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``SECURING OUR NATION'S PRESCRIPTION DRUG SUPPLY CHAIN''

THURSDAY, APRIL 25, 2013

House of Representatives,

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

The Subcommittee met, pursuant to call, at 10:01 a.m., in Room 2322 of the Rayburn House Office Building, Hon. Joe Pitts [Chairman of the Subcommittee] presiding.

Members present: Representatives Pitts, Whitfield, Shimkus, Murphy, Blackburn, Gingrey, Lance, Cassidy, Guthrie, Griffith, Ellmers, Upton (ex officio), Pallone, Dingell, Capps, Schakowsky, Matheson, Green, Butterfield, Barrow,

Christensen, Castor, Sarbanes and Waxman (ex officio).

Staff present: Clay Alspach, Chief Counsel, Health; Paul Edattel, Professional Staff Member, Health; Sydne Harwick, Legislative Clerk; Robert Horne, Professional Staff Member, Health; Carly McWilliams, Professional Staff Member, Health; Andrew Powaleny, Deputy Press Secretary; Chris Sarley, Policy Coordinator, Environment and Economy; Heidi Stirrup, Health Policy Coordinator; Tom Wilbur, Digital Media Advisor; Jean Woodrow, Director, Information Technology; Alli Corr, Democratic Policy Analyst; Eric Flamm, Democratic FDA Detailee; Elizabeth Letter, Democratic Assistant Press Secretary; Karen Nelson, Democratic Deputy Committee Staff Director for Health; and Rachel Sher, Democrat Senior Counsel.

Mr. {Pitts.} Ten o'clock having arrived, the subcommittee will come to order.

The chair will recognize himself for an opening statement. There is an echo.

Members of this subcommittee have been interested in securing our Nation's pharmaceutical supply chain for many years. While some supply chain provisions were included in Title VII of last year's FDA user fee bill, the Food and Drug Administration Safety and Innovation Act, FDASIA, a comprehensive track-and-trace package has yet to be finished.

Today's hearing will focus on the importance of securing the downstream pharmaceutical supply chain, which includes manufacturers, wholesale distributors, pharmacies, repackagers and third-party logistics providers.

In order to ensure that counterfeit or stolen drugs do not enter the supply chain and harm patients, States have passed laws that require, or will require, those involved in the downstream supply chain to keep pedigrees or transaction histories of drugs. Some believe that these differing State requirements should be--

Mr. {Shimkus.} Mr. Chairman, if you would yield for a minute, I just want to let you know, they are trying to fix this, so they are working on it.

Mr. {Pitts.} Thank you. Some believe that these differing State requirements should be replaced with a reasonable, practical and feasible federal policy.

On Monday, Representative Latta and Representative Matheson released a discussion draft to enhance the security of the pharmaceutical distribution supply chain and prevent duplicative or conflicting federal and State requirements.

I would like to thank all of our witnesses for being here today. I look forward to hearing their thoughts on the draft.

[The prepared statement of Mr. Pitts follows:]

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Mr. {Pitts.} At this time I would like to request unanimous consent for Congressman Latta to participate in this subcommittee hearing. Without objection, so ordered.

I now yield the remainder of my time to Representative Latta.

Mr. {Latta.} Well, thank you very much, Mr. Chairman. I appreciate you having this legislative hearing today on this important issue of securing our Nation's pharmaceutical supply chain. I also appreciate the subcommittee for allowing me to participate in the hearing today.

This is an important issue that was brought to my attention when I was first elected to Congress over 5-1/2 years ago by concerned stakeholders in Ohio, and I have been working on it ever since. I am pleased the subcommittee is holding a hearing on the issue, and I am honored to be leading the effort in a bipartisan effort in this Congress.

The pharmaceutical supply chain touches every part of our health care system. It is imperative that we get the structure and the segments of it connected in a safe, secure and effective manner that provides the best protection for

patients. This draft legislation Mr. Matheson and I have released on Monday is a commonsense, practical approach to making improvements to the current supply chain while facilitating continued collaboration among all parties before taking the next steps toward the additional requirements.

To protect patient safety, this bill would replace the patchwork of multiple State laws and create a uniform national standard for securing the pharmaceutical distribution supply chain, therefore, preventing duplicative State and federal requirements. It would increase security of the supply chain by establishing tracing requirements for manufacturers, wholesale distributors, pharmacies and repackagers based on--Mr. Chairman, should I just continue on without the mike?

Mr. {Pitts.} Go ahead.

Mr. {Latta.} Thank you. It would increase security of the supply chain by establishing tracing requirements for manufacturers, wholesale distributors, pharmacies and repackagers based on changes in ownership. The bill also establishes a collaborative, transparent process between the Food and Drug Administration and stakeholders to study ways

to further secure the pharmaceutical supply chain.

The timeline put forth in this bill is reasonable and would allow enough time for stakeholders to comply with these new national standards and ensure that through feedback from these stakeholders that the next phase of the process is done efficiently and effectively.

There has been significant work done on this issue over the years, and I appreciate all the feedback and suggestions I have received on this bill draft. While this bill is still in draft form, Mr. Matheson and I intend to introduce it in bill form in the coming weeks, and we fully understand that California law relating to implementation of an e-pedigree system is quickly approaching. It is imperative that we move this bill swiftly through the committee and then to the House Floor.

I look forward to working with our Senate colleagues on this legislation along with the FDA and all the other interested stakeholders, and I urge the support of this draft legislation soon to be in bill form.

Thank you, Mr. Chairman, and I yield back.

[The prepared statement of Mr. Latta follows:]

128 ********** COMMITTEE INSERT **********

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Mr. {Pitts.} The chair thanks the gentleman and now recognizes the ranking member, Mr. Pallone, 5 minutes for an opening statement.

Mr. {Pallone.} Thank you, Chairman Pitts. I am pleased that we are having this hearing today because drug distribution security is critical to public health and safety. The public deserves the piece of mind that the prescriptions they pick up contain quality ingredients and were handled throughout the supply chain by licensed companies adhering to strong safety standards so that the final products they receive are safe and effective drugs.

U.S. companies providing drugs to other international markets have already begun to serialize their products to comply with these countries' track-and-trace requirements, and the American people should be afforded the same protections.

Last summer, we had meaningful bipartisan bicameral conversations about this topic. While we were ultimately unable to reach an agreement, the discussions with our Senate counterparts and a number of stakeholders certainly

demonstrated our commitment to the issue. As we revisit drug distribution security, there is a lot at stake, and that is why I am disappointed that we were not given the opportunity to work with our Republican colleagues on the draft bill that was released earlier this week. I am also concerned that this draft seems to me to not reflect where our discussions left off last year. Mr. Chairman, as we move forward, I urge the subcommittee to make sure we get this proposal right and that we work together to get there.

Now, some States such as California have already begun to address drug distribution security to ensure the safety of their patients. It is crucial that if we are going to preempt these State efforts, that we must have a strong federal standard. This standard should serve as a true building block to track drugs at the unit level so that each and every product is authenticated at the lowest unit of sale before they reach patients and counterfeit or contaminated products are eliminated. We cannot rely on Congress to revisit this issue in 10 years. The time to establish this path forward and set up phase-in requirements is now.

It is also important that everyone who is part of the

system including the manufacturers, the repackers, the wholesale distributors, third-party logistics providers and dispensers play a role in tracing the safety of the Nation's drug supply.

In addition, I believe that in order to establish the most effective drug security system, it is critical that we include strong national license standards for distributors and third-party logistics providers so that only reliable companies are handling the Nation's drug supply, and FDA has immediate access to needed company information in the event of a drug recall or other public health threat.

