generated. And the light is flashing, so thank you very much for the opportunity.

MR. BROWN: My name is Chris Brown and I'm vice president of sales for Inksure Technologies. Thanks for the opportunity for us to present our anticounterfeiting technology solution.

Inksure's technology is a covert, machine-readable solution. We use tagants or chemical markers that are optically sensitive and mixed into any commercial inks or commercial varnishes and applied with all common printing processes. This means that any printer can apply these security inks and the tagants, of course, being covert are not visible.

We have a broad range of tagants that we can choose from and our new advanced-reader technology actually enables us to create thousands of custom chemistry codes, which gives each customer or distribution channel their own unique chemistry. This licensed chemistry creates a highly secure channel for the inks and the materials and the coded ink distribution is secure.

The unique customer chemistries are called Smartinks and, of course they're resistant to copy, alteration, or tampering.

The applications for Smartink are in primary or secondary packaging, on secondary adhesive labels, or on the tamper-evident seals and closures.

Smartinks can also be integrated into overt features, such as holograms or color-shifting inks to create a layered approach.

Smartinks can be used in bar coding with inkjet printing or other printing formats for bar coding to give you a confirmation that the bar coding is authentic without actually accessing the database or reading the bar code data.

Smartkinks are compatible with all types of inks. They can be printed in all colors. They can be printed in black ink and also in clear varnishes.

Smartink readers, signature readers are hand-held detectors and they perform a complex code interrogation with unique optical engineering software algorithms. It's a simple design which requires minimal field training. With a single push of the button, the operator in the field will get a positive green light or negative red light reaction.

The hand-held reader can store up to 10

Smartink codes and the new signature reader line has the most advanced analysis available with full spectrometer signature analysis measuring wavelength, absorption, decay time, and background colors, still with no field training and we are bringing technology to the field that is actually at the forensic level.

Last slide, since I have a blinking red light. The Smartink readers or signature readers are also available in OEM kits so they could be included into other products. We also have high-speed sortation [ph] equipment available for QA or return centers that can read Smartink codes at 10 meters per second or give a pass/reject indication within 12 milliseconds. Thank you for your time.

[Applause.]

MR. RUDOLPH: Greg Metcalf. Steven Crane.

MR. CRANE: Thank you, my name is Steven Crane. I'm the chairman of the board of NNC Group, LLC, a healthcare services company.

We supply recall, return and communications services to pharmaceutical and medical device manufacturers.

The focus of my comments today is on one aspect of the counterfeiting problem that I feel

has been given little attention. The recall of counterfeit product that has found its way into the hands of distributors, pharmacies, doctors, hospitals, clinics, or consumers.

Once a decision has been made to recall counterfeit product, it should be done in an efficient, effective manner, so as to minimize the chance that any significant amount may remain in circulation.

In certain circumstances, however, the task of executing such a recall may fall to an organization with little or no experience in accomplishing such a task. I believe this could cause problems in making sure: one, adequate notification reaches all known recipients of the counterfeit product; and two, that as much counterfeit product as possible is recovered and accounted for.

Having handled more than 500 product recalls, NNC Group understand that each recall presents a unique set of challenges regarding notification of consignees, be they wholesalers, distributors, retailers, medical personnel or consumers. It is important to deliver a consistent message in a manner that is meaningful to the

recipient and that allows the recipient to respond effectively.

Multiple notifications are usually required via telephone, fax, Internet, and mail. Such notifications contain specific information and instructions for the recipient.

Notifications may be as timely as urgent as detailed as circumstances warrant. Just as an example of a very timely and urgent notification, earlier this year, we received a request to notify most of the pharmacies in the U.S. of a potential tampering situation.

This request came in on a Friday afternoon. By Saturday morning, we had given verifiable notice via telephone to over 40,000 pharmacies and followed-up with overnight mail instructions.

Instructions to recipients should be clear and unambiguous. Return of the product should be simple, secure, and immediate with no lapse of time between receipt of the notice and return shipment of the product.

Finally, there should be requirements for storage, document retention, inspection, and final disposal or destruction.

In short, existing technologies and business processes exist and are used on a daily basis for the effective, efficient removal of counterfeit product from the normal channel of commerce and should be brought top bear on the recall of such counterfeit product.

Thank you.

[Applause.]

MR. RUDOLPH: Michael Feinstein. Brian McCarthy and then Jay Fraser; J. Christopher Philips, Jim O'Hagan, and Tom Klaff.

MR. McGREENY: Good afternoon. My name is Bill McGreeny. I'm with Owens Illinois, I'm the business manager for healthcare. Brian McCarthy threw his back out yesterday, so I'm pinch-hitting.

We've got a couple of different technologies that are commercial today that we want to present. And hopefully we can do this in a minute or two. We've introduced a new technology, a plastic alternative to type-I glass for pharmaceutical liquids that need a clear, autoclaved or lyophilized package.

With this technology, we've got one layer of a material sandwiched between another material or two layers of another material. In that inner

layer we can put a microtagant, which is, basically, a forensic device that gives an identity code to each of the lot numbers or however the customer wants to separate the product line. There's over 37 million code combinations and we've partenered with MicroTrace in doing that. MicroTrace has been doing it for decades, in the explosive market and it's a proven technology. And we're ready to launch that product now.

There are several different signatures it can be given. We can give you more details if anybody's interested.

That second area that we're looking into and we've done quite a bit of development and testing on the viability of FDIR--I'm sorry, RFID technology in-mold labeled into the bottle. And we've done very high-heat molding and tested the RFID components and found them to read very successfully. So, we're pretty happy with the results of that and we're waiting to see how we can proceed with that with a customer.

I'm skipping a few of these, that's why I tripped on myself there for a minute.

The RFID commitment, we do have an internal sales force with senior management and a

commitment from Capitalwize and so forth to launch the RFID technology when a customer wants it.

We have a knowledge-base, we've been working with the Ilian [ph] Academy on developing our technology to handle these. We're collaborating with integrators on best practices and we do sit on the HDMA Product Safety Forum. And then we're ready to develop that at the pallet, case, and item levels.

And our position in RFID technology, because my red light's blinking, is we think it's a capable technology today. We're ready to implement. We've completed the readiness maneuvers and now we're searching for direction from our customer base.

Thank you.

[Applause.]

MR. FRASER: I'm Jay Fraser from Tracer Detection Technology with my associate Larry Webber.

Our technology exploits random patterns and we're commercializing our exclusive license from Oakridge National Lab, as well as our own patent portfolio, with a cradle with Native Laboratory, we have assurances of a continual

supply of fibers for our manufacturing and commercialization.

