security products.

For more information, please see us in the back, and thank you for the time.

[Applause.]

DR. HUNTER: Hello. I'm Dr. Julia Hunter. I'm the Medical Director of Applied DNA Sciences, and we manufacture botanical DNA-embedded, anti-counterfeiting, anti-diversion and anti-piracy security solutions.

We produce DNA-embedded inks which can be printed on anything; DNA-embedded labels which can be affixed to anything and be tamper evident; and DNA-embedded microchips which can be placed anywhere in packaging; and DNA-embedded textile markers, which we have developed with the Departments of Commerce and Agriculture. We also have an edible-grade DNA marker which we hope is going to fast track through the FDA.

Each of these products that we have provides instant authentication, overt, covert and forensic. So product legitimacy and security can be tracked and traced and guaranteed from manufacturer to end user.

Our living biotechnology integrates easily into layered security technology. By using encrypted DNA from plants, vegetables and fruits,

we can assure, with 99.99-percent reliability, that whatever we protect cannot be authenticated illegitimately.

We can custom manufacture for each customer, for each medication, for each application unique signature botanical DNA. So Amgen can have their unique code, Pfizer theirs, as many as needed. Our DNA itself can be read and authenticated for more than 100-plus years, despite the most adverse conditions, because our biotechnology stabilizes and protects it from sunlight, extreme heat, freezing, radiation, chemicals and even physical stressors like high-volume printing machinery.

The instant authentication tests are simple, fast to perform. They require minimal training, they're nonintrusive, and they're very flexible. Our security solutions are simple to implement, and they're cost competitive.

Applied DNA Sciences' botanical DNA-embedded technology can significantly secure the pharmaceutical supply and, bottom line, protect the people.

Thank you. Come by our booth.

[Applause.]

MR. RITTENBERG: I'm Jim Rittenberg, Vice President of Biocode, Incorporated. I'd like to thank the panel for allowing us to speak today. Biocode has been in business since 1992, and we've been providing security technologies to a variety of industries, including pharmaceuticals, and in pharmaceuticals we are currently providing technology to mark packaging, as well as the dosage form.

Today, what I'd like to focus on is the use of technology to mark to dosage form. We believe security should go beyond the package, since the product doesn't always stay associated with the package. Technology is available today to provide rapid authentication of the dosage form. The technology is fully developed and proven. It's already being used in some tablets and capsules that are on the market. It's in use in a blockbuster product, and it's been through the FDA approval process as part of an NDA.

The technology uses trace levels of inactive ingredients that are already CDER approved for use in pharmaceutical products. These taggants can be inserted into the dosage form through the film coating, through inks, gelatin or through the

active ingredient.

Authentication is based on the use of highly sensitive and specific amino assay technology. This is the same sort of technology that's used for home pregnancy testing and drugs of abuse testing, as well as a variety of other analytical purposes.

This is an example of what a field test kit looks like. The test is performed by placing the dosage form in a small vial of buffer that's shaken briefly to extract the taggant. The liquid is then placed onto the test device, and if the product is authentic, one line will form; if it's not authentic, two lines will form.

We are speaking with manufacturers now who would like to use this technology with approved products, but in many cases are held back by their uncertainty of the regulatory process. FDA has been working on new SUPAC guidance for the past three years that would address the use of taggants. However, this still has not been put out yet.

By issuing new guidance that specifically addresses the use of taggants, both in the product and on the product packaging, we believe many manufacturers will take additional steps to protect

their products. In this regard, we have put forward a suggested decision tree, and we'd be happy to speak with FDA further about this.

In conclusion, we would like to urge FDA to consider additional guidance that would make it clear to manufacturers what type of filing, especially for products that are already on the market, would be required to retrofit those with security features.

Thank you.

[Applause.]

MR. SMALL: My name is Lyle Small, representing Quantag Systems. That little light comes on really quickly, so I'm going to move along here.

Quantag has developed a product that we think is going to change the security world. We have developed some unique polymers that have some very interesting characteristics. We use full-spectral analysis to identify highly complex polymers that we ourselves have synthesized in our own labs. So these are not commercially available materials.

They're extremely complex and have a high degree of versatility. There's a thousand

different polymers that can be combined in up to 20 different polymers in a given system, whether that's an ink coating or embedded in a plastic, allowing for billions of possible tags, so an individual customer, individual product or individual batch number could be identified. Essentially, we're talking about RFID without the expense.

The detectors themselves are off-the-shelf spectrometers or scanners. A full hand-held spectrometer might cost several thousand dollars, a scanner several hundred dollars, so a very cost-effective solution.

This gives you just a quick idea of how we observe our marks. We use a hand-held spectrometer that looks at a target and gets a response back. This is different than some of the filter scanners that are out there right now. It looks typical, but we're actually looking at the entire spectral signature of a material.

These materials are not only unique in their signature, but they're extremely intense in their responses to infrared light, up to a thousand times more intense than regular materials. So we can use these things in small quantities and

recognize them easily in thin films. So putting them on blister packs or tamper-evident seals or on labels is a simple process.

I am now out of time, so I will tell you that the product that we provide, we're essentially calling it foolproof because these materials, when combined, are impossible to replicate because there is no comparison that can be made between that signature and another material.

So we're very pleased with this product, and if you have further interest, come by.

Thank you very much.

[Applause.]

MR. PARISH: Good afternoon, I'm Gary Parish, President of Complete Inspection Systems.

We've taken a little different look at product identification and authentication by being able to do on-line and real-time verification much like a fingerprint. So we're going to kind of step through this very quickly.

What we can do, the printer can actually create abnormalities or defects or create a screen print code during the printing process. We can then take and use a different screen or remove some of the dots out of the pattern and basically, in

real time, create a barcode or a 2D code within the pattern. So the manufacturer does not have to add anything into the process, and then all they have to do is take it and compare those two codes.

Let's say if we have a test document and we want to move some copy around, we then can take--I'll step through this real quick--and create some defects within that pattern. Now, this can be done on-line. So all the user has to do, let's say if we have a questioned document in China, you could go on-line over the Internet and compare the two documents, and it will pick up the difference in the patterns, same thing if we're creating a screenprint pattern to verify.