I want to thank our witnesses here today including the FDA for all your hard work throughout this process. Many of you contributed to the discussions last year in a productive way to educate us on the supply chain process, and I look forward to better understanding what you believe is critically important to any bill that moves forward, and I want to extend a special welcome to Mr. Michael Rose, who is here testifying from Johnson and Johnson, which is headquartered in my district. I look forward to J&J and all the stakeholders as well as my committee colleagues to

achieve a reasonable solution that will safeguard the public health.

I would like to yield the remaining 2 minutes of my time, Mr. Chairman, to our chairman emeritus, the gentleman from Michigan, Mr. Dingell.

[The prepared statement of Mr. Pallone follows:]

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Mr. {Dingell.} Mr. Chairman, I thank you for these hearings. I commend you and also my dear friend, Mr. Pallone. I want to commend Mr. Latta and Mr. Matheson for their leadership on this, which has been a long thorn in the side of this committee, being very, very difficult to achieve our purposes.

I would observe that we have before us an opportunity where the two parties are working together, where the House and Senate are working together, and I am delighted to see that that is happening because there is no real Democratic or Republican way of protecting the American public.

We have to work with all the stakeholders, and I have to observe that the pharmaceutical industry and the stakeholders have been most helpful in the matters as they have gone forward, and I want to thank again Mr. Latta and Mr. Matheson for their work on these matters. I am hopeful that we will be able to move forward toward legislation that will be accepted and acceptable to all parties, and I note that the industry has been working closely with us as has the Senate. It is my hope that we will understand that 10 years on some

things within this matter might be a bit long, and I think that while we do need to see to it that Food and Drug has clear instructions from the Congress, we don't want to get to the point where we are micromanaging things and having meetings set up by Food and Drug which may or may not be of value to the country and to the industry and the consumers.

Having said those things, I would return 22 seconds to my dear friend from New Jersey, who has been so gracious as to yield to me.

[The prepared statement of Mr. Dingell follows:]

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Mr. {Pitts.} The chair thanks the gentleman and now recognize the chairman of the full committee, Mr. Upton, for 5 minutes for opening statement.

The {Chairman.} Well, thank you, Mr. Chairman, and hopefully the mike will work long enough before our helium bill gets to the Floor.

I appreciate today's hearing, and that is for sure, on securing the prescription drug supply chain. Keeping our prescription drugs safe is certainly a bipartisan issue, and we have got the world's safest drug supply, but that doesn't mean we can't make it even better.

I would like to thank the discussion draft's authors for their bipartisan leadership on this very important issue. Earlier this week, as has been noted, a comprehensive discussion draft was released that would increase the security of the supply chain for America's patients while at the same time preventing duplicative federal and State requirements. The draft also sets forth a collaborative process so the Food and Drug Administration and supply chain stakeholders could work together in an effort to better

understand how and when to move to unit-level traceability.

We spent a significant amount of time working on this issue as we successfully moved the Food and Drug Administration Safety and Innovation Act through the legislative process in 2012 and our efforts continued beyond enactment. During that process, we also sought input from stakeholders like Pfizer and Perrigo, two important companies in my district in Michigan, as well as our small pharmacies. The hard work allowed us to better understand the issue, and the bipartisan discussion draft reflects that understanding. Now it is time to move this legislation down the field and across the goal line. We have a lot of good friends in the Senate that agree with us on that sentiment, and this is certainly a priority for this committee to get done, and I look forward to embarking on that, and I yield to Dr. Gingrey and then to Ed Whitfield.

[The prepared statement of Mr. Upton follows:]

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Dr. {Gingrey.} I thank the gentleman for yielding.

Mr. Chairman, I am pleased that there has been generally bipartisan acknowledgement that a secure pharmaceutical supply chain is not only necessary for patient safety but becoming obtainable and tracking technology continues to improve, and I would hope that the legislation that is ultimately the result of this hearing today will balance both the reality of today's emerging technologies with the flexibility to change as the result of innovation. It is also necessary that we provide a clear and a concise list of expectations and directives to all companies up and down the supply chain. Steady industry progress toward increased drug security should not be impeded by a lack of clarity from Congress as to the ultimate goal of this legislation for both the sake of innovation and security and for the patients who may be adversely impacted from counterfeit or stolen drugs.

Thank you, and I yield the balance of my time to the gentleman from Kentucky, Mr. Whitfield.

[The prepared statement of Dr. Gingrey follows:]

286 ********** COMMITTEE INSERT **********

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Mr. {Whitfield.} Well, Dr. Gingrey, thanks so much, and thank you all for having this hearing today, and we certainly appreciate the witnesses being here.

Last week, I attended a forum over at Georgetown University with the title of ``Combating the Threat of Counterfeit Pharmaceuticals'', and I really was taken aback by the amount of money being made by organized crime and other groups and entering into the supply chain counterfeit prescription drugs.

Another point that came out, and I am delighted that Mr. Latta and Mr. Matheson have introduced legislation at the federal level because we know individual States are moving forth, California, I guess out in the front right now, and I think we need to set a federal standard in this issue because I heard a lot of concerns about individual States moving in this area, which can create real problems for the manufacturers, but we want to do it safely, and I really look forward to the testimony of the witnesses today.

I would also ask unanimous consent to simply submit into the record a statement from a company called Laser Lock

Technologies, if that is acceptable. They are an anti-counterfeiting company.

Mr. {Pitts.} Without objection, so ordered.

[The information follows:]

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Mr. {Whitfield.} And with that, I would yield back.

[The prepared statement of Mr. Whitfield follows:]

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The {Chairman.} I just want to end by saying that this is a priority. We intend to start the markup process next month, May, and our goal will be to try and get a bipartisan bill to the President before the August recess. So we are going to work very hard and we appreciate all those that are here to help us achieve that goal.

Thank you. I yield back.

Mr. {Pitts.} The chair thanks the gentleman and now recognizes the ranking member of the full committee, Mr. Waxman, 5 minutes for an opening statement.

Mr. {Waxman.} Thank you, Mr. Chairman.

Today's hearing will examine ways to improve the integrity of our drug supply chain. The entry of falsified and substandard drugs into our drug supply chain poses a grave public health threat. Time and again, we have read stories about patients getting drugs that were unsafe or ineffective counterfeits or that were stolen and not stored properly, so no longer worked. Without action, this is a problem that is likely to grow.

Today, there is a regulatory void at the federal level

because the United States does not have laws requiring the tracking and tracing of pharmaceuticals. So some States have stepped in and enacted their own laws. My State, California, has a law that would mandate one of the most robust pedigree systems in the country. Many have suggested there is a need for a single federal system that would preempt these State laws. I believe having a system at the federal level makes sense, if done correctly. But I have grave concerns about preempting a strong State law like California's and replacing with one that is not as effective at the federal level.

Our fundamental goal in establishing a federal system should be to prevent Americans from being harmed by counterfeit and substandard medicines. If we cannot assure the public that legislation would accomplish that goal, then it is not worth doing.

Throughout last year, members on a bipartisan, bicameral basis engaged in extensive discussions about how best to protect our supply chain. I was part of this group, as was Chairman Upton and Representatives Pallone, Dingell, Matheson and Bilbray. We heard loud and clear from FDA, Pew and others that if we want a secure drug supply chain, we need an

electronic, interoperable unit-level tracking system that can identify illegitimate product in real time so that it does not end up in the patients' hands. We also heard that creating this kind of system is doable. In fact, it is already being done in China, as we will hear today from one of our witnesses.