Every product that is protected by our security feature is self-authenticating and uniquely identifiable. In fact, to defeat our security feature, a counterfeiter would have to duplicate six overt and covert elements simultaneously. With our proprietary design and scanner we image and encrypt the random pattern. The symbology also enables definitive product tracking; provides manufacturer's tracking information; as well, as information required by the FDA.

Our technology is both visible and covert. In fact, a logical combination of covert elements prevents reverse engineering. Our security features accomplishes both the authentication and track-and-trace objectives.

Further, it can be stand-alone, integrated, or bundled with IT products and linked to a database, with data entry occurring at every point of the distribution. It is applicable to labels, bottles, outer packages and tamper-evident seals. Even linking the seal to the label or the bottle.

And, finally, our technology is combinable [ph] with most other security features without interference.

Our engineered materials and manufacturing process have been perfected. We have a functioning demonstration system to create and authenticate our security features and our photo-optics design is production ready and has been qualified by our OEM manufacturers.

We're in active discussions with the Department of Homeland Security, New York State Department of Motor Vehicles, AMVA, and a range of private-sector partners and customers.

Our system is easily adopted by pharmaceutical manufacturers and packagers. We use off-the-shelf printing equipment to permit printing of the variable product information and inventory information by the manufacturer or label supplier. Our off-the-shelf scanner design and components accomplish high-speed throughput and printing.

Additionally, our security feature is consistent with the pending FDA bar code regulation.

From a track-and-trace point of view, our technology provides a definitive identification of

pharmaceutical products, packaging, seals, and shipments, individually or linked to each other.

The scan that's performed at manufacturing creates a unique electronic pedigree that is confirmed at each level of distribution. Each re-scan provides real-time track-and-trace and location data. In fact, our track-and-trace aspect can be extended to the pharmacist or the consumer who can track it by Web or by telephone.

We look at FDA as an organization that not only deals with high-end pharmaceuticals but, also, products that have safety and efficacy issues at the consumer level, including HBAs. We're looking at this as an opportunity where the bar code regulation will provide a platform for our symbology as it is applied.

And, in summary, our technology offers an unbreakable anticounterfeit system that can be stand-alone or linked to a database. It creates a unique product pedigree for each piece, each individual label, bottle, seal or package will have both overt and covert features. It's machine-readable and, therefore, provides track and trace data for the full chain of distribution.

Importantly, the security feature is

readily updated to stay ahead of counterfeiters and is ready for manufacturing. All system components, including the hardware, the software, our data acquisition and storage can be customize for the end user and it's fully combinable with most of the other security features that are being discussed here today. And if you have any questions, Dr. Webber and I will be available for questions. Thank you.

[Applause.]

MR. PHILIPS: Good afternoon. I'm Christopher Philips of Verification Technologies Incorporated, doing business as Veritec in Centerbrooke, Connecticut.

Since 1996, our sole focus has been to provide solutions that ensure product integrity throughout the supply chain. This process begins with a patented fluorescence technology to fingerprint products. Once the fingerprint is available samples from the real world can be authenticated in a very simple practice, either in the laboratory or in the field. And this authentication product takes place without the use of tagants or tracers ever in the distribution channel.

So, that's fingerprinting and authentication on the product side. The package side involves infrared dyes, covertly marked on packages and for track-and-trace, and that allows field testing also, as you might guess.

So, on the authentication side, with products, we matched real-world samples to an existing fingerprint by looking at the fluorescence of the field sample versus fluorescence of authentic product, again, with no tracers or tagants used. This is highly scalable, we are fully automized [ph], robotosized [ph] in the laboratory so that we can do hundreds or thousands of samples in a very short time. And via portable units, this is globally deployable so that authentication can be done in the field. And we're in use since 1996 with Fortune 500 companies.

Here's an example of a real fingerprint of a pharmaceutical, a blockbuster drug. The circle on the bottom left, shows about somewhere between 30 and 40 authentic samples of that pharmaceutical; small circle up at the top there, is a counterfeit product and, again, what you're looking at here is a two-dimensional representation of a three-dimensional object. The fingerprint of the

authentic material that takes into account the manufacturing of the actual authentic process.

And, of course, all of this is done with multivariant pattern recognition. So, it's very easy to visually represent a real fingerprint and visually see whether a product matches the fingerprint or not.

On the package side with authentication or track-and-trace, the Variguard 300 System involves infrared dyes that are covertly employed for use on packaging to provide authentication and track-and-trace capabilities. These are as infrared dyes, these are truly invisible to the eye an to UV light. Our partnership with Video Jet, who's the largest inkjet printer in the world, seamlessly allows implementation of this technology and existing packaging lines.

So, on the track-and-trace side, we provide real-time digital images that are downloadable to databases that allows integrated supply chain protection and this system is currently in use with a global consumer products company.

In summary: We offer three major capabilities: The product fingerprinting and

authentication system, without tagants; package authentication and track-and-trace capabilities; and field testing or portability for both of these.

Again, our partnership with Video Jet allows integrated solutions for data application, for data capture transmission and database management. These solutions work in production facilities. And in the field today. We can and would like to effectively integrate into the proposed counterfeit alert network. And welcome the opportunity to demonstrate our capabilities.

The last slide simply gives a Website where you can go for a copy of this presentation or to see more about our capabilities.

Thank you very much.

[Applause.]

MR. O'HAGAN: Hello, I'm Jim O'Hagan, director of technology transfer for Zebra Technologies Corporation, a leading manufacturer of on-demand printing solutions used for supply chain tracking, business improvement and security. Zebra's publicly traded and we're headquartered near Chicago.

Zebra provides automatic identification solutions to both small suppliers and worldwide

corporations including pharmaceutical manufacturers, contract packagers, drug distributors, retail pharmacies, and hospitals. We've assisted these firms in complying with the FDA's proposed unit of use labeling requirements. We've also assisted several healthcare organizations, including the VA hospitals, with leveraging unit-dose data and positive patient ID for patient safety.

In addition, Zebra's participated on several committees and subgroups assisting interest he development of patient safety and security, including the HDMA and their industry coalition for patient safety.

Zebra's solutions are an integral part of supply chain tracking systems. Not only in life sciences but, also, in other industries; in automotive manufacturing, personal shipping, retail distribution systems, the U.S. Department of Defense. And in other industries where tracking and tracing individual items is essential to efficient and dependable operations.

These businesses use bar codes to improve the security of their supply chains. Each item, case, or pallet is bar coded with the information

that needs to be shared between two trading partners. Since these bar codes follow industry standard formats, the information is easily shared with or without access to an electronic database.

In addition, each tracked item has a unique identifier allowing each item to be linked to other more specific information made accessible only to trusted partners with a need to know.

Since each item has a unique identity, each item can be tracked to and from each trusted partner. Because this identity is encoded in a bar code, or an RFID tag, tracking is extremely reliable at very high speed and, therefore, at very low cost.