So no matter what you have, whether you're using a hologram or a code, we can compare the two on-line and in real time to tell you if it's authenticate or not and create the pattern. Anything from 2D codes to linear codes to just small, little prints or defects in the printing, we can compare it on-line and tell you.

Conclusion, ability to authenticate any product, no additional cost. We can do it in real time. We can provide product identification, and we can use other technologies to help improve this

process.

We have a demonstration in the back room and would welcome you there.

Thank you very much.

[Applause.]

MS. BURNS; I'm Carolyn Burns with DuPont Packaging in Brand Security, and there are a couple of booths here representing some of our products. I'm here to describe DuPont's role in solving your package and brand security needs.

So why is DuPont, the chemical company, here talking about brand security? We have a rotisserie in safety, and we're no longer just chemicals. You probably recognize package names like Tyvek, Mylar, Sirlan. We also work with a lot of companies to upgrade their safety processes.

We've invested over a million dollars per year in R&D, and we have thousands of scientists who are developing solutions to problems. We collaborate with many, many disciplines, which lead to beneficial relationships and connections for those we work with.

Our focus is primarily in package components. We're taking a broad view of package components and how we can evaluate their

vulnerabilities. We look at these components as potential sources of solution, rather than just the problem.

Additionally, we know that track and trace is where we need to focus for the most secure way, eventually, to prevent counterfeiting.

We specialize in taking inventions and turning them into profitable products. And for 200 years, we've managed complex projects and routinely build and manage large manufacturing facilities.

So come see our booths and start the dialogue. We plan to translate our history in safety to a future in security.

Thank you.

[Applause.]

MR. WALLE: I'm Leonard Walle from Flint Ink Corporation. For those of you who don't know Flint Ink, we're the second-largest ink manufacturer in the world. We're American owned, based on Anne Arbor, Michigan. We're a global company. We're a leading supplier to the package industry.

In terms of our capabilities, there are four at the bottom I'd like to point out. Our expertise in package technology, not just in inks,

but in the substrates and the design and manufacturing of packaging. We have a division, a subsidiary, Jetrion, that their whole focus is digital integrated inkjet solutions, turnkey solutions, PRECISIA, which is print as manufacture, that's another division of Flint Ink, and we have global distribution and customers throughout the world.

Our response to the authentication and counterfeiting problem is to ID critical technologies, form relationships with specialty producers and IP owners; for example, Keymaster Technologies that's exhibiting with us today. We've developed infrastructure for system solutions; for example, with CGM Security Solutions. CGM has been in business for over 25 years. They have strong expertise in cargo theft and security.

I might also mention we're members of the Auto-ID Center and are working with the Auto-ID Center in the implementation of RFID.

We are focused on providing complete turnkey solutions from the concept of developing a strategy for counterfeiting prevention to implementation, to verification that the solution

has been actually applied during the manufacturing process to full interrogation in the field.

We have evaluated a number of different platforms. We have over 20 platforms, technology platforms, available for implementation. I have listed here some overt platforms, as well as covert technology, RFID, XRF. We have qualified and developed brand protection platforms on how to apply those platforms, not just to have technologies.

A case in point, Jetrion. They provide integrated solutions from software to design, to equipment, to full implementation. One example would be a 2D barcode that's printed inkjet. Every single package has its own license ID.

Thank you very much.

[Applause.]

MR. WILLS: Good afternoon, ladies and gentlemen. Ian Wills from Flying Null.

This is a name ID tag. I'm sorry if you can't see it, but it is very small. We're going to pass some samples around.

So where does EMID technology get positioned in the Auto-ID market? It's in the middle between optical barcodes and RFID. The cost

and functionality is obviously compared with its covert and embedded capabilities, but at a very low cost.

So we have passive RFID functionality at a fraction of the cost. However, it is more scalable. The sample that you will see is a simple authentication tag. We can then scale it up to a track and trace tag, which is this size. Again, you're going to have trouble seeing it at the back, but it's going to be very small.

Like I say, you can bury EMID tags into tamper-evident packaging, read it and relate to FDA preparatory papers without line of sight. This also means that it can be integrated with other overt technologies such as OVIDs and hologram labels.

Such integration provides a first level of assurance to the public by the image and further levels of assurance to the professions by machine reading the tags.

EMID is production ready, the material supply is secure, and it can be applied within standard pharmaceutical production processes and with standard application equipment.

The tag readers are applied with RFID and

barcode readers, allowing them to be integrated into technologies and systems for total solutions.

Very briefly, this is EMID technology. I'd love to talk to you a bit more about it.

Thank you.

[Applause.]

MR. POLINSKY: I'm Stephen Polinsky. I am with GenuOne. We are a company that provides technology solutions for either authentication or tracking of products. And one thing that I knew, and I think we've all learned today, there's a lot of ways out there to authenticate your product very cost-effectively and, at the same time, ease of operation. There's also a lot of ways that aren't so cost-effective that are out there.

Putting that aside, what GenuOne is focused on is--I didn't bring any slides--but we have an electronic pedigree software solution that we've had implemented into other industries for a very long time up and running to solve issues like gray-market diversion. And basically it runs on software. It's very easy to implement. It works with the EPC code. It works with RFID. And the software is out there, and it's available today.

It's very compliant. What we need is the

availability to get compliance with distributors. That's the last step moving forward, and at that point, it's very simple to bring into returns and to work with product recalls or where we're working, with the CPG industry, where they have problems with shelf life.

So I think the important thing to understand is that there are solutions out there today that are actually very cost-effective, very easy to implement from a software point of view, and the bottom line is that's really the major part in putting together a pedigree system.

So there's a lot of marks that are out there today. We work with all of those marks, and that's what makes us unique. We are at worldwide web.genuone.com.

Thanks a lot.

[Applause.]

MR. RUDOLPH: I guess I just wanted to let everybody know it is pretty clear I guess already we're not going to have an official break. We're going to work straight through and then go to the final panel. If anyone does need to leave, obviously, we'll just try and keep going so we can try and be out of here before 6 o'clock.

MR. GREEN: Well, since I've got two minutes. Hi. Bye. I'm out of here.

[Laughter.]