Last fall, the bipartisan, bicameral group issued a proposal that although far from being complete, reflected agreement about the need for assuring that we ultimately get to a unit-level electronic system. And just last week, the Senate distributed a draft bill built upon that proposal and made a concerted effort to address issues that were raised on both sides of the aisle throughout last year's discussions.

Unfortunately, the House discussion draft under consideration here today doesn't take that approach. The bill does not require an electronic, interoperable unit-level system. Instead, it provides that in ten years, FDA and GAO would make recommendations to Congress about what legislation should be enacted to better secure the supply chain. And even though we never get to a unit-level electronic system, the House bill would preempt State law on day one. That is

unacceptable to me as a California member, but it should be unacceptable to all members. We know how long it has taken Congress to act thus far. The discussion draft preempts strong State laws and puts a weak federal program in its place. That is a step backwards for public health. There simply is no reason to wait to put enforceable standards in place. We have been told repeatedly, and I am confident we will hear today, that in order to secure our drug supply chain, we need to track products at the unit level using an interoperable, electronic system. We fail to protect the Nation's public health if we do not take this step. I yield back the balance of my time.

[The prepared statement of Mr. Waxman follows:]

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Mr. {Pitts.} The chair thanks the gentleman. That concludes the opening statements of the members.

We have two panels before us today. On our first panel, we have Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. Welcome. Thank you for coming today. You will have 5 minutes to summary your testimony. Your written testimony will be placed in the record. You are recognized now for 5 minutes.

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^STATEMENT OF DR. JANET WOODCOCK, DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION

} Dr. {Woodcock.} Thank you, and good morning Mr. Chairman, Ranking Member, members of the subcommittee and authors of the discussion draft.

We are all seeking the best way to protect patients from medicines that aren't what they pretend to be. That is why we are here. Or that may cause harm to them without providing the help that they expect from their medicine, and that is the goal we want to achieve mutually. So I thank you for continuing to work on this program. We hope to do this by strengthening the safety net that we currently have in place for medicines so that counterfeit drugs can't get in the drug supply because right now there are some loopholes where they can enter the drug supply, and they are. Diverted or stolen drugs can't reenter the drug supply after being perhaps taken by criminals and stored in unsafe conditions, and suspect products that happen to get in can be rapidly identified and removed from the drug supply before they get

to patients. And additionally, we need to be able to find drugs wherever they are in the supply chain. If dangerous products have been dispensed to patients, we want to be able to find them and get them out of the hands before the patients are harmed.

And why do we need this? Well, as people have already said, the problems with counterfeits are well documented and actually growing. Around the world, criminal networks are counterfeiting drugs at a growing rate and many countries, their patients in their countries are exposed to very dangerous drugs and even some of the organisms, the resistance problems that we are seeing with drug resistance, are partly driven by these counterfeits because people are taking drugs that actually are subpotent that are counterfeit drugs. And we are seeing this in the United States where often expensive, lifesaving medicines are targeted. I can't imagine what it is like for a person battling cancer to hear that they have been receiving a fake therapy or their cancer or for a diabetic to lose blood sugar control because their insulin came from a stolen batch that was improperly stored, and these things actually have happened in our country.

And there are other equally compelling reasons to strengthen drug track and trace that we haven't really discussed as much, and that is to enable recalls of FDA-approved drugs. This is really a non-trivial problem. Over the last 5 years, there have been over 6,500 drug recalls in this country. Over 400 of these have been class I recalls, and a class I recall is where our doctors at FDA have determined that there is an immediate risk to health if people would take these drugs, serious risk. And we need to be able to find these recall drugs, as I said, and get them out of the hands of patients rapidly. For example, this has happened, there could be a label mix-up and what is labeled as an innocuous drug, perhaps a pain reliever or something, could actually have a dangerous drug such as a blood thinner or cancer chemotherapy drug in that vial, and so if that type of thing happens, we need to be able to rapidly identify the patient who may have these drugs and get them right down to the patient level.

So right now, we have a great deal of difficulty finding which patients got these drugs, particularly at the lot level. What we may end up doing is recalling the entire

drug, and sometimes these drugs are lifesaving drugs that we don't want to remove completely from the patients; we only want to get the tainted lots. So this is a large and growing problem, and good track and trace would help the entire health care system, people taking care of these patients to secure these products as soon as possible and avoid further harm.

And finally, I think and most importantly, I want to say, whatever is put in place by Congress should not fray or weaken the existing safety net. A recent investigation conducted by your colleagues' Ranking Member Cummings of the House Oversight and Government Reform Committee and Chairman Rockefeller and Chairman Harkin in the Senate identified a gray market of business that was capitalizing on the way drugs can move through the system to buy up drugs and resell them, perhaps at 1,000 times markup that were in shortage, and desperate hospitals, saying caring for children with cancer had no choice to buy these drugs at this markup because they had to treat their patients. So the existence of that paper pedigree, as noted in the report, enabled them to track back each transaction and figure out the markup and

document what actually happened with these shortage drugs. So this paper pedigree right now is a mainstay of us figuring out where those drugs have been, not always followed but that is the law that they should have that pedigree and we mustn't weaken that, so I really ask you that any system that you put in place not diminish our ability to figure out where these drugs have been. It was astonishing if you read the Cummings report the Murphy trail these drugs followed and their successive markup as they went through multiple hands, none of whom, arguably, had a real interest in getting these drugs to patients. They were simply marked up at each step.

So we really ask that we not lose the ability to figure out where drugs have been. That is critical, and we recognized that changes will not happen overnight and a stepwise process is needed, but it should be expeditious. There are technologies available in various industries that can track things. I order a lot of things online so many of you do too and they are tracked throughout the system.

So we have to make sure we strike the appropriate balance between the need to establish a secure system that protects the public health and the costs and feasibility of

such a system and we need to make sure we put something in place, I think, that evolves over time to a common goal that we all have is a system that prevents criminals from taking advantage of our patients, prevents people from diverting drugs and marking them up, prevents us not being able to identify recall drugs and actually people being harmed while we are doing investigations and trying to figure out where these drugs ended up.

Mr. {Pitts.} Could you please conclude?

Dr. {Woodcock.} I am sorry. So our ultimate goal, as yours, is to protect the public from counterfeit, stolen, diverted or unfit medications and make sure that we establish a meaningful and enforceable track-and-trace system. Thank you.

[The prepared statement of Dr. Woodcock follows:]

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Mr. {Pitts.} The chair thanks the gentlelady and we will now have questioning, and I will recognize myself for 5 minutes for that purpose.

Dr. Woodcock, if the FDA has a particular concern that a drug could cause an immediate threat to individuals and the sponsor refuses to take action, what would the agency do? Do you believe that the agency's persuasive authority is strong enough that sponsors will take correction action? Does today's regulatory regime seem adequate given the increase in quantity and sophistication of counterfeiting?

Dr. {Woodcock.} Well, we have authorities to--seizure authorities and other authorities that require judicial actions to do. We also, though, usually will go public with our concerns rapidly and start notifying the health care system. It is uncommon but does happen that firms argue with us over recalling drugs or removing them. It is uncommon but can occur.

Mr. {Pitts.} Will national uniformity increase the security of the supply chain and improve patient safety? Please explain.

Dr. {Woodcock.} An effective system will help secure the supply chain from the incursions that we have seen that probably are a growing threat over the years by criminals, so that will protect patients and probably prevent harm that we have seen.

Mr. {Pitts.} Is it important to preserve the States' ability to license and enforce national standards?