In addition to supply chain tracking our printers and supplies print authenticable [ph] identities, including state driver's licenses, airline boarding passes, event tickets, consumer electronics, computer software licenses and tax stamps. Custom materials, holographic films, magnetic strips, covert marks, and invisible bar codes are widely used by our customers, but discretely implemented.

But these anticounterfeit technologies are worthless without secure operational methods,

including hiring practices, access control, and controlled access to information.

All these technologies depend on differentiating between trusted partners in an unsafe world. The FDA already plays an important role by making sue that certain manufacturers are trusted to manufacture certain pharmaceuticals. And that certain pharmacists can be trusted to dispense pharmaceuticals.

Adding the ability to confirm that a trading partner is who and what he says he is, can go a long way to addressing diversion and counterfeit problems within the supply chain, giving each partner a unique authenticable and automation-friendly identity is key to doing this in an effective but cost-efficient manner.

Trading an authenticable identity and tracking it through the supply chain is proven technology and Zebra is an experienced and trusted advisor. Over 90 percent of the Fortune 500, uses Zebra products in over 90 countries throughout the world.

Thank you for this opportunity to work with your important issue. More detailed information and specific comments on the interim

report will be submitted to the docket.

[Applause.]

MR. KLAFF: My name is Tom Klaff, I'm CEO of Surety. Surety's mission is to enable regulated industries to guarantee the trustworthiness of their electronic records indefinitely. We have patented absolute-proof data integrity services which generate irrefutable evidence of exactly what was created and precisely when.

The company was founded in '93, we're headquartered in Herndon, Virginia. We were spun off from Belcore in '94. We're an iso standard imminently by the end of this month for digital time stamping. We have patented and proven technology and we're focusing on the regulatory markets. We have regulated customers, including a track record of success with life science customers.

The value proposition that they see in Surety is that first, we help them protect their intellectual property. We help them prove, first to invent claims; we help them defend their electronic records. To date, about a billion records have been transacted through surety services. And about a million records have been

submitted to court without challenge.

We also help them comply with regulatory mandates, like, 21 C.F.R. Part 11. We address the data integrity issues surrounding long-lived archival, a record-integrity archival and secure audit logging.

The fourth such value proposition is pertaining to today's discussion is proving the validity of the electronic pedigree from the manufacturer to the retailer.

Let me briefly tell you how this works and how our technology works. It all starts with a record. A document. It could be an e-mail or it could be a data element from a bar code.

These elements reside as database entries in databases, managed by people who need to be trusted. And we all know what happens surrounding trust these days, vis-a-vis, Enron or Credit Suisse First Boston.

Essentially what happens is, a document is hashed over two--hashing algorithms that hashes a unique fingerprint that is sent directly to our servers, hosted at Exodus. And it is inserted into a secure hashing chain, which has been running since 1993, all records have been hashed and are

now computed in the hashing chain.

Every second we do a recomputation. The hash is then sorted, then we recompute the chain and then we send a notary record and the time stamp back to the consumer. The document never leaves the consumer's office.

This happens second-after-second and every week we publish our hash values in The New York Times in the Sunday section where the public notices reside. This is a completely integrity--a cryptographically verifiable process. We've taken trust out of the equation entirely.

So, from the standpoint of the anticounterfeit drug initiative, we are applicable to any bit stream. We work with bar coding, RFID, Track and Trace Technologies. Again, we prove the validity of the electronic pedigree over time from the manufacturing to the retailer. And we're a cryptographically and independently verifiable process.

We actually, firmly believe that a good process does not necessarily necessitate a good record. And we are part of the holistic solution. We're located at surety.com and we also have a booth outside.

Thank you very much.

[Applause.]

MR. RUDOLPH: We'd like to move to the next panel, if everyone could come forward for that. The speakers, in order would be Lou Kontinik, Jay Johnson, June Shelp, Patrick Schmidt, Guy Woods, Eric Turkewitz, Michelle Forzley, and Don Regan.

MR. KONTNIK: Thank you, my name is Lou Kontnik and I want to thank the FDA for having this meeting. I think it's very valuable.

I'm an independent here today. I'm not representing anybody in particular. I do have some experience in the area, having written the book with co-authors, "Counterfeiting Exposed." Published the manual of anticounterfeiting solutions for the biomedical industry, back a year ago. And was the facilitator of the product surety process, which was a project of the FDA. I am also a technical advisor to the safe medicines Website and there's a little flyer going around, I'll mention that in a moment.

First off, I want to say congratulations and thanks because I think the interim report is an excellent beginning. It's a serious and in-depth

examination of the issues and some of the problems.

Second point is that I think collaboration is of fundamental importance. Again, I congratulate FDA on bringing that forward as forcefully as it has. Having done the product surety project, which involved ten focus groups with the industry, we saw that that was collaboration in knowledge, communication was an essential piece. We're on the same side of the table here. It's a little bit different than most regulated activities of the FDA.

Moving, really, to the third part, I want to encourage the agency to do what you can do now. Do what you can do now and then do what you can do later when you can do it.

Keep your momentum in this process. To go ahead and delay, I think, would be unfortunate and in certain areas we know there are problems. Pedigree is one of those areas. So, with your wisdom and examination, recognizing that there are high-risk drugs and lower-risk drugs, I encourage you to take action there.

Also, inspections--I think that there is an opportunity to send a message to gain wisdom and knowledge by going ahead and having some FDA people

detailed to wholesaler and to repackager inspections with the states. It would build communication and it would sent the strong message to the manufacturers.

I guess, finally, I want to just mention the Website that I'm working as a technical advisor with. And it's www.safemedicines.org. And it is meant to be, really, a portal on the issue, not a notification system, as we've heard a number of the pharmaceutical or pharmacist associations mention.

With that, I want to say thank you. And I beat the light. [Applause.]

MR. ARMSTRONG: Good afternoon, I'm Jay Armstrong, principal with Life Sciences Group at IBM Global Business Consulting.

I'd like to take you through--I'm not going to waste a lot of time on this--a number of other speakers have already developed these ideas.

Successful anticounterfeiting technologies must have the following characteristics: cost-effective; adaptable; scalable. There's been a number of initial forays into these areas about bar coding, tamper-evident packaging. And we kind of see at IBM RFID being a cornerstone for a number of these other technologies but, also, in coordination

with these technologies to create a really secure drug supply line.

I won't belabor the point of RFID. We see solutions that from RFID, at the individual level, where individual units are tagged to the manufacturer. And we can begin to associate a code with each particular unit. We can show where it was produced, when it was produced, a lot number. We can also create shipping information and data. Along with that, very strong tracking capabilities. As a number of speakers have pointed out, tremendous data capabilities with RFID.