MR. GREEN: Anyway, briefly, we're an RFID. Basically, this is an RF tag, 96 bytes. This is an RF tag, more than 96 bytes. We're shipping right now in quantity under a penny, and we use overtly, covertly, as the slide shows some of our overt. Covert applications, we'll be happy to talk privately with anyone.

If you want to see the RF tags in operation, please go to the show room there. We have it in paper, we have it in labels, special packaging. We demonstrate that we can read an RF signature on a box 10 feet away or we can read 10 millimeters away, depending on what the requirement of the client is.

It is RF. We don't use a chip. It's in the paper, as you can see here. We embed our resonators in paper, and when we illuminate the paper with low energy, you get a signature back. The signature is now interpreted as a number. The number remains as part of the database. We are deployed. We're in somewhere between 50- and 100 million items a year, more covertly.

We're now looking into the overt market. It's easy to identify. We can create numbers as large as you'd like. And basically they are created randomly, chaotically random, so it makes it very difficult for anyone to know what the next logical number in a sequence is. Also, our database is variable. We're not fixed size. We can have 16 bytes up to 6,000 bytes, depending on what the client requires.

Basically, we have come up with a system by which a patient buying drugs can authenticate what they're buying, and that's the best policeman you've got out there. Because if he buys a counterfeit drug, he dies.

I'm getting a red light, and he's standing there with a big hook to pull me off. So I'm out of here. Come on back and take a look, kick the tires and see what you like.

Thank you.

[Applause.]

MR. FORTH: Hello. I'm Jerry Forth with IntelliDOT. I'd like to go through a little different approach. I'd like to propose three hypotheses that can be tested very simply and quickly in a short-term pilot that would be quite

inexpensive.

First of all, we really don't know what we don't know with respect to the scope of this problem.

Secondly, it is possible today to install a comprehensive and affordable drug tracking and authentication system. And by affordable, I mean something that would have no net cost to the drug supply network. And such a track and trace system, using tamper-evident labels and a secure printed symbology will effectively protect most packaged drugs.

We all know what doesn't work, and I'm not in favor of moving-target technologies. I believe a specialized and industry specific to the pharmaceutical industry solution is quite possible, and it needs to have a lot of characteristics, but I'm only going to focus on the first and the last.

The first is that it needs to have two independent elements for authentication; one on the package, one in the database. And the last one, it needs to provide an accurate electronic pedigree that will sort out the market, make it more efficient and more trustworthy.

Feasibility. This technology exists

today, it's ready to implement, and it's affordable. Implementation won't require significant changes on manufacturers' part, drug distributors or hospitals or pharmacies. It's an incremental approach that can be used on the drugs that are most likely to be counterfeited today and then moved, if proven,into the whole drug chain, and each step forward reduces risk.

Finally, we offer a secure symbology with a global registry much like a fingerprint. The industry owns the universal database. It provides more information than they could get today and that they, incidently, purchased today.

Finally, it offers one-scan productivity. One high-density symbol contains all product and security information.

Thank you very much.

[Applause.]

MR. MARTIN: My name is Philip Martin, Vice President of Isotag Technology, Incorporated. We use a wide variety of leading-edge technologies to deliver strategic solutions.

There are three components to the effective implementation of a product authentication solution. They are:

Technology, such as overt, covert and forensic technologies, delivered in a layered solution; information management tools such as integrated software applications and field analysis devices; and, lastly, infrastructure and expertise to leverage these technologies and tools to ensure their maximum benefit.

These technologies, tools and expertise exist today to deliver cost-effective solutions that protect both brand owners and the public.

Isotag is different in that we consistently deliver all of these components in a global context.

We recently worked with a client to develop and implement an FDA-approved layered security solution in little more than three weeks. The result was the aversion of significant product revenue losses and enhanced patient safety in the field. With the ISOGARD program management tool, we established a vital information management link between the product and those responsible for managing its security. The result was the closure or debranding of 500-plus points of distribution in a little over three months.

We encourage the FDA to look to industry

to provide these critical components because industry is best suited to ensure secure and cost-effective solution evolution. The FDA should continue to build their partnership with industry, providing guidance and support by establishing output parameters that support the desired outcome of public health and safety, such as encouraging authentication solutions that include end product markers and layered security and packaging, facilitate industry's development and integration of these critical components by considering the implementation of rapid integration processes and/or safe harbor for the development and introduction of product authentication features.

And, finally, urge industry to adopt a voluntary product authentication guideline and certification, such as those used by Underwriters Laboratory and the Financial Stationers Association.

Thank you for your time. We are exhibiting in the back room if you have further questions.

[Applause.]

MR. OLD: Good afternoon. My name is Peyton Old. I am the sales manager for ITW

HoloPak.

ITW HoloPak is one of the industry leaders in optically variable technologies. We are a founding member of the IHMA. We are involved with the NASPO Security Products Organization, and we're also a very active member of DSA.

For the protection of pharmaceuticals, we have developed a COVID system, which has come forth from us from our technology and passports and other identity documents. It's basically a transparent technology that is applied over the variable data or over the printed data on a label or it can be involved as part of the label.

Very limited sources. It is only available to brand owners. It uses multiple overt and covert technologies. It is presently being, if you look at--the light is pretty bad--by the way, the use of this package is for illustrative use only, and it is not accepted or approved by Glaxo. We just borrowed their package.

In white light, you basically don't see anything. Slightly rotated in the white light, you see the Level 1 security of the holographic image. Illuminating with UV light brings up a Level 2 security feature, which just happens to be waves,

but could be anything printed under there. We also have an authentication of a Level 3 device with a laser. It's evolved for security brands. When you use the laser you're bringing up--it's very hard to see. Right in here is the letters "OK."

This technology is available today. It is being used today. We are on some biotech products in the United States. We are being used in China. We are being used in neutraceuticals in both the United States and Canada. It is cross-platform. We can fit it into labels, in boxes, IUD valves, shrink sleeves, tubes, tamper-evident seals.

Thank you. I have a booth in the back, and we have a CD back there that will give you a lot more information. I appreciate your time.

[Applause.]

MR. TOEDTLI: My name is Sergei Toedtli. I'm with m2t, Management to Technology.