Dr. {Woodcock.} Obviously, national standards are useful because of the uniformity because most drugs move across State lines. So I think it is important that both the federal government and the States have the ability to enforce appropriate laws.

Mr. {Pitts.} Will product serialization increase the security of the supply chain and improve patient safety, and please explain with your answer.

Dr. {Woodcock.} All right. So companies make batches or lots of drugs, okay, and those are large amounts of a same drug. It might be a thousand, it might be a million units would be made. Those are packaged into crates or whatever and sent to distributors, who then send them around the country. At some point those are broken up and then sent to

pharmacies and, you know, all around to hospitals and so forth. At that point that's when incursions by counterfeiters can come in if they simply use the same lot number. The criminals are becoming very sophisticated so they can get a few vials of that lot, they can copy the label and put something that is totally fake into the system. So a serialization procedure coupled with some verification at the various levels of distribution would enable us to rapidly identify incursions like that of fake parts of the lot and remove them quickly, and I believe that's why the manufacturers, the pharmaceutical manufacturers, as I think you will hear later today, are moving towards serialization.

Mr. {Pitts.} Will data exchange and systems between participants in the supply chain increase the security of our drug supply and improve patient safety? And explain with that.

Dr. {Woodcock.} Well, you know, I think it is necessary. It gets to what we were talking about earlier about the pedigree. If we don't know the chain of custody of the product, and if we have to reconstruct that later when--say some defective product, dangerous product is found out

there in the hands of a consumer, or worse, they have a side effect which happens, we have to deal with that, and we get a report of serious side effects, then we want to know where did it come from, how many are out there, is it real drug and so forth. And so unless we have that pedigree and we know what hands it moved through, and if we have to reconstruct that later by querying people, that will cause great delays. So if you intend to replace the paper pedigree system, it needs to be replaced by something that has capacity to do that tracking back. So we can rapidly identify other people at risk if we get, say, adverse events or report of a substandard drug, we can rapidly identify where that came from and how it happened.

Right now, we have instances where we get adverse-events report, people die, and we get a large number of reports like this every year for various reasons but some of them might be related to substandard drugs, and we have a very difficult time tracking that back from the patient to the pharmacy and figuring out what the patient actually got. So we would really ask that that pedigree, that whatever is established is at least equivalent in performance to the pedigree we have

now.

Mr. {Pitts.} So finally, would a national track-and-trace standard increase the efficacy of product recalls?

Dr. {Woodcock.} Absolutely. That would be a tremendous tool for us.

Mr. {Pitts.} Thank you. The chair now recognizes the ranking member of the subcommittee, Mr. Pallone, 5 minutes for questions.

Mr. {Pallone.} Dr. Woodcock, your written testimony lays out a disturbing series of cases illustrating the risk to our drug supply chain posed by counterfeit and stolen or diverted products, and it is not a new problem. We tried to address all the way back in 1987 with the Prescription Drug Marketing Act but for a variety of reasons that didn't work. You described the fact that we need a robust track-and-trace system. I know there are a variety of ways this could potentially, be done and the summary of the House discussion draft indicates that it would require lot-level tracing. Other proposals set up a system that would track at a more granular level at the packaging or unit level. You talked about this with questions from the chairman. Can you

describe the differences? I mean, I know you basically have described the differences between the two types of systems but tell me the benefits to a unit-level tracking system that cannot be achieved by the lot level.

Dr. {Woodcock.} Right. Well, to reiterate because I think this is sometimes unclear, all right, having a unit-level tracking means that fake units couldn't be put in, and often there are thousands of them that would be made by a counterfeiter right down to the lot number and inserted into the supply chain somewhere and then distributed to patients. By having that verification down at the unit level, we would know that those were extra, those were illegitimate and they could be rapidly identified and removed. And also it would help us, I think, in determining what patients got, what lot they got.

Mr. {Pallone.} I mean, it sounds like the lot level would certainly be better nothing but that the gold standard is the unit level, but it seems to me in order to have an effective unit-level system, it simply has to be an electronic one in which information is exchanged quickly and is available in real time. And I don't think it makes sense

over the long term. We would not move beyond a relatively primitive system in which this information is maintained and passed with pieces of paper going back and forth.

So I recognize that creating an electronic system is no small feat, a lot of technology, time, I am sure, investment. But I think we need to ensure that we allow time for an electronic interoperable system be set up. So let me ask you this: do you agree that an electronic interoperable system is ultimately the goal so as long as we allow for enough time to get that kind of a system set up?

Dr. {Woodcock.} I agree, because that would provide the greatest protection for our patients.

Mr. {Pallone.} Now, my concern is that the House discussion draft does not even set up the goal of an electronic interoperable unit-level system. It merely requires that the FDA and GAO report back to Congress in 10 years on ways to enhance the safety and security of the pharmaceutical distribution supply chain. If we all agree that our goal should be an electronic interoperable unit-level system, we need to spell that out. We need to require that it be the end game and set a date certain when it must

be implemented. Congress can play an important role in driving the technology, and as I said, we need to allow for sufficient time for it to develop and we don't want to set it up with unrealistic expectations, but I think we do need to set requirements or it will never happen. So again, Dr. Woodcock, do you agree that it would be important for Congress to require that this system ultimately be set up?

Dr. {Woodcock.} The goal is ultimately to protect patients and make sure the drug distribution system as drugs are distributed through the system is not porous at different points and has holes or gaps where counterfeits or other things can be inserted. So to reach that goal, ultimately you want to have an electronic system that can identify down to the unit level. However, there obviously are logistic and timing issues, but I think we all mutually share that goal of patient protection.

Mr. {Pallone.} But I am just trying to get you to say--I mean, don't you think we should require this at some point, that Congress should require it at some point?

Dr. {Woodcock.} Articulating that goal would certainly probably speed achievement of the desired end, which is to

have a system that is capable of preventing these incursions.

Mr. {Pallone.} I appreciate that. I mean, look, you know me. I have been around here for a while, and I just can't say there is a phase I and hope for the best. If Congress wants a phase II, I think they should say. Otherwise we are not going to get phase II because inertia unfortunately often characterizes this place unless you spell something out. So I really hope we can work together with our colleagues to improve upon the bill. I think we all share the same goal. We need to better safeguard our Nation's drug supply but we need to make sure whatever legislation we enact actually achieves that goal, it doesn't just give people the hope that someday we will achieve it. That is my concern, Mr. Chairman.

Mr. {Pitts.} The gentleman's time is expired. The chair thanks the gentleman and now recognizes the gentleman from Louisiana, Dr. Cassidy, 5 minutes for questions.

Dr. {Cassidy.} Listen, you explained as well as anybody as I have heard it the need for serialization today so I am going to ask some things to explore, not to challenge. As I gather, California has pushed for a more rapid

implementation, but as I gather, they have had to delay this, correct? They have had to delay the implementation of their law. Is that true?

Dr. {Woodcock.} I am not familiar with what California has done. I am sorry.

Dr. {Cassidy.} I have learned to say what I have been told, not what I know, but that is what I have been told, which suggests to me that even in a market as large as that that there could be problems with rapid implementation of this serialization.

Dr. {Woodcock.} Well, I think some of your other witnesses may be more familiar with the pragmatic aspects of this.

Dr. {Cassidy.} Yes, I think really what is a key here is not the goal which we should go to serialization, it sounds, but the question is, how do you track supply chain, how do you have in one sense an in-the-cloud inventory where someone is not gaming it to figure out that they need to suddenly purchase because it is about to go in shortage. Fair statement?

Dr. {Woodcock.} There is one issue. That is right.