And, finally, at the end points, either in the pharmacy or with a physician or with the individual user, confirmation of authentic product.

Also at the bulk level, we are able to follow from the supplier--this is why, particularly with IBM--we're interested in the integration of the raw materials in the supply chain, as well, which some of the technology probably don't adequately address. You have the capability to actually begin with the raw materials and follow it all the way through the supply chain to the distribution centers, hospitals, or retail pharmacy. And can also track the number and time

of units dispensed at the final pharmacy location. And we can, through database integration, go back and see, even back to the point of raw materials what was incorporated. So we create a continuous assurance chain of information about how and where this was created.

This is something IBM, obviously, does extremely well. The IT linkages and product track-and-trace, using both secure local databases and central database repositories to allow instantaneously queries and redirected queries back to confirm that we have authentic products all the way through the process line.

IBM is now in the process of integrating a number of preliminary pilot studies, both in retail and at the pharmaceutical level, using something we're calling global goods. Tracker, it's a wireless RFID and bar code capable solution for tracking goods.

As I said, we do see the cornerstone of the solution being RFID but, also, with ancillary support from a number of other technologies, as well, so this is a seamless integration, in this case of bar coding and RFID.

I won't bore you with reading through

that, other than to say that it incorporates a strong network solution system that allows integration between ERP, SCM and warehouse management systems to occur in real-time, simultaneously.

Additionally, with RFID, as a number of other people have indicated, we see beyond just counterfeiting and anticounterfeiting capabilities. But things like reduced costs, improve product availability, drug accountability and, another area that we're starting to focus a lot on, intensely, is recall capability. And with RFID you have the ability to do almost instantaneous recall.

I will be around for any questions or you can contact the IBM Website, ibm.com for white papers on RFID and on the value chain.

Thank you very much.

[Applause.]

MS. SHELP: Thank you. I'm June Shelp with Sharon Car Associates. And thank you for the opportunity to speak. I'm sure it's been a very long day for everybody here.

SCA's experience goes back in the securities industries over two decades. And the last ten years we've really spent working with

brand owners, helping them protect their products and their customers.

My comments are really directed at three specific areas and are based on our experience, not just in pharmaceuticals, but in a wide range of industries across a lot of geographic areas.

SCA is probably best known for our work that we do in technologies. But in talking to you today, I think that in all the industries, regardless of where it was, good management of supply and distribution chain is, in our experience, the single most-important factor in product protection. While we believe in all the other technologies, that still is key.

We've seen the most positive results in product protection from brand owners that feel that they can trust the companies with which they do business and don't do business with those they cannot trust.

Brand owners have solved much of their own counterfeit and diversion problems with positive changes just in the way they have managed that supply chain and the way they do business. With that said, we certainly endorse your efforts to work to make sure that all of the stakeholders

within the supply chain are, in fact, a positive force in it and are actively involved in it. Every entity needs to be part of the solution. In our view, if you're not part of the solution then, by definition, they are part of the problem.

The guidelines for secure business practices that you put forward are very relevant, particularly Option 7 in your interim report where you suggest that limiting the supply chain for drugs at high risk is an interim measure. I would propose that, perhaps, you want to look at that not as an interim measure, but as a long-term measure; in the same way that, at the beginning of the day, today, the Bureau of Printing and Engraving tells you they do more with the high-value currencies than they do with the lower-value, the same thing applies here.

Education and public awareness. When it comes to public awareness of the dangers of counterfeiting, I urge the FDA to ally their education efforts with other industries. Counterfeiting is very often--and we've certainly heard that today, as well--an organized, multiline, criminal business of which drugs are only one of a counterfeiters profitable product lines.

The best defense for all of us U.S. consumers is to understand the interaction between the seemingly harmless counterfeits of fake T-shirts and sunglasses, and purses--and the potentially dangerous fake products, like pharmaceuticals.

When the United States is a very poor market for all types of counterfeits, then everyone is going to win. There are individual industry associations, I'm sure you're aware of some of them. There are, as well, multi-industry associations, such as the International Anticounterfeiting Coalition in Washington; the ACG in London, that already have experience in any anticounterfeiting consumer awareness campaigns. They would certainly benefit from some efforts from the FDA and some support for these types of products, which are easily for the consumer to see they're really dangerous.

And my last one is an issue of developing and maintaining data. The interim report addresses the need to update databases in several different contexts, including the ones for packaging and product tracking.

Missing in this report is the discussion

about a reliable database to evaluate the actual extent of the problem. And I think, throughout all industries when you talk about counterfeiting, there is no good information. It is mostly anecdotal and it is not very effective, in my personal view, in getting consumers to be able to move forward.

The U.S. government has always played a very significant role in actually providing accurate, reliable, ongoing information for all of us, both businesses and individuals to make our decisions. Be it consumer prices or unemployment. And this is an area for which there is very little information and one that really requires a government hand.

There is a current recent study out from the Economic Union in Europe, proposing some realistic and cost-effective measures of putting forward collecting accurate information across industries, including pharmaceuticals. And I would urge the FDA, in spite of the fact that I know funds are always limited and data being one of the last things that gets put on the agenda, to consider expanding the efforts that they've already made in coming out with things like the joint

report that you did with customs recently that really did detail exactly what was coming into our ports.

Thank you very much.

[Applause.]

MR. SCHMIDT: Good evening. I'm very grateful for the opportunity to be here and quite a bit more grateful that most of you are still here. So, thank you very much, appreciate it.

My name is Patrick M. Schmidt and I'm the president and CEO of FFF Enterprises. My company's the largest distributor of human serum albumin intravenous immune globulin and amophylic cardia factors in the United States. IVIG, you might recognize one of the products that you've encountered that has been counterfeited or tampered with.

But out company's best known for our long-term commitment to find a safe and responsible channel for the distribution of biopharmaceuticals. When FFF first entered the biopharmaceuticals marketplace in 1998, the distribution channel was rank with unstable pricing, ill-managed shortages, and unpredictable product allocation.

In response, we have vigorously pursued

our goal to find a responsible distribution channel to assure availability, safety, and cost containment and a secured pedigree for every vial of every drug that we distribute.

Though we've made great strides at promoting to find a responsible channel, there's, clearly, much more work to be done. Recent cases of pharmaceutical tampering and counterfeiting are compelling examples, obviously, why we're here today.

The proposed technological, regulatory, and legislative solutions we're learning about can provide important hurdles to counterfeiting, but such solutions are treating the symptoms of a larger more fundamental problem. And if I can convey one thing today here, during my time I hope I can convince some of you that the counterfeiting of drugs is a symptom of the source problem: that is an ill-defined, irresponsible distribution channel. We must address the fundamental problem because it is irresponsible distribution that opens the supply channel to illicit behavior, such as counterfeiting.