To build up a track and trace system, you use a lot of devices which are available on the market, but to identify which type of printer, scanner, marking system, laser or whatever you use or you need is not simply made, and that's our business.

What we do is we are doing the system

architecture, the supply chain management required for it, business processes, and we also take care of the cost-effectiveness. But if it goes down to realization, there is question of system integration, project management, engineering and research.

And if we talk about track and trace solutions, as you can see here on this image, this image has been taken two week ago during a ramp up of a large track and trace installation in the tobacco industry, then, you need all of these components to have the system running.

Now, what's the specific characteristics of the solutions we promote? This is the numbering of each package, inner and outer package, with an individual number. Each package got an individual number. We can trace it from the cradle to the grave, and the system we promote is cost-effective because it's based on existing barcode technology. That means all technologies available today.

And the standards, we use UPC.EAN standards spread out in all distribution centers today, and so everything is proven technology.

What are our competences in this game? We are pioneers in security track and trace. We

started four years ago when nobody was dealing with track and trace. So we have a large experience in that specific field, and I think the most important part is our solution is result-driven and based on large existing installation, real-world installations running under industrial conditions on shop-floor level.

Thank you.

[Applause.]

MR. JIANG: My name is Vernon Jiang. Medicine Alert is located in Palo Alto, California.

What do we offer? We would like to present a solution. A digital real-time solution is often raised in Silicon Valley to the problems of counterfeit and also with drugs; a cost-effective tool for good manufacturing and business practice; a secure platform and open environment for information gathering and communication.

These are our products. As FDA stated in the interim report, there are significant concerns with the use of a centralized database in drug authentication and tracking. Some of the important issues are highlighted here.

In contrast, at Medicine Alert, we advocate an entirely different and simple system

based on cardition codified labels. Cardition code symbology uniquely identify each discrete object and binds the manufacturer and current owner to the object. Symmetry and asymmetry encryption assures the security and privacy to high mathematical certainty.

Discretely distributed, portable encrypted identity data simply for IT infrastructure and reduce capital and operating expenses, worldwide rapid authentication and tracking system operates in real time, in open environment, further reduces the maintenance costs.

Medicine Alert technology is complementary to all other input devices such as RFID and barcode. The principle of RAPID is responsibility, accountability, privacy, importable identity data for each package of a product.

Our value propositions are to the manufacturers complete electronic pedigree for after-market support and logistics. I have to highlight a few of them. For the channels and health service providers, efficient inventory control and efficient logistically handled returned goods or overstock drugs.

And I have to skip the public and

regulatory agencies. We have a demo on-line, and we welcome you for a test drive.

I would like to thank FDA for the opportunity and thank you for your attention.

[Applause.]

MR. BROGGER: Good afternoon, my name is Brian Brogger. I'm Vice President of Microtrace, LLC.

We've been in business since 1985, at which time we acquired the sole rights to 3M MICROTAGGANT identification particle.

We have been working with industry specialists, companies and various government agencies around the world since 1985 to deliver identification and authentication solutions.

Originally, it was developed for the tracing of explosives in the post-detonation blast. The code would be recovered, and then the code sequence would identify what batch it came from, and then you could trace down who had access to that batch.

Microtrace has since refined and advanced the technology, and now it's used for anti-counterfeit product identification purposes. Each particle has a unique numeric code sequence.

Essentially, it's a unique numeric code sequence which is in a colored sequence format. It is certified and registered on the Microtrace central database and never used again for any other purpose.

The MICROTAGGANTs range in size from 1,200 microns down to 44 microns. They are thermally stable to 220 C for extended exposures and 350 C for short exposures.

They have been proven as evidence in a court of law.

There are several different delivery methods that Microtrace uses to incorporate the products to the customer.

We have several wonderful industry partners. For the plastics, AMCO and RTP compound the MICROTAGGANTs. For the films, Clear Foil produces an acetate film that can be used for holograms. Packaging Specialists, Owens, Illinois, has incorporated the MICROTAGGANTs into opaque bottles and clear bottles and holographic labels.

As I said, AMCO produces compounded resin, as well as RTP, used for blow molding, injection molding. And Clear Foil produces the acetate film that can be used in packaging and in holograms.

And Owens, Illinois, produces the MICROTAGGANTs in bottles for authentication and tracking purposes.

You can visit us on the Internet for more information at www.microtaggant.com or give us a call.

Thank you.

[Applause.]

MR. JASPER: Hello, my presentation is entitled "Pharmaceutical Isotopic Authenticity and Homeland Security: Tracing Pharmaceuticals by their Natural Stable Isotopes."

I'm John Jasper, the chief scientific officer of Molecular Isotope Technologies. This talk is co-authored with Dr. Cindy Bucci [ph] and colleagues from the CDER lab.

Just want to show quickly that we observed that in nature that there are natural variations in isotopes. They've been there since the time of the origin of the universe and they're propagated into tills. And when we finally measure each and every batch drugs it has a highly specific fingerprint of carbon, hydrogen, oxygen, and nitrogen isotopes that are already there.

In seeing that, the FDA sent to us a batch

of 20 drugs that were unknown to us. And we measured their isotopic composition in terms of hydrogen isotopes and oxygen isotopes and we were readily able to differentiate different manufacturers and batches of drugs.

In this case, there were four drugs that were sent, we were told tropicamide, hydrocortisone, quinine and tryptophan. As you see there's one manufacturer and one lot or actually one lot of tropicamide, but there were five samples. When we measured them, they were all virtually the same. There was one manufacturer for they hydrocortisone, but there were five lots and they all separated well with the isotopic measurements.

When we looked at quinine, which came from two manufacturers, again five samples, they were widely distributed across the graph and tryptophan came from five manufacturers and they were, again, markedly similar.

All based on the natural isotopic tracers that already exist in the drugs.

The FDA then sent us, again, a suite of unknown samples to us of naproxin from four different countries and six different

manufacturers. And, again, by measuring their natural stable isotopic composition, we were able to separate, in this case by carbon isotopes and by oxygen isotopes which batches came from which countries; Ireland, Italy, India, and--

Quickly, in summary: Stable isotopes are naturally occurring, highly specific tracers. They allow fingerprinting of batch-to-batch variations; manufacturers in batch; and isotopic provenance is a function of the source of the material and its synthesis. Thank you.