Dr. {Cassidy.} And as I gather, those issues have not been entirely worked out?

Dr. {Woodcock.} No.

Dr. {Cassidy.} And so putting a date certain that has to be done in a year presumes that they will be worked out within a year but that is clearly not--that is imagining, that is not necessarily knowing that that will occur.

Dr. {Woodcock.} Right. Well, clearly there should be a stepwise approach, but whatever is built now should enable the attainment of the ultimate goal, and there should probably be, as Mr. Pallone was saying, some kind of time frames put so that everyone's mind is focused on the ultimate goal.

Dr. {Cassidy.} I accept that. There is nothing like a deadline to sharpen a man's mind. I totally get that. On the other hand, I think we have seen with some things like the exchanges in the Affordable Care Act just putting a date certain doesn't mean that it is going to smoothly happen, and so knowing everyone is impatient to protect patients from criminals, we still have to recognize there are issues to resolve.

Dr. {Woodcock.} Yes.

Dr. {Cassidy.} Let me change gears a little bit and talk about drug shortages. You have written a paper. I have had to look over it, the state of the art about the economic factors involved with that, and it seems--no offense--you give a little bit of a short shrift to the role of price competition. Knowing that you know this paper like the back of your hand, in figure two you have a little bubble saying price competition as a factor. But it makes sense to me that if you have declining margins and a 6-month lag so ASP plus six, the provider can only be reimbursed which was the price 6 months ago if it has hit this low point, you can try and raise the price, but if the provider is only getting paid the lower price from 6 months, she cannot afford to pay for the higher price. Fair statement?

Dr. {Woodcock.} Yes, but I am sure you appreciate, I can't really comment on federal--

Dr. {Cassidy.} I understand that, but you can observe that, as your paper does, that lower margins may decrease the ability of a company to invest in manufacturing redundancy, quality, etc. Is that a fair statement?

Dr. {Woodcock.} That is a fair statement, and we feel that there is only competition on price because quality is non-transparent to the buyers.

Dr. {Cassidy.} Now, theoretically, though, FDA is going to ensure that there is adequate quality to ensure safety, correct?

Dr. {Woodcock.} That is our job.

Dr. {Cassidy.} Yes, it is your job, and so if I am the purchaser, really, as long as I know that it at least meets my minimum standard, why not.

Dr. {Woodcock.} Yes, except--and this is what we try to raise in the paper--there is another aspect to quality, which is reliability, which any of you purchase a car or electronic or anything realize is true, and some of that is reliability of supply.

Dr. {Cassidy.} But if you have concentration of manufacturers, you are down to five, six or seven, really, it is not as if you can go someplace else.

Now, let me ask you just in the interest of making this--I understand the numbers of shortages are now down.

Dr. {Woodcock.} Yes, a 50 percent decrease.

Dr. {Cassidy.} Are these shortages down because we have actually addressed these issues of lack of redundancy or because we are allowing more foreign product to be introduced?

Dr. {Woodcock.} Primarily because of actions we have taken. We thank the Congress for your leadership in dealing with shortages in the Safety and Innovation Act that was passed last year. We have intervened. We have earlier notification.

Dr. {Cassidy.} I got 26 seconds. And so is it from more product coming overseas or is it the ability to work out things domestically?

Dr. {Woodcock.} I don't think the domestic supply has improved.

Dr. {Cassidy.} So it is actually more product coming from overseas?

Dr. {Woodcock.} Yes.

Dr. {Cassidy.} Let me toss out one thought. I just spoke to a man who has got extensive contacts with foreign pharmacies. He suggests that you put an RSS feed on your website. He says that my guys elsewhere have to constantly

monitor what is in shortage. They really can't do that. If there is an RSS feed, look, boom, propathol is going on shortage, and it would feed out to them, then they would be able to come to you and solicit. So can our office follow up with you regarding that?

Dr. {Woodcock.} I would be happy to do so.

Dr. {Cassidy.} It just seems like a great idea.

Dr. {Woodcock.} Yes, good suggestion.

Dr. {Cassidy.} Okay. I yield back. Thank you.

Dr. {Woodcock.} Thank you.

Mr. {Pitts.} The chair thanks the gentleman and now recognizes the ranking member emeritus, Mr. Dingell, 5 minutes for questions.

Mr. {Dingell.} Mr. Chairman, I thank you for your courtesy.

Dr. Woodcock, you know that there is a lot to be done here so I will ask that you respond with a yes or no to my questions. Do you agree that a traceability system would help to better secure our drug supply chain from counterfeits, theft and intentional adulteration? Yes or no.

Dr. {Woodcock.} Yes.

Mr. {Dingell.} Do you agree that a traceability system would help identify and detect illegitimate pharmaceuticals? Yes or no.

Dr. {Woodcock.} Yes.

Mr. {Dingell.} Do agree that a traceability system would help to ensure the safety of pharmaceuticals for patients and consumers?

Dr. {Woodcock.} Yes.

Mr. {Dingell.} Do you agree that a traceability system would improve the efficiency and effectiveness of recalls or returns?

Dr. {Woodcock.} Absolutely.

Mr. {Dingell.} It also must be fair, must it not? Yes or no.

Dr. {Woodcock.} Yes.

Mr. {Dingell.} And we have to see to it that it is of course workable?

Dr. {Woodcock.} Right.

Mr. {Dingell.} And not impose undue burdens on anybody if we could possibly avoid it? Yes or no.

Dr. {Woodcock.} Yes.

Mr. {Dingell.} Do you agree that a federal traceability system should include participation from everyone in the supply chain?

Dr. {Woodcock.} Yes.

Mr. {Dingell.} Do you agree that a federal traceability system should take a phased-in approach, meaning the first phase would implement lot-level tracing and the second phase would implement unit-level tracing? Yes or no.

Dr. {Woodcock.} Yes.

Mr. {Dingell.} And there are reasons for differences in the different parts of the system for manufacturing and delivering the commodities to the ultimate consumer. Is that right?

Dr. {Woodcock.} That is correct.

Mr. {Dingell.} And those make it necessary that we should consider not only the differences but to phase in because of the different levels of difficulty that Food and Drug will confront, right?

Dr. {Woodcock.} Yes.

Mr. {Dingell.} Now, do you agree that a federal traceability system with a phased-in approach should include

clear requirements and a clear time frame for a second phase? Yes or no.

Dr. {Woodcock.} Yes.

Mr. {Dingell.} Do you agree that the goal of any federal traceability system should be unit-level tracking? Yes or no.

Dr. {Woodcock.} Yes, an ultimate goal.

Mr. {Dingell.} Ultimate goal but very, very difficult to achieve?

Dr. {Woodcock.} It should be the goal.

Mr. {Dingell.} Well, and it will also cause a lot of difficulty to get everybody together on this.

Dr. {Woodcock.} Absolutely, because there are tradeoffs here.

Mr. {Dingell.} Do you agree that traceability legislation should avoid placing undue burdens on FDA so that the FDA can focus on proper and efficient implementation of this particular program and all of the others which we have been loading Food and Drug down with lately?

Dr. {Woodcock.} Yes.

Mr. {Dingell.} And with which we have not been giving

you enough money? You may not want to comment on that, but that is my feeling.

Dr. {Woodcock.} It is difficult. We try our best.

Mr. {Dingell.} I know you do, and it is an enormously difficult task. Do you believe that the traceability legislation should ensure adequate systems are in place to trace prescription drugs before current pedigree requirements are eliminated? Yes or no.

Dr. {Woodcock.} Absolutely.

Mr. {Dingell.} Now, this traceability system and the phase related to it must also focus very carefully upon imports. Is that right?