Irresponsible distribution is the result of two things: the gray marketplace and bad

intentions. There is, indeed, a great market for pharmaceuticals. As much as some might like to dismiss or diminish its impact and, frankly, calling it gray is generous.

You may be surprised, though, that the gray market is perpetuated by both bad guys and good guys. All of whom engage in purchasing practices that directly create opportunities for counterfeiting, tampering, drug diversion, and theft of drugs. When manufacturers must move inventory quickly and will sell to anyone who can pay.

When hospitals and physicians sell overstocked drugs back to the marketplace. When wholesalers and distributors see a chance to make a buck and redistribute products to each other. When these transactions occur, the effective drugs have entered the gray market place.

And when safe drugs are diverted into the gray marketplace for whatever reason, the result is inevitable: these drugs are no longer safe because in the shadowy landscape of the gray market, where lot numbers aren't tracked, prices are irrational and safety is not a consideration. These drugs are now vulnerable to mishandling, tampering,

counterfeiting and unfair pricing.

Most important, they are now putting patients--and I learned earlier today--pets lives at risks. And as we have seen in Florida and across the country, counterfeiters do not care about patient or pet risk. They are just waiting with open arms for those drugs to cross into the gray. Unfortunately, there's no anticounterfeiting measure that will eliminate their bad intentions. Criminals always seem to find a way to overcome the hurdles put in their way.

But there is a way to eliminate the gray market. If every entity along the distribution channel--manufacturers, wholesalers, distributors, hospitals, pharmacies, and physicians--if we all adhere to a safe and reasonable standard of distribution, there cannot be a gray market.

The standard is simple. It is a standard my company is helping to define and we've been practicing for over 15 years. We call it responsible distribution or channel integrity.

Drugs in the responsible distribution channel move only from the manufacturer to a sole distributor to a sole customer with no gray in-between. If manufacturers sell only to

distributors who honor this standard; if distributors buy only from manufacturers and not each other; if pharmacies buy only from the distributors who honor this standard, then channel integrity is guaranteed.

And when channel integrity is guaranteed, drug pedigree remains in tact and patient safety is secured.

Clearly, the battle against counterfeit drugs must be waged on multiple fronts, but the ultimate weapon is integrity. Distribution channel integrity and the solution is achieved by three low-tech, but high-concept steps: Manufacturers distributors and customers must embrace and honor this highest standard of channel integrity; they must formally be recognized for this commitment; and the FDA must endorse this standard.

When we take these steps, we will restrict the flow of drugs into the gray market and keep them out of the hands of counterfeiters. I thank you for your time and attention for a long day and staying here, thank you very much, we appreciate it.

[Applause.]

MR. WOODS: Good afternoon ladies and

gentlemen, thank you very much for inviting me to speak to you. I'm managing director of a British company. We have, for many years investigated serious and complex drug provenance issues, including cases involving counterfeits, market abuse, and fraud.

The threat of counterfeits begins, I'm afraid, not half-way through the supply chain, but actually at the very moment that pharmaceutical ingredients are released for sale. Unfortunately, it is not just packaging or the downstream problems, though, obviously the threat certainly increases the further along the value chain you go. Certainly the challenge is to separate out the good guys from the bad guys.

Counterfeit product networks are highly focused on market entry points and operate by breaking down and separating out executive control, funding, production, and assembly. Frequently networks will employ the use of long-supply chains, spanning many, many jurisdictions.

Drug counterfeiting involves creative accounting; having an ability to neutralize anything, including official paperwork and being able to cover tracks.

The networks thrive because market-driven economies encourage startup businesses and make setting up companies simple and instantaneous. Counterfeiters love hiding behind shell companies, nominee directorships, and accommodation addresses. They also thrive because of the regulatory inconsistencies that exist between jurisdictions and because counterfeiters know that there is usually poor cross-border cooperation between countries.

Networks also thrive because, especially, in the multichannel market, enforcement officers cannot be everywhere. And because counterfeiters rely on ignorance.

I have to ask the question, do governments expect those enforcing border prohibitions and restrictions to be pharmacology graduates? How else, can they immediately recognize that an 11B dihydrate 4alphapehan chloride 2 androsta acid [ph], which by the way is a fictitious compound, is a banned substance or, indeed, is really a fictitious material.

And how do they know that at the moment in time that they capture the product at the border, which products are subject to some form of

restricted medical prescription reserved for use in certain specified circumstances? I would suggest that it's a very, very difficult thing to do.

Ladies and gentlemen, in order to secure the drug supplies, it is vital for the FDA, to vet, test, and monitor any part of the value chain. I regret, regardless of geography, and also of corporate size.

I might also venture to suggest that an industry that some commentators claim to be rather defensive, perhaps, intraspective is possibly not the best place to carry out due diligence on itself. For the sake of transparency, therefore, I urge this role should be devolved to a third party organization tasked with collating, analyzing and verifying all incoming intelligence. This organization must be neutral and it also must not be financially dependent upon the industry in which it is monitoring, otherwise the risk of the tail wagging the dog and this very excellent FDA initiative being devalued may increase.

Thank you very much.

[Applause.]

MR. TURKEWITZ: Good afternoon, my name is Eric Turkewitz and I am counsel to Tim Fagan [ph].

Last year, he was injected for two months with counterfeit epegin [ph]. He has just had a liver transplant and he's 16 years old. At the time it happened, the family sought to find out where the drugs came from. The pharmacy pointed the finger at the distributor; the distributor pointed the finger at the manufacturer; and the manufacturer pointed the finger back at the distributor.

We have since learned that the drugs have come from this unregulated gray market. Nobody knows where the drugs originated; the conditions under which they were stored; who owned them; how old they are; they knew nothing about it.

The question of why it is that drugs would circulate in this gray market and be purchased by big-name distributors was answered by the Florida Grand Jury report and I'd like to read you a couple of short sections.

"The fact that these criminals act with such callous disregard for human suffering is immoral and despicable. But we find that others involved in the industry bear responsibility by turning a blind eye to this activity for the sake of profit. By doing so, they enable these counterfeiters and re-labelers to thrive.

Counterfeiters and re-labelers simply wouldn't be in business if they did not have a steady supply of willing buyers in the marketplace."

The Florida grand jury also talked about pedigree papers, which you've heard quite a bit about now. I want to read a short section from the same grand jury report about what they had to say and the effectiveness of pedigree papers and why it is that they don't work.

"The purpose of pedigree papers is to give buyers a tool with which to protect themselves from buying diverted or counterfeit pharmaceuticals. That is why pedigree papers have to be provided before the transaction. If pedigree papers don't work, it's because wholesalers have stubbornly refused to take advantage of this tool by not verifying their contents.