[Applause.]

MR. STEENBLIK: I'm Richard Steenblik, I'm with Nanoventions, I'm the chief technical officer. We are a company that manufacturers polymer micro-optic and micro-particle materials. We make micro-optic systems that are not holographic. These incorporate real three-dimensional, geometrical optical systems. And on this side you can see some examples of some of those micro-optics.

We take those micro-optics, we put them together into polymer films to make unique document security and authentication materials.

We also make a product called Nanotagants

[ph]. Nanotagants are microstructured particles that can carry information by means of shape or by surface sculpting, which can incorporate text, bar codes, graphics, data patterns, portraits, and other symbols. You might think of these, like, little tiny coins that bear information. These can be incorporated into products of all kinds. We can make them from consumable materials; we can make them from starch and gelatin, as well as interpolymers. They can be incorporated into packaging or conceivably into consumable and topical drugs themselves.

Unison, is a material that we developed for replacing holograms effectively. Holograms are not, in most cases, very secure. They are relatively easily counterfeited. Unison is a material that uses about 1 million micro-optics per square inch to create a three-dimensional effect.

This film can be applied over text, yet the 3-D effect appears beneath the surface of the text. So it's an overlay that can be put on top of text that adds a very high level of security. If somebody tampers with it, then it will destroy the micro-optic system and you'll see that there's nothing there.

Conseal is a tamper-indicating film that appears to be clear or it can be muddleised or it can be pigmented until it's tampered with. And then, when it's tampered with, it peels, the layers separate and then it reveals a micro-optic that isn't visible without peeling. These were supposed to have been animations, so I apologize that you're not seeing what's happening.

I do have some samples of these materials, particularly the Conseal and the Deep, Unison Deep material. I don't have a booth or table, but I'll be outside the room for another half hour or so and I'd be happy to show anybody who's interested. Thank you.

[Applause.]

MR. MATSUMOTO: Good afternoon, everyone. My name is Hirouki Matsumoto, manager of NHK Spring Company. We are operating an optical security device, which we call DIOVIS.

DIOVIS combine optical battery image device and with interference security measure structure so it can be color shifted by tilting it. And it can be checked with a hand viewer, as you can see in this slide, one side dark and one side bright.

This is transparent type. This shows color shifting and this shows one side in background image, in photograph it is here and one side diffractive image.

Our customer use this DIOVIS to protect their branded product. These are applications. Thank you very much.

[Applause.]

MR. WEIS: Good afternoon, ladies and gentlemen. I am Alexander Weis, I'm with November AG, a biotech company from Germany, specializing in anticounterfeiting technologies. I would like to take this opportunity to address some of the questions that FDA folks posted on their Website.

First of all, in our opinion, what is an ideal security prescription drugs. In our opinion, a system that fulfills that promise has to enable everybody involved in the drug distribution network, the public, patients, healthcare professionals, and, also, the FDA and manufacturers to establish authenticity of prescription drugs whenever they want to and at in no time with no effort.

Therefore, we opt for a layered approach featuring both covert and overt technologies. As

the ideal solution for covert technologies, we would choose DNA because of its vast coding capacity, because of the molecular lock-and-key mechanism. Mother Nature's simplicity making DNA the perfect coding covered agent which is absolutely counterfeit proof. And with our brand protection technology, also machine readable on-site. This is a real DNA test on-site.

As overt technology, for patients mainly, we would recommend optical seals that have a distinct color-switch effect, which is also machine readable and can be coded with optical seals with our patented brand sealing technology. They are optical seals that are machine readable inside the distinct color effect, so this feature is overt and covert at the same time.

We already have tried these features, prominently, the brand protection feature with Bristol-Myers Scripts Company in Germany to fight trading and to track individual packages back to the manufacturer and to the wholesaler. And I'd be glad to tell you more about that. And I can also give you a contact address at Bristol-Myers Scripts Company, Germany. Here are some of our partners. And I will be glad to answer your questions at our

booth. Thank you very much for your time.

[Applause.]

MS. BADINELLI: Good afternoon, everyone. I'm Ellen Badinelli, the founder of ScanAvert. And I hope you all are Evelyn Woods speed-reading graduates, because I'm going to fly through this very quickly.

ScanAvert is a method to give consumers the ability to determine which products are harmful to them, based upon an allergen profile, prescription profile, or anything that may exacerbate an illness or disease.

And here are some fast facts: Primarily the fact that we have a senior prescription drug bill looming in our future, we need to be a little more responsible about how our funds are managed to pay for that. And what ScanAvert does is it puts a measure of responsibility in the hands of the person who is really the primary care physician for each of us: Ourselves.

And this just explains how those little leaflets that go with prescription drugs are so useful, as many of us have had difficulty deciphering them.

Now what ScanAvert is a particular

solution that is available to grocery chains--although it's also available for home and healthcare facilities; any food service facility, whether they be in school districts or public entities.

And what a consumer would do is actually pick out their diet, if they had an allergen in their family or their prescription and you can see all the ingredients that are used in synonymous terms and labels. So the mapping process doesn't just look for egg, but it looks for all those other terms used in a label to alert you to the harm of that particular product.

You can see Lipitor has its contraindicative substances--grapefruit juice and hebaphrodil [ph]. And you would actually be able to pick out carbohydrate counts if you had someone in your family who was diabetic or vitamin A, potassium, anything that's found in a nutritional label, including the recently regulated fatty acids.

You go to your grocer and through either micro-kiosks or self-scanning portable shopper scanners, you would be able to scan your little card which would have your profile imbedded in it

because it would be linked to your check-cashing account or loyalty account. And receive information about everything and every product and whether or not it's harmful to you. And by clicking and touching on that screen, you would realize that, perhaps, the vitamin you purchased three months ago, which contains zinc or magnesium is in conflict with the antibiotic you're being prescribed and would suppress its effectiveness.

From a cost basis for a senior that may be receiving a drug that might not realize it's consuming particular substances that were contraindicative of that drug, this would really be a cost-saving basis to the taxpayer.