Dr. {Woodcock.} Yes.

Mr. {Dingell.} Particularly imports that are components of pharmaceuticals ala the situation which we had with heparin but other examples of this, and of course, as a matter of fact, also with regard to food and other things that you have to contend with. Is that right?

Dr. {Woodcock.} Yes. Well, I think the components of drugs is different, and the supply chain issue is different than the distribution chain but equally important to keep

substandard ingredients out.

Mr. {Dingell.} And I am not here to sell foods at this particular time but we have to look at that and other things too.

Now, Doctor, do you agree that traceability legislation should provide FDA with adequate enforcement authority to ensure stakeholders comply with the intent of Congress? Yes or no.

Dr. {Woodcock.} Yes. Can I say, we don't want to be a paper tiger on this?

Mr. {Dingell.} I sure don't want that. It is also fair to observe that Food and Drug has been working very carefully with Members of Congress, House and Senate, Democrats and Republicans, but also that you have been working with the industry to try and see that we get something with which everyone can work and to do so comfortably. Is that right?

Dr. {Woodcock.} That is correct.

Mr. {Dingell.} And of course, that would be the goal of Food and Drug, as it would be of everybody, I think, in this room.

Mr. Chairman, I return 19 minutes. Thank you.

Mr. {Pitts.} Seconds. Thank you.

Mr. {Dingell.} Nineteen seconds.

Mr. {Pitts.} The chair now recognizes the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions.

Mr. {Shimkus.} Thank you, Mr. Chairman.

Dr. Woodcock, welcome. Glad to have you back.

Dr. {Woodcock.} Thank you.

Mr. {Shimkus.} I am going to do a kind of intro and then go to my specific question on a specific item.

We have seen many instances in recent years of how technology can help us modernize and create efficiencies in communications, and I am referring to stuff that we moved, actually signed by the President in my other subcommittee, which is a hazardous-waste issue, and we were able to through legislation kind of relieve the burden of paper copies throughout the supply chain all the way to the fact when the President signed the law, and we know in the old days carbon copies, triplicate papers, they are stored throughout the entire chain, that can be costly. We also have recently seen where the EPA has on their own with some prodding from us now is able to notify water users--the water plants can notify

the users of the water on changes based upon email notifications versus mailing paper copies of changes and the like.

So that leads me to this whole debate that Ranking Member Pallone is also very interested in, the e-labeling requirements reflected. There are some reflected in this discussion draft with more standardized electronic approach that will increase, we believe, patient safety and provide significant quality improvements and cost reductions to patients and industry. This is something that, as I mentioned, that we have been following, and Ranking Member Pallone has also been leading on this. Do you support this e-labeling policy?

Dr. {Woodcock.} I have long supported this. We have worked with the National Library of Medicine. We have something called Daily Med, and Daily Med has, I think, 24-hour update so at the National Library of Medicine you can get any drug label, the actual on-time, real-time label with any safety updates within a day of FDA changing that label. So that should enable easy electronic access from almost anywhere.

Mr. {Shimkus.} So with respect to this proposed legislation and what the bipartisan members are trying to work out, there is obviously some language that deals with this. I guess we would be concerned as to where are you at as an agency in issuing guidance and moving forward on your own?

Dr. {Woodcock.} My understanding is, this requires rulemaking. The fact is that we are planning to issue a rule is on our agenda, and we plan to issue a rule this year, we would hope, a proposed rule.

Mr. {Shimkus.} So I guess from the cosponsor of the legislation and the committee and ranking member would have to look and see the time, your time frame as rulemaking sometimes takes a long time and a decision made of whether we want to add that in legislative language, but you are really supportive of the overall process and principles, it seems like.

Dr. {Woodcock.} For drugs, all the pieces of this are in place so there is a labeling repository. We do all our reviews electronic at the agency at CDER and so everything is in place to enable electronic access from anywhere to the

real-time drug label.

Mr. {Shimkus.} And the real-time drug labeling is the key because things can change pretty rapidly, and you can get it electronically versus something stuffed in a box that gets transmitted forward. So I appreciate your response and I appreciate you being here, and Mr. Chairman, I yield back my time.

Mr. {Pitts.} The chair thanks the gentleman and now recognizes the gentleman from Texas, Mr. Green, 5 minutes for questions.

Mr. {Green.} Thank you, Mr. Chairman. Track-and-trace is an important issue, and I ant to thank my colleague and neighbor, Representative Matheson, for his leadership on our side on this issue. Finding bipartisan agreement on any issue is difficult, and on more complex issues, such as supply chain for pharmaceuticals, remains even more elusive. However, I do have some concerns about the Latta-Matheson. Most importantly, the bill never really gets us to an interoperable electronic unit-level system. In fact, it prohibits FDA from moving ahead with interoperable electronic system in absence of new legislation, which we won't on until

10 years after the enactment. I understand the concerns that market participants have problems moving too fast toward such a system. We should be sensitive to this and make sure the law we pass is workable. But we have an opportunity to move the ball further down the field, and it my understanding that quite a bit of necessary technology already exists. Pharmaceutical companies, large and small, have stated they can work on a shorter timetable. We can do more to ensure the safety and security of our drug supply, and I think we should. But instead of moving toward requiring an enhanced system, the bill only requires the FDA to conduct one or more pilot projects and conduct public hearings and report back to Congress on the result within 10 years. I am concerned that these pilot projects do not seem to be designed to test the electronic interoperable unit-level system that everyone seems to agree we need.

My question is, if the goal is to get to an electronic interoperable unit-level system, which I thought was based on last fall's draft with indeed a shared goal, wouldn't it make sense for the legislation to explicitly direct the FDA to conduct the pilot program, testing out whether such a system

could be established, and instead of just mentioning in vague language about better securing the supply chain. Would you like more definitive black-letter law and guidance instead of come back to us every 6 months and in 10 months from now we might get to this?

Dr. {Woodcock.} As I said earlier, I think within the standards world where people are being asked to conform to a standard over time and they have to change processes, they have to make investments to do that, clarity is critical and predictability so that people know what is going to happen and they can plan for it and plan their investments, plan their programs. So I think to the extent that there is a shared goal that Congress can provide clarity on where we are going as a country and where we plan to end up, that would be beneficial to all the stakeholders, even those who feel right now that this is a tremendous burden to provide clarity of a path would be extremely helpful.

Mr. {Green.} And we authorize legislation and sometimes Congress doesn't reauthorize, we just kick the can down the road, and telecom is a great issue. The 1996 Telecom Act, I think it was outdated when we passed it but it is well

outdated now. So my worry is that we won't continue to oversee it.

My next question is my concern about, it requires the FDA to conduct a public hearing every 6 months until FDA submits a report to Congress, which could be up to 10 years from enactment. Transparency is important. I agree that open and public hearings of these issues with interested stakeholders makes sense, but twice a year for 10 years seems like it is a little much. Can you talk about all that is involved in setting up a public meeting? Do you have any sense how much these meetings may cost over the 10 years twice a year for 10 years?

Dr. {Woodcock.} These meetings often cost, you know, maybe up to $20,000, depending on how they are structured, but I think the opportunity cost is the cost we are really talking about here. Don't forget, we are trying to work with patient groups, and they are extremely excited about having meetings about their disease and how we can better study it, and under PDUFA that you all passed, we agreed to have 20 of these meetings over the next 5 years. Now, we would like to have more. We have heard from so many patient groups that

they aren't maybe on the list and they are really concerned about their disease. So it is really important. We also have pediatrics and how we develop drugs in children. We have many other pressing issues that have immediate impact on patients that we need to have various public meetings on. So there is a tremendous opportunity cost there if we are having--if we meet on a certain subject excessively.