"This refusal has allowed phony pedigree papers to proliferate and has given counterfeiters easy access to introduce their products into the legitimate stream of commerce.

"It appears that no one in the industry cares enough to call and verify for fear of losing a purchasing opportunity. It's not surprising to us that no one checks the pedigree papers, because

they simply don't want to know the true background of what they're buying. This is nothing less than a blatant example of willful blindness.

"The problem is not only the counterfeiters and the criminals. The problem also exists from within the pharmaceutical industry from people who are leaving the door open for those counterfeiters to come through."

Now the solutions, one of which the Florida grand jury talked about was the pedigree papers. But the other is to limit that supply chain. The more people that touch the drug, the greater the opportunities for counterfeiting to occur.

This is not a technology solution. You've heard plenty about technology, some of which is ready and some of which is not. That has got nothing to do with technology. This has to do with the fact that our drugs should not be treated like a commodity. They should not be traded on open markets like gold or silver or pork belly futures. They're used for people with cancer and HIV or people with transplants and other life-threatening diseases and conditions.

The crimes exist because it's a crime of

opportunity. And just as if you had one house with five doors and windows and another house with five to 10 thousand doors and windows, you know which one is going to be more secure. Nobody can secure five to 10 thousand doors and windows. You've got to close down those doors and windows, you can't let them in.

If you let them in, there are people within the pharmaceutical industry who are going to take advantage of it, who are going to turn that blind eye.

We're asking you to restrict the number of times that drugs can be sold to cripple that gray market. Because if it exists, it will be exploited. Where there's money to be made, people will go after it. You know that whatever technology comes up, people will work right away to find a way around it.

On behalf of the Fagan family, I thank you. I know, it's late. They want their voice heard.

I thank you.

[Applause.]

MS. FORZLEY: Good afternoon, I'm Michelle Forzley, I'm a lawyer and a public health

professional. I'm associated with the Johns Hopkins School of Public Health and am the director of the Public Health law and Policy Clinic, here in the D.C. area. Thank you for the opportunity to address this important public health problem.

I'm here to tell you about a study I conducted this past year. It's the first systematic study done to quantify the problem of counterfeit goods from a public health perspective.

A comprehensive literature and database search revealed that: counterfeit goods are more than just an intellectual property problem. Indeed, death and morbidity are associated with counterfeit goods, particularly counterfeit alcohol, drugs, food, and personal care products. It's a global problem, as well. And some of the findings are summarized on the slide.

Counterfeit drugs are part of a larger problem of counterfeit goods. As well as they are part of the problem of substandard drugs.

My message today is to urge this task force to broaden the scope of it's inquiry beyond drugs and beyond the confines of the jurisdiction of the FDA. Let me continue my findings to demonstrate why you should take my advice.

There is no systematic, integrated, global detection and surveillance system, nor an early warning system. I think you know that, which would alert law enforcement, customs, consumers, healthcare industry, or brand owners that counterfeits have been detected. Thus, no concerted action can follow to protect anyone.

None of the essential functions of public health have been directed at the problem of counterfeit goods. And this being a public health agency, I think you know what they are. We would not know, for example, if there was an epidemic of injuries stemming from any kind of counterfeit good. And that is simply unacceptable.

The most important task at hand, therefore, in my view is to collect data. To do that, we must refine the international classification of diseases to code for counterfeits as a mechanism of injury and disease. And then, U.S. existing databases such as that of the National Center for Injury Prevention and control can be refined very easily to capture events related to contact with a counterfeit good of any kind.

Without appropriate data collection, no

early warning system can function nor can we develop and test appropriate interventions.

Numerous factors lead to an increased risk of exposure to counterfeit goods. Drugs are not qualitatively different in this respect. A Hadden Matrix analysis indicates that the four focus areas of this hearing are relevant, but are not all the possible areas. And while these may be the only ones within the jurisdiction of the FDA, they may well be insufficient to solve the problem.

Thus, my recommendations: First and foremost, let's stick to the basics. Conduct the basic functions of public health starting with data collection and require our public health agencies to collect data and conduct basic research. Collaborate with other agencies, as well, of the federal government and international organizations such as the WHO the ICC and others.

The goal of collaboration must be to share data, share information and develop a global alert system. As for laws, this is my last sentence: Promote the development of laws to support the public health infrastructure in the developing and less developed world.

About two-thirds world's countries have

inadequate or no drug regulatory authority. Clearly, this one aspect of the deficiencies in public health should be addressed.

And, last, it's time for a global frame work to address the problem of counterfeit drugs, if not for drugs, in general. The WHO may serve as the facilitator for such a frame work, but the process should involve all constituencies as indicated earlier.

Thank you and I look forward to your questions.

[Applause.]

MR. REGAN: Good evening, ladies and gentlemen. And you're at the end of a long process that started in May of 2003, as I understand and we're at the end of a day. And I gather you didn't measure the end of the day by saving the best for last because it's me.

My name is Don Regan, I'm the president of the Seniors for Fair Access to Pedigree Drugs. I have a little more specific suggestions, but some more general things. And fortunately, Captain McGinnis left because every time I see four stripes, the ensign in me causes my blood to quiver a little bit, so, I have to be--okay, then I've got

to be careful.

There's two key words in our association's title: One is fair and one is access. And there's two capacities in which I can speak.

The first is as a consumer for fair. And as a consumer, I'm attempting to be one of the educated, vigilant public to which you refer in Paragraph G of Section 2 of your good interim report. And this day has helped that in a long way.

Secondly, as a consumer, I eat broccoli and I work out and go surfing, I don't smoke, try to avoid drugs, don't have any insurance, but last night, before I hoped on a plane in California to come here. I had an infection, got a drug and from my observation as a consumer, the system really works well. I don't want to toss that good distribution out, in spite of some of the stories that here, we've just heard and have certainly touched our heart.

But I'm also in the second word, in access, I'm also an attorney, I guess you finished three for three at the end here. And I have had a lot of administrative experience before a body such as the Security and Exchange Commission, the SEC,

IRS, and state regulatory agencies, as well as the California Board of Pharmacy.

And there's an analogy to that that I'll get to, you'll see how it comes in. And what makes me thing, particularly in the nautical sense here of this situation of the drug industry that we're addressing is that if--there's an immutable law of the sea and it says if everything works, it's not a ship. And if there's four bolts that need tightening, only three are going to go down easily.

And you've got--this is such an amazing industry, my personal experience last night for what I've seen the other experience, the three bolts are there. We need to twist the fourth one down. And what's the fourth one? Well, I think we keep the distribution system essentially as it is in place. I realize this may seem a little far fetched, but Trader Joe's has helped another marketplace which isn't as serious as this, but it has worked in a very--in a less regulated situation.