And we have some other on here, you'll see some total fat and maximum and minimum evaluations are established; allergy alerts. And prospective substitute products.

Now, the nice thing about being a registered ScanAvert subscriber is that you are able to be contacted post point-of-sale, in the event of a recall. Kellogg recently recalled 750,000 boxes of egg-free pop tarts, because they were not egg-free. And, yet, as a parent purchasing that box, what a life-saving service for

me to be contacted by my retailer directly that this particular product was being recalled.

Now, whether or not I actually received my Lipitor from my retailer or from the Internet or a stand-alone pharmacy, because I've identified myself as a Lipitor user, I will get all public service announcements regarding any type of counterfeit activity, contamination or tampering that would be of use to anyone in my family.

So this is a real aid to anybody whether or not they actually have a personal computer--although 33 percent of American households report they do--just by entering your grocery store and scanning your card, you would receive this public service announcement, as well.

This is just sort of a case-in-point: A very tragic incident where five children basically, I guess, died and this was reported February 21. The very next day another child that was reported, had also died. All in the same area and, maybe any of you folks in this room, might know differently, but my last contact with the CDC there was no specific information about this. But it looks like they were all in the same area; certain retailers or distribution points that were common to these

children could have been learned if ScanAvert were in effect.

And that's just pretty much how this works into some of your regulatory issues and I'm out of time. So if you would like to speak with me, I am in the display by the vendors and thank you very much.

[Applause.]

MS. HERBST: Hi, I'm Ellen Herbst, I'm with Spectra Systems Corporation. I'd like to thank the FDA for the speaking opportunity. I'd like to thank everybody who's still in the room for hanging in. And to that end, would everybody please stand up. I'll use 10 seconds of my time for all of you stand up, please. Move your arms around, whatever.

And as you're sitting down. I'll ask you to do one thing for me and that is to remember our Website name SPSY--Sam Paul Sam Yellow.com. If you contact us there at information at SPSY.com you can get the complete presentation downloaded to you.

Spectra is a materials science company. That is, we develop and sell engineered materials for use as both overt and covert tags for authentication and tracking. We've been in

business since 1996. Our customers today include various customer agents, government agencies, both within and outside the United States, as well as commercial businesses in pharmaceuticals, luxury goods, software, the music and entertainment industries.

Now, to service all of these customers, we segregate our solutions into solutions that are only available to government agencies. Then solutions that are only available as forensic-level solutions. And then other solutions that are high-level covert, medium-level covert and overt solutions.

Our solutions are physical materials. They are used to tag and authenticate both a product, primary packaging, and secondary packaging. As well as providing the reader devices and software to detect or verify that our tag is present.

We believe in layering authentication solutions and we believe in ongoing investment in solutions. So, you need to invest today in solutions that are available and commercial today. When other solutions are commercially viable, they should be considered. But engineered materials and

electronic solutions that are available today should be implemented today and not wait for the ultimate solution, because there is no ultimate solution.

Our products can be incorporated in paper, board stock, metal, glass, plastic, and take the form of particles, fibers, threads, inks, and coatings. Additionally, because of the broad range of products with unique signatures, we can offer dedicated solutions, i.e., each customer can have a dedicated solution.

Again, please visit us next door, or visit us at SPSY.com to learn how you can implement a solution today and a secure supply chain. Thank you very much.

[Applause.]

MR. RUDOLPH: I want to make one slide change in the schedule, due to time constraints, we want to actually have John Myers from the Canadian International Pharmacy Association come up. We understand he has to leave in a few minutes. So, we'll interrupt this panel for this one speaker and then we'll continue with Tim Saarinen.

MR. MYERS: Thank you very much for accommodating my flight schedule today. I'm the

general counsel to the Canadian International Pharmacy Association and I've come just to speak to the task force a little bit about issues relating to education and educated patients in the United States.

CIPA represent Canadian pharmacies that provide international prescription services to U.S. consumers. And regardless of what the outcome may be of current legislative changes, American consumers are continuing to turn to Canada for affordable medications.

The interim report identified Canada as a potential portal on the counterfeit question. And CIPA is an organization that has taken the time and the effort to develop standards and procedures essentially to augment existing federal and provincial regulations to address and mitigate what those concerns might be.

I've provided a handout to you, as well, with my slides, seeing as I'll have to go very quickly.

The consumers of this service are seniors and insured workers losing benefits. And those are the people that we're seeing that are coming to Canada to purchase their medications.

These are the types of medications, that generally the profile of what U.S. consumers are coming to Canada to purchase. For many years they've been coming to Canada in person, on bus tours as you've heard. And only recently, have the visits actually been surpassed by electronic means using mail order and the Internet.

If you take anything from my presentation today, consumer protection's a shared responsibility in our respectful view. Regulators, pharmacists, and educated patients are the most important component in terms of dealing with the counterfeit issue.

This is what an educated patient needs to know before choosing a Canadian pharmacy and members of the Canadian International Pharmacy Association adhere to all of the criteria that I've set out in the notes that I've left you with and I'm not going to take you through all of that information now. But one of the critical components is that anything that the Canadian International Pharmacies sell are approved by the therapeutic products directory in Canada. So, it's critical in making a choice as to what Canadian pharmacies consumers are going to use. You had

better address whether they're going to meet these types of criteria.

The customer agreement also forms a very important component of the Canadian pharmacies' relationship with the U.S. consumer. I'm not going to take you through that now, but if you go to a Website like crossborderpharmacy.com, and take the time to review the customer agreement that U.S. consumers enter into with Canadian pharmacies, it will give you an idea of what a CIPA customer agreement looks like or a CIPA-member pharmacy agreement looks like. That's our certification mark. And this is how you would verify whether the pharmacy that you're dealing with is a certified member of CIPA. And you can go to the CIPA Website, which is at ciparx.ca for more information about the association.

We have a licensing agreement in place requiring pharmacies who participate to comply. And meet or exceed existing standards.

And CIPA stands ready to work with the FDA going forward if, out of your task force and your deliberations you come up with certain choices that you want to make about tamper-proof packaging or other counterproofing measures, we're certainly

interested in sitting down with your representatives to make sure that our pharmacies are meeting those standards. And I think you very much for your time and for fitting me into the schedule. Thank you.