Mr. {Green.} I only have about 30 seconds left, and I would like to match our chairman emeritus in giving time back. I think the bill is a good step, but I don't think it goes far enough and it fails to give us an interoperable electronic unit-level system before 10 years, and frankly, I think industry may be ready much earlier than that, and we don't want to tie our hands where we can't do it.

So Mr. Chairman, I appreciate the hearing today and hopefully we will provide some more flexibility. Thank you, and I yield back my time.

Mr. {Pitts.} The chair thanks the gentleman and now recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. {Griffith.} Thank you, Mr. Chairman.

Dr. Woodcock, I appreciate you being here today, and I have heard a number of folks say this is not an issue where there is one side or the other, and that is true. I do have some concerns.

I represent a very rural district, and we have a lot of community pharmacists tucked in various nooks and crannies of my community. That being said, people are used to going to those pharmacies. They like those pharmacies. And I am just wondering as we go forward, you know, these folks have a lot of competing issues that they are facing already from other issues. As we go forward in looking at this, while we all want to make sure our supply chain is safe, can you describe what efforts the FDA has taken into account to accommodate and incorporate the small community pharmacies and make sure that they are not overly burdened by any system that we put into place?

Dr. {Woodcock.} Well, we talked to all stakeholders about this. As I said earlier, developing standards and implementing that in a stepwise way is probably the best approach to not impacting small entities excessively so they know what is coming and they can plan for it over time, and

if Congress were to establish that plan, then vendors will come in and develop solutions over time and they can be adopted somewhat earlier by a larger chain, say, and would be affordable for smaller groups.

So I think we need to--if Congress decides to put forth a plan, I think that would be very helpful in having everyone understand where we are going and then getting the power of commerce and entrepreneurialism and invention to develop the technologies that will make this or actually craft these technologies to this situation in a way that will make it affordable.

Mr. {Griffith.} Well, I have to say that makes sense to me. If you give people time to respond and to figure things out and there is enough time to come up with new ways of doing things, I do believe that vendors will come forward. Of course, the key is, as I have heard from some folks, they want to do things faster, and we have to find that sweet spot, which is why we have draft language to talk about as opposed to an actual bill at this point. But I do appreciate the sponsors who brought it forward for us to at least have something to work on, and I appreciate you being here today.

You also mentioned in your testimony a track-and-trace public workshop held in February of 2011. Can you just speak generally about feedback you received, and keeping in mind my community pharmacies that are a big concern? It is not that I don't care about the big chains but they are in a much better position to adapt quickly to the changes that may be coming.

Dr. {Woodcock.} We understand the concerns of the community pharmacists, and there testimony today that I read that was submitted and last year also, so we understand and certainly we have talked to that community and heard at our public meeting about these concerns--logistical concerns, time concerns, the fact that they feel stressed already between various demands on them. There is other competition. But it is really important in these rural communities to have a pharmacy there. So we understand all that, and I guess what I am saying is that putting in the goal and predictability over a time frame I think would be very helpful for everyone because they get their mind around what is going to happen in the future.

Mr. {Griffith.} Yes, ma'am. I appreciate that. It

makes sense to me as well.

Mr. Chairman, with that, unless somebody wants my time, I will yield back.

Mr. {Pitts.} The chair thanks the gentleman and now recognizes the gentlelady from Virgin Islands, Dr. Christensen, for 5 minutes for questions.

Dr. {Christensen.} Thank you, Mr. Chairman, and I look forward to this discussion because I have a specific issue that I wanted to discuss, and of course, the issue of altered, counterfeit, substandard or tampered-with medicines entering the drug supply is a real concern and it is a very important issue for FDA and this subcommittee to address, but I want to raise a consequence that may or may not be intended but it is not warranted, and I hope that the proposed legislation can help or that there is something that FDA can do about it.

In the efforts to keep substandard drugs out of the U.S. marketplace, re-importation from a foreign jurisdiction is prohibited. The U.S. Virgin Islands, as the name indicates, is a part of the United States. Our pharmacists are U.S. trained. They have U.S. licenses. Our pharmacies are

regulated by U.S. law, and our pharmacies including our hospitals only order medication from U.S. distributors. As a provision of the treaty that was signed when the United States bought the Virgin Islands, we are outside of the U.S. custom zone so for shipping only we are international. Again, we are totally domestic except for shipping, and because of that, our pharmacies have been unable to ship back their medication that might have been oversupplied, spoiled, expired. They are unable to ship it back to their supplier, and it incurs costs and those costs are passed on to the patients. So we have met on this in the past in the past Administration. I have legislation to try to address it. But we are willing to work on anything that can be worked on and maybe, you know, we want to work with our colleagues on the committee but maybe there is something that FDA would be able to do.

So if this national track-and-trace system in place, would that be a way to help us fix that, do you think?

Dr. {Woodcock.} Probably, but I can't opine on the legal aspects because it would require analysis. You raised this issue with me last year, and we agreed that your staff

would talk to our folks, and I had thought this had been resolved or improved. So I would also urge you to talk to FDA staff again and raise this issue. We can follow up with you. But I do believe obviously things can be put into legislation that would remedy a situation like this as well.

Dr. {Christensen.} But you would not oppose it, would it, if we were--

Dr. {Woodcock.} No, I think--

Dr. {Christensen.} --only shipping back to the distributor?

Dr. {Woodcock.} Well, a track-and-trace system would actually enable this because we would know what the drugs were.

Dr. {Christensen.} And I thought it was resolved also. They were shipping by FedEx and it wasn't being checked but now it is back to square one. So thank you very much, and I don't have any further questions, Mr. Chairman.

Mr. {Pitts.} The chair thanks the gentlelady and now recognizes the gentlelady from North Carolina, Ms. Ellmers, 5 minutes for questions.

Mrs. {Ellmers.} Thank you, Mr. Chairman, and thank you,

Dr. Woodcock, for being here today.

I have a couple of questions on the basically moving towards the electronic access for, you know, data for patients, which now of course are the package inserts that accompany medication. You know, I do believe that the real-time access is very, very important but I am concerned about our seniors and their ability to have that information right there for them. You know, I have heard from many seniors who--you know, as a nurse, I know how important it is for them to have that information. So what exactly is the push there? I mean, I understand the technology, the ability to access it online is very important, but there again, many of our seniors are not Internet savvy, and I am concerned that maybe we are moving a little quickly with this. So what are your thoughts on that?

Dr. {Woodcock.} Well, what we are talking about is package inserts and, you know, many physicians have trouble with the package insert.

Mrs. {Ellmers.} Well, it is a lot of information.

Dr. {Woodcock.} Yes, so we are also working an initiative we call Patient Medication Information, all right,

and we have been working on that for some time, and we are about the only country in the world that doesn't give patients a leaflet about their drug in patient language. So we are moving to do that, and it would be a combination of electronic and paper, depending on what the individual desired.

Mrs. {Ellmers.} Okay.

Dr. {Woodcock.} Yes. And it would be one page probably with access to more if people wanted more information or instructions on how to get more information.

Mrs. {Ellmers.} So that wouldn't automatically come with the medication is what you are saying?

Dr. {Woodcock.} It would.

Mrs. {Ellmers.} It would automatically come?

Dr. {Woodcock.} Yes.

Mrs. {Ellmers.} Because I am thinking a combination approach is definitely the way--

Dr. {Woodcock.} For consumers.

Mrs. {Ellmers.} --that we should go, and, you know, certainly, again, the package inserts do come with more than enough information obviously for different reasons. So you

do favor more of a combination approach?

Dr. {Woodcock.} For the patient.

Mrs. {Ellmers.} For the patient?

Dr. {Woodcock.} That is right. We feel that people who prescribe drugs or dispense them, all of them are going to have electronic access.

Mrs. {Ellmers.} Right, and availability. So the electronic access is more for the physicians?

Dr. {Woodcock.} Technical.

Mrs. {Ellmers.} Okay. Thank you for clarifying that for me because that was definitely an area I was very concerned about.

Now, I do want to talk a little bit about--oh, I only have a few moments. But the track-and-trace as far as, how do you basically figure out which things would be tracked and traced based on drugs and based on other things like saline or additives, you know, things that mix drugs? I mean, will that also be included in track-and-trace?

Dr. {Woodcock.} They are drugs, so obviously whatever is included is up to Congress, but we would feel that anything that goes into a drug should be. So we regulate

saline bags and so forth as pharmaceuticals now. They have their own code, they have lot numbers and so forth, and often we have to recall those.

Mrs. {Ellmers.} Okay. So you are looking at anything that is considered a drug?

Dr. {Woodcock.} Yes.

Mrs. {Ellmers.} Thank you very much.

Mr. {Pitts.} The Chair thanks the gentlelady and now recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes for questions.

Mr. {Waxman.} Thank you, Mr. Chairman.

Dr. Woodcock, as you know, California has a law that once completely implemented will require that all transfers of ownership of prescription drugs from the manufacturer through to the final pharmacy dispenser be accompanied by a so-called pedigree that maintains a record of each successive transfer and tracks information about the drug product at the unit or package level. Under the law, these pedigrees must be transferred electronically and the entire system will have to be interoperable so that all the information on any prescription drug will be readable and updatable by all

members of the drug distribution chain. This law is quite comprehensive and ambitious and has been the subject of criticism by some industry members as being too ambitious, either in its scope or its time frame for implementation.

But I was glad to hear on your answers to Mr. Pallone's questions that you agree that an electronic interoperable unit-level system should be the goal here. I agree that we need to allow enough time for the technology to evolve and for the system to be put in place. We don't want to set unrealistic expectations. But I think California had it right when they insisted upon this kind of system, and I think this system is ultimately the right one for the country.

As Mr. Pallone mentioned, the Latta-Matheson draft doesn't even set this up as a goal even at some distant point in the future creating an electronic interoperable unit system. In fact, they prohibit FDA from moving forward with this kind of system ever. I think that is the wrong policy. The Latta-Matheson bill also doesn't require any kind of tracing of drugs until 5 years after enactment at the earliest. But perhaps even more concerning to me is that on

day one, as soon as this bill would be passed, it would preempt State law even though they never created an effective alternative at the federal level. On day one, all State laws on the subject are wiped out, and to be clear, this is not just California's law. According to the Health Care Distribution Management Association, at least 11 States have laws requiring distributor licensing and pedigree requirements. Some States like Florida have a requirement that a pedigree be passed with most drug transactions, and you mentioned this in your testimony, but last year Representative Cummings and Senator Rockefeller issued a report detailing their investigations of the gray market in drug trade in the United States and some of the dangers it poses, and they discussed the importance of pedigrees for law enforcement in these cases. But the very law requiring these pedigrees would be erased under the House's bill on day one.

Again, you mentioned this in your testimony but I would like to hear more. Can you tell us whether you think preempting these State laws on day one makes sense when we never get to the system you say we need? Please explain in more detail what would be the consequence of wiping out

currently existing pedigree requirements? I am deeply concerned about preempting not only California's law but the other States that clearly provide a benefit today, and I agree that if we can't get to a strong federal system, it might make sense to preempt State laws but the Latta-Matheson draft certainly does not create a system worthy of broad preemption on day one. Would you elaborate on this?

Dr. {Woodcock.} I think it is really important that whatever is enacted does not lower the safety of the drug supply, doesn't decrease or put bigger holes in the safety net. That is really important. So the pedigree requirements now, as I said--

Mr. {Waxman.} Just for clarification, safety net--

Dr. {Woodcock.} Of tracking.

Mr. {Waxman.} We are not talking about poor people. That is usually what--

Dr. {Woodcock.} Oh, I see. Okay. Maybe I used the wrong term. But the safety around drugs, of the drug supply, okay? Eliminating the paper pedigree until we have something else in place would be creating greater loopholes for insertion of counterfeit drugs and substandard drugs into the

distribution chain because we wouldn't be able to track them backwards, all right? And putting a law in place that eliminated States' ability to require that tracking without providing something comparable in its place would be lowering the safety of the drug supply for whatever time it took.

Mr. {Waxman.} I agree. Let me ask you one other question in the few seconds I have. California law also ensures that all entities in the supply chain participate in the e-pedigree system. One of the major issues we have confronted in the context of this debate is whether pharmacies should be required to be part of the system. Do you think it makes sense to exempt pharmacies from a nationwide track-and-trace system?

Dr. {Woodcock.} I think ultimately if we want to know what drug the patient got, okay, and several times in the last several years that has been imperative for us to figure out what drug each patient got because sometimes we hear about the problem from the patient dying--

Mr. {Waxman.} So you think the pharmacies should be included so we know what the patient got?

Dr. {Woodcock.} Eventually, you know, that is the only

way to know what the patient got, and so we end up doing these elaborate investigations to figure out which drug the patient got, and yet often, as I said, we can't pull the drugs out of the patient's hands because they may be lifesaving medicines. So we may in the next several years get into a tragic situation because of that. So I think the ultimate goal really ought to be our ability to track down to that level.

Mr. {Waxman.} Thank you. Thank you, Mr. Chairman.

Mr. {Pitts.} The chair thanks the gentleman and now recognizes the gentleman from Pennsylvania, Dr. Murphy, 5 minutes for questions.

Mr. {Murphy.} Dr. Woodcock, great to have you back here. I always appreciate your candid testimony.

This may have been asked before, and I apologize if I am asking it again, but I would like to know. So how are things done now? How are you made aware that if there is a problem with something that may be counterfeit, toxic, contaminated, what is the process now by which we find out?

Dr. {Woodcock.} Well, there are a whole variety. We may be alerted from the health care system. They may find it

and they look at it and they see something is wrong. We may be alerted by whistleblowers who see, you know, this drug's label is in Turkish, this can't be right, okay? We may--and the ones that we are very concerned about is where we get harm, patient harm, and so we get adverse-event reports, people are dying and we don't know why, and then we have to go out and do a huge investigation of what did they get and so forth.

Mr. {Murphy.} So right now it is towards the end of the supply chain that you may find something by an adverse event or someone--

Dr. {Woodcock.} Yes, and we feel with the law that was passed last year, now manufacturers have to tell us if they get a component that is falsified or substandard, they need to tell us that now, but out in the world, usually it is sort of voluntary. Pharmacists will call us, a nurse or whatever, and we will find out about it that way.

Mr. {Murphy.} And this may be at the end of things. What about in terms of the ingredients that go into these? Do you pick up anything on that too, or is that the manufacturers on their site testing the quality of their

ingredients?

Dr. {Woodcock.} We ask them to test, and as I said, the Innovation and Safety Act included additional provisions on the supply side, the incoming side to make a drug, to strengthen that, making them strengthen their controls on the supply chain and the testing and so forth when they receive the components.

Mr. {Murphy.} So now if the FDA has a particular concern about a drug that would cause an immediate