What's our fourth bolt here? It's counterfeiting. It's not a simple problem you're right. The Pilgrims, well, I won't get to that, okay. But early last century, there was a

proliferation of unlawful financial products, flooded all over the country. What happened?

Well, maybe the depression, but in 1934, there was the--and '33--the Securities and Exchange Commission was adopted, the Securities and Exchange Act and all the states got regulatory commissions. For 50 years, the federal and the state blue-sky commissions worked together and, but not cohesively.

And it was only until the last 15 years that a system of really effective laws were put into place at both levels. It used to be you could go to New York and have to write a Ph.D. thesis to sell 10-cents' worth of stock and in Nevada, you could do it on a handshake. Now, resources of those administrative agencies are focused on chasing the bad guys rather than making the good guys go through hoops. And I think that's possible in this industry.

And the counterfeiting--it's that fourth bolt--what would I suggest from the outside of your industry, looking in? I think there's two key things: One is, you decrease the profit potential; and two, is you increase the risk. And by decreasing the profit potential, I would suggest,

as has been done by Messrs. Mayberry and Trealeaven and your Panel 3 that the focus should be not so much on the distribution system, but on unit-dose, tamper-proof packages. And that is a simpler solution and it would seem to cover a lot.

I would also, from my perspective, I'd toss the pedigree system, as was, I realize that flies in the face of the statute, but this is one person's opinion. I believe Carmen, if I pronounce his name correctly Catizone, on Panel 2 observed, that it's a lot easier to counterfeit a piece of invoice with a product list than it is to open a container, a tamper-proof package and start to adulterate.

So, I would add to that a layer of law at the federal and state level which had really serious criminal--I'm sorry, federal and state criminal code which would have really serious consequences for anybody that is involved in any part of any of the chain that leads to counterfeiting. And I think you use both of those.

And, finally, what you suggested earlier, is educate. I think the wholesaler should have a continuing education system; the public, we as the public have a continuing education system; of the

Seniors for Fair Access to Prescription Drugs stand ready to help you in educating the public. And I trust that on January of next year that you have proved that you have the force to accomplish the task that you have so well done.

Thank you very much for the opportunity.

[Applause.]

MR. TAYLOR: Okay, well that's the end of the seventh panel. However, I wanted to give the task force members an opportunity to ask any questions of the last group of speakers. So, Bill?

MR. McCONAGHA: At the risk of inciting a riot, I will prolong with a quick question. Again, Bill McConagha with FDA's Office of Chief Counsel, I direct this question to Mr. Schmidt and Mr. Turkewitz in turn. Mr. Schmidt, I just want to make sure I understand, your testimony. You both spoke about the gray market and your view that that was one of the problems in this phenomena. Am I correct in understanding it's your view that we should not allow a distributor-to-distributor exchange, in other words, wholesale distributors, ought not to be able to sell back and forth to one another?

MR. SCHMIDT: That is a practice that our

company's adopted over 15 years ago. And that would be our recommendation. That eliminates the gray market. That eliminates the profit that potentially exists there.

MR. McCONAGHA: Mr. Turkewitz, do you have a view to that?

MR. TURKEWITZ: Well, I think that anytime you expand the number of people that are going to touch the drug, you're opening the door a little bit more and a little bit more. And whether you come up with a system that just goes manufacturer/distributor/pharmacy or add in the possibility of a second authorized distributor, you know, that's something for you to decide. But, obviously, the narrower you get, the more secure it's going to be. If you open the door up for those drugs to fly outside the system, for the authorized distributors to stop buying drugs from unauthorized sources, the ball game's over, I mean, the doors are wide open, the locks are gone. And that's going to be a problem.

It has to be--it seems clear to me, and I--this is coming from the perspective of an outsider that the system certainly has to be restricted. I mean you can't have five to 10 thousand wholesalers

floating around the country swapping drugs back and forth and buying them and picking them up from diverted sources. And then selling them back into the distribution system.

So the FDA's going to have to come up with some way to tighten up dramatically, not just a little bit of fine tuning, but very dramatic way of doing it. And that comes from my perspective of somebody that represents somebody who was actually injected with it. To this day would fear that the next piece of medication--the next bit of medication he's going to get is going to be counterfeit. He's going to be on drugs the rest of his life, if he's a transplant patient. And every day, he's taken in. Every week, he's still getting injections. And every time he gets them, he lives in fear that this is going to happen again.

And, certainly from his perspective, I think it's important. And it's not just Tim Fagan, you remember, you heard earlier about the example of the procrit. An the State of Florida has estimated that that one instance of counterfeiting, but that was injected into 25,000 people.

And so you're talking about 10s of thousands, if not 100s of thousands of people who

are likely getting the counterfeit drugs.

And the problem that you're faced with, I think is far more widespread than anybody has appreciated. In large part because you're dealing with something that's almost a perfect crime. The actual evidence is injected or swallowed, the packaging is thrown away. So the evidence is gone.

And then when the patient doesn't get better. The doctor and the patient presume it's because they're sick. As far as I know, there's only maybe two or three lawsuits out there against various entities in the pharmaceutical business regarding counterfeit drugs.

If there were 25,000 people just from one instance of counterfeiting, that being the Procrit. And I think you're dealing with now, about 20 instances a year? You're dealing with a vast number of people and a huge problem that's lying below the surface that people don't know about and people undoubtedly staying sick and dying from it and no knowing.

And I think it's really important for the FDA to take action and shut down--shut down that system, even though it's flying below the radar for a great portion of America.

MR. SCHMIDT: I'd like to reverse the question and ask your understanding of why those distributor-to-distributor sales exist? Why do they exist from your understanding?

MR. McCONAGHA: I'll respond to that with another question.

MR. SCHMIDT: It proves you're a lawyer.

MR. McCONAGHA: The follow-up question I was going to ask and I think this may be responsive is: Based on your voluntary practice and you said you basically have been dealing directly with pharmacies--

MR. SCHMIDT: Exclusively.

MR. McCONAGHA: Exclusively, for the last 15 years.

MR. SCHMIDT: With manufacturers.

MR. McCONAGHA: With manufacturers--do you find that you are able to fill the needs to service all of the pharmacies and consumers that want the drugs that in some cases, at least, traditionally, had been served by secondary wholesalers?

MR. SCHMIDT: No, we do not, but we do not succumb to the temptation. Where we're living right now an example. Right now there's a shortage of flue vaccine in the U.S., it's been quite a

surprise to a lot of people. Our company distributes 10 percent of the flu vaccine in the United States.