[Applause.]

MR. RUDOLPH. I just ask if any, since Mr. Myers is leaving--does any task force member have questions? No. I just would make a request, if it's possible for you to submit any of the documentation as to the standards or any, you know, documents that you have about the standards, if you want to submit them to our docket, I think that we'd be interested in reading those.

MR. MYERS: Sure, I'd be happy to do that.

MR. RUDOLPH: Thank you, now we'll go back to the previous panel now. I don't know.

MR. SAARINEN: I'm Tim Saarinen and I'm representing Alcan Packaging. Our presentation didn't get up here, but I think I can summarize pretty quickly what we do.

We're about a $13 billion company. We are one of the world's leading global manufacturer of packaging materials, including vials, plastic bottles and flexible packaging. I'm going to be

focusing on flexible packaging today. And primarily because of the interest in unit in use and also some of the technologies we have.

Our package is called Encrypt and it involves somewhere in the order of 30 to 35 different types of tagants for flexible packaging materials.

On the overt side, we've got color shifting inks; we've got banknote printing, very, very fine text printing. On the covert side, we do things like putting in UV fluorescent inks, which aren't visible in normal light but will show up under fluorescent conditions.

There are shifting inks, which can shift with heat or with light. And we can incorporate various tagants into our inks. One of the nice things is that there are a lot of products that are already on stability with our foils and using a new ink will be on the outside of the foil, so it should be relatively rapid transfer. It is a commercial product. There are a number of pharma companies that are working with us currently with these encrypt technologies and it runs on their regular packaging lines, so they're investment is minimal. Thank you.

[Applause.]

MR. PEER: Good afternoon. I'm Ron Peer, I'm the CPO of Bsecure Group, company out of Israel. We consist of eight technology companies that we have one factor in common, which is all of us are in the technology of security protecting documents and products.

And we have diversified experience for more than ten years our products are all over the world and we believe in AT&T which is not the telephone company, which is authentication, track and trace and tamper-evident.

So, in that case, instead of continuing my marketing speech, I'll go directly to technology and I'm not going to cover all this. This is just a sample of a suit of a multilayer tailor to a problem. And like the technology provider who tailors the problem to the technology, we usually tailor the solution to the problem.

And I'm going to focus on few technology. One of them, it's marking where we can mark in glasses or in plastic, which is not laser etching. It's not on the bottle, it's in the walls of the glass, like the cosmetic industry believed that for track and trace, you need something the diverter or

the gray marketeer would have to destroy the product. So, this information is embedded and if you try, even to abraise it, like you can look here down, they try to abraise it, but you still can see it. And where the--stamp that can read the--bar code and provide the information for track and trace.

So you have two layers there that you can embed it in any bottle. It's overt, so it can give some perception to the user but, also, it can identify the product and everything that you need in.

Taking this technology farther, we are doing what is called multilayer. for instance, one of the problem that some of the speaker talked about is counterfeited of the expiration date.

So if you are going to take the shrink, and you can use this technology, you can print, so-called print, the expiration date, which is going to be first embedded in the polymer itself as part of the polymer, not on top, you cannot scratch it, you cannot take it out, but, in addition, on the cap itself. If it's plastic or on the plastic bottle. If, after the customer is opening the shrink, still the expiration date is on the cap or

on the plastic bottle, wherever you prefer.

So for authentication, it can look at the shrink; it can see whatever message that you know. This technology can provide alpha/numeric or 1-D or 2-D bar code, but, in addition, you can use scramble indicia even images, if you'd like to use.

Other technology that also started from authentication, this is our DMID, it's digital magnetic ID, it's a low-cost chipless RFID. It started for authentifiber [ph], which is a glass-coated microfiber, that as it creates a signature that can embed it in the box or under an aluminum cap and can be read out of the box. So if you would like to authenticate any product, you don't have to open the package, you can read it out.

Taking it a little farther, we make it even carrying information. You can read it out of the shipping container four centimeter, which is one and three-quarter of an inch deep and it carries multiplication of 20/40 and so on.

Another technology that we believe--it's a temper evident that you need a special evident to be also not only on the individual package or individual product, you need it also on the shipping container. This special tamper-evident is

print on demand as a selective release, you can leave on the package what you like, you can add to it any authentication and also using, what I said, the marking where you--the one that mark on the shrink and the package, you can print on the plastic, you see it stayed on the cardboard after you lift up the tape itself.

Last but not least, this is our circle vision. It's based, also, on a long-time proven system, authentication system that is fielded in the world more than ten years with many brand owners, and many governments, including here.

This is a machine readable ink that has special characteristic, but what we did, we moved it and we make it invisible so you can--you see a label that is printed, if you try to see wither with video or with other vision system, you won't see anything. But you can see embedded a 2-D bar code.

So, all these three that I showed before, it's not just track and trace. the first level, it's authentication, because if someone in the lower level--because you don't need to track and trace all the time. So you getting the same tokens simultaneously authentication feature in the low

tier or in the general or whatever you like.

And, in addition, in a certain area, you can add this feature. So, you get one, for price--two for a price of one, even though that you said there is no one-size fits all in your documents. This is something that started to go into that.

Okay, so, thank you very much, if anyone of you want's to see any demonstration, I'm around here for another ten minutes and then I have to run back home. Thank you.

[Applause.]

MR. SZUKALSKI: I'm Al Szukalski, sales manager of Enercon Industries and we build induction sealing equipment.

Induction sealing equipment has been around for probably, oh, since--been popular since the time of Tylenol. The FDA recognizes induction sealing as an effective method of product protection and tamper evidence.

Some of the things that induction sealing will accomplish--it will accomplish tamper evidence; it will prevent leakage; preserve freshness; extend shelf life; prevent pilferage and deter counterfeiting.

Now, it's not a cure-all for

counterfeiting, but it can be used with certain other materials in order to assist in deterring the counterfeiting. It can be used with holograms, holograms with reversed metalized [ph] messages, UV inks. It's not really bar codes, though, that's a mistake. Custom colors, inks and foams and multimessages in colors. Here's an example of a holographic induction seal.

Induction sealing works--there's an inner seal. Traditionally, it's placed in the cap by the cap manufacturer. And it's a simple inner-seal design. It has, in this case, four layers: it'll have a pulp board, a wax holding the pulp board to the foil, a foil or a polymer that will match the land area of the bottle.

Induction works by inducing an electromagnetic current into the foil layer of the innerseal. The foil then becomes hot and melts the wax layer into the cap and the polymer onto the bottle.

Why would you want an induction seal? It's a cool heating process; there is no heat; creates a hermetic seal; requires little, if any, modification to packaging lines; an the seal takes place after the filling and capping.

There are a couple of different--there are a number of different models. There's semi automatic or table top systems that can be used for lab use. There's also the conveyor mounted systems. This system here has an integrated inspection seal and rejection system.

Induction sealing systems have been used for round container openings traditionally, but now we've also been able to come up with the technology to seal oval and rectangular containers.

We've also, just recently, got into cap induction sealing, which typically was done by a conduction system, which was a hot plate. In this particular case, we're doing this with a sealing head that would create no heat at all.

In summary: Induction is a simple and efficient sealing creates a tamper-evident, hermetic seal. Holographic printing of the induction seal deters counterfeiting. Induction seals can be installed on all production lines. Induction seals are available in table-top models and can be accomplished with or without a cap. Thank you.

[Applause.]

MR. DIETRICH: Thank you. I congratulate

the FDA on convening the public meeting to address this pressing national issue. And I think you for allowing us to present information about a cost-effective anticounterfeiting solution in use today. I name is Ed Dietrich, I'm the director of sales and marketing for Flex Products.

Flex Products, Incorporated a JDS Uniphase company, embedded, color shifting security technology. We pioneered the use of optically variable pigment, which is now a world standard that protects over 25 billion bank notes in 89 countries. Our OVP technology has been in widespread use since the early 1990s and its robustness as a frontline anticounterfeiting solution has been tested time and time again.

The newspaper USA Today recently reported that the U.S. Secret Service found that color-shifting inks were the one feature that counterfeiters have been unable to reproduce on U.S. currency.

Recent European reports on counterfeit Euro 50 banknotes, also indicate that counterfeiters have been unsuccessful in copying the unique color shifting effect.

In response to the growing problem of

product counterfeiting, Flex Products, launched the SecureShift line of color shift solutions to specifically address this threat.

We've drawn on five decades of experience in optical design, interference physics, and high-tech manufacturing to create a unique anticounterfeit solution; backed by a capital investment of over $110 million in proprietary equipment, and secured facility we believe SecureShift technology offers an unsurpassed combination of easy-eye authentication; application flexibility, esthetics and affordability.

SecureShift technology, this unique technology, has gained rapid acceptance in the pharmaceutical industry. And, today, six of the top 20 largest research-based pharmaceutical companies use SecureShift technology to protect seven leading brands of ethical drugs against fraud. These market leading products generate over $10 billion in the annual worldwide revenues for their brand owners.

Why is SecureShift technology such an effective solution against counterfeiting? SecureShift offers a combination of four key benefits that we feel make it a unique counterfeit

solution: Easy eye verification; application flexibility on labels and packaging; esthetics, to be able to blend with a package design; and affordability.

And, finally, we feel that SecureShift provides a an effective, rapidly deployable, and affordable cornerstone for a multiprong strategy to combat counterfeit drugs. Thank you very much.

[Applause.]

MR. VEERBEEK: Good afternoon. My name is Dirk Verbeek, I'm from South Africa and the company I represent is Industrial Fingerprinting.

The Industrial Fingerprinting system is based on a patent registered in the United States, originated in South Africa. The registration in Europe and Japan is pending.

It describes the application and subsequent tracking a unique and secure code for individual item. Now there are a lot of unique serialization systems available. In this case, the codes are issued from one central database. Also make use of DNA to make it country specific. You can add additional functionality, in other words update an item's history throughout the supply chain.

Designated products are recorded and monitored on the patented central loss-control system database and we have a reaction center that monitors any exceptions flagged by the database and is actioned [ph] according to protocols set by the owner.

The system, as I said, is from one central database that issues unique and secure encrypted codes. It is hardware based. And the items are monitored by having these codes applied to individual products. Now they can be 2-D bar codes, they can be RFID tags and they are authenticated by a scanning process to the central database at various points of acceptance throughout the supply chain.

Individual codes can be updated with mixed destination on the central database. This will provide for a secure environment for products to move through. And it, obviously, provides protection against counterfeit products and the like. It ensures supply chain integrity.

Just to quickly run through this is really the greyhound version due to the time constraints. Various 2-D bar codes can be used that are recorded on the central database. RFID tags which also

relate back to a number can be recorded similarly. The designated products can have different statuses, like, in transit, export, product recall can be done centrally, expired stock can be monitored.

I just want to emphasize that each individual packet down to blister pack, can get a unique code. It is then married to the outside box to create a parent/child relationship. Other of the statuses are for theft are flagged in case of an investigation.

I'm quickly going to run through just the basic system architecture. There is a code generation component, which is then put into a database. It is encrypted in the database. And then there's a Web application component. This is then fed through a secure messaging component through the Internet and through a manufacturer. Now, a manufacturer will request codes from the central database. They will be dormant until the manufacturer actually fixes them on the products, registers them on the central database by a method of scanning and through the parent/child relationship, one can go up to pallet level and know through one scan exactly what is down to

blister level.

Once the product leaves the manufacturer to a warehousing or distribution, it is scanned out. Similarly, at the same time, the destination can be identified, where it's going to. When it arrives at the warehouse or distribution, it is scanned in and that is correlated back to the central database. Any exceptions are then flagged and reacted upon.

If it leaves the warehouse or the distributor to a service provider, a pharmacy or a doctor/hospital, it is scanned out once again and scanned in at the service provider and the final but the most important is at-patient level, it can also be scanned out and scanned in to provide exactly the track and trace.

This provides the complete from the manufacturer right down to the patient level, everything that has been discussed, we believe this system can do it.

It has been developed by Industrial Fingerprinting and Side Base South Africa. We make use of the Side Base IQ Database and various of the Side Base components, we use a cipher machine that provides the encrypted codes, so it is hardware