We cannot get enough to meet the demand, but we can buy it from secondary channels. And we refuse to do that. And the only reason that it's a distributor to distributor sales exists is an economic reason. Because if I can buy it from the manufacturer--and we get offers--if I can buy it from the manufacturer for less than I--if I can buy it from the distributor, excuse me for less than I can from the manufacturer--you have to think that that's something wrong. Something untoward has happened, either drug diversion or counterfeiting. It's the buying practices that I think maintain the motivation with counterfeiting than do criminal acts. And we just avoided that temptation. Continue to avoid that temptation.

MR. McCONAGHA: Thank you.

MR. TAYLOR: Any other questions, Paul?

MR. RUDOLPH: I had two questions for Mr. Schmidt and one for Ms. Shelp. Mr. Schmidt, I just, a quick question. I'm not clear do you represent a manufacturer or a distributor?

MR. SCHMIDT: I represent a distributor.

MR. RUDOLPH: In terms of the good business practices that you mentioned--I might have asked this of the orthobiotech panelist earlier today, how are those actually enforced by a manufacturer or a distributor? The notion that you shouldn't buy from anyone other than a manufacturer, how would a manufacturer enforce that and how would a distributor go about?

MR. SCHMIDT: Well, unfortunately the manufacturers do not endorse that, because we make a commitment to our manufacturer we'll only buy it from them and we'll only resell to an end-user or healthcare provider. We do not redistribute to other distributors. Frankly, it never made sense to us because it seems like you respond to a competitor, but from a competitor standpoint it never made sense to us. We only buy from the manufacturer and we only sell to other distributors. Now if you buy from a distributor, it obviates, I think the responsibility that a manufacturer to due diligence on the distributor. I mean, these are prescription pharmaceuticals, they're expensive to make, and sometimes almost everybody that handles them--an that just never made sense to us. So we talk about a real defined

distribution channel, we make a commitment from our customers, when they get something from our company they don't have to worry about where it came from. If there's counterfeiting involved, the manufacturer did it. Because that's where we got it from.

MR. RUDOLPH: The second was just sort of a follow-up, are these written policies that you have or, because maybe if you'd be kind enough to share any written policies you have about your business practices with us with the docket. As you know, we received a document on HDMA on good business practices and I think it would be interesting for us to be able to review what your business practices are, especially in the context of what they're planning to do. Thank you.

And for Ms. Shelp, two questions, for you. One is, I was wondering if, I don't know if your presentation was part of our record, because I couldn't find it, but I missed the names of the organizations, it might be helpful if you know the names of organizations that we can partner with in terms of general counterfeiting, in terms of consumer education, that might be helpful to submit to us so we have a good idea of all those.

MS. SHELP: Yes I submitted one, and I will submit a little bit longer piece that for he docket that details some of those organizations.

MR. RUDOLPH: And the only other question I wanted to ask you is you also talked about companies trusting each other and the importance of business practices. Could you elaborate on that, I don't know if you were thinking along the same lines as Mr. Schmidt or do you have more, does your company have a more detailed document about that?

MS. SHELP: Well, I don't have any detailed document about it, it's just that we, as a company have worked with brand owners across a wide range of industries. And when you go in and they tell you they want to deal with their problem and the first thing you need to do is talk to them about what the problem is and do they really want to deal with it. There's very little you can actually do regardless of how wonderful it all is, if, indeed, you're going to give them some sort of security thing and they're going to put it into a plan where there's nobody takes care of any of this stuff, you know, and the guy can walk out the back door with half of whatever the security element was.

I think apropos of what you said before, the more global we get, the more difficult it is for us to go back to our roots where you do business with people you know. And, rather than having to look at the list that tells you what the rating is at the bank, better you know the bank. And especially in an area like this where it's so crucial to you.

I know that we have companies that have talked to us about helping them and it may be something like handbags or that type of product, and they have a problem with being diverted product. Well, they sell their product, they actually sell their product into a department store, at the end they are not going to take the product back. They refuse to take any of the extra product back, the department store finds another thing for it. Well, you know, it's not very surprising that it shows up in Costco or it shows up in some flea market area where they didn't expect it to be.

The easiest way to solve that problem, obviously, is change the way you do business. And we've seen companies who've done that and, literally, gotten rid of most of the problem right

there. And we've seen others who put a blind eye to it and go forward, in large part because they're making more money doing it this way than they are the other and it's the lip service.

And, I guess, when you get down to your, the industries that you're regulating and dealing with, none of us can afford for that to happen.

MS. BERNSTEIN: I just have a quick thing. When you submit your longer testimony, could you submit a copy of the EU study that you mentioned about the cost of counterfeits?

MS. SHELP: Yes, in fact it was one that I thought was really very interesting because what they had done, it was from the Center for Economic Research that comes out of the UK. And they did one for the Economic Union, going through talking about how do you get a handle on the size of the problem. And each industry was very different. And one of the things that they determined is that the pharmaceutical industry was probably the most difficult of them all, because you can't the fact and I heard that question asked today to your commissioner. Do you know how big the problem is? And one of the answers is, well, we've had more seizures. And the answer is, well, if you've got

ore seizures, what does that really tell you about the problem? It doesn't. And what they proposed in this was, in my mind, very logical and it was a sampling technique where you go out and you sample among all of those distribution channels that are out there, the drugs, bring them in, get them analyzed and then you're able to really come back and to say to people what the real story is.

I guess in my personal view, when I saw the report that you had done recently with customs on it, you know. That was one where there was some hard evidence that actually said what came in from here was this much counterfeit. And that on an ongoing basis is a much better--it's a much better measure for all of us to be able to put our faith in.

I guess, you know, for us we have always had such faith in the way the U.S. government can come around and tell you what the unemployment rate is, what consumer prices are, all of those kinds of things. And this entire business is just it's anecdotal information. Which is not, in my mind, very persuasive to people because it tends to be very emotional based, as opposed to factual based.

And in our view we find it very difficult

to get manufacturers and brand owners themselves to actually take action because they're looking to say how big is the problem. And they only know how big the problem is when they've done something about it. Then they've discovered that maybe, you know, it was twice as big as they thought it was. They had no way of knowing how bad the problem is.

MR. TAYLOR: Thank you. Any other questions?

Well, it's been a long day. I want to thank all of you for coming and I also want to remind you that, indeed, the docket is open until November 3.

A lot of you, in addition your shorter presentations cited to longer presentations, and longer studies that you deemed are helpful or have read and thought have--and based on your review thought they would be helpful for this debate, if so, I mean we welcome seeing all these documents and we think that they will play a crucial role in the deliberations to come.

We still are committed to getting out a final report in January. As I also said earlier, we hope that the transcript of the meeting will be available within a week after the meeting. So,

please look at our Website and continue to participate, we really appreciate it.

[Whereupon, at 6:10 p.m., the proceedings were concluded.]

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CERTIFICATE

I, **SONIA GONZALEZ,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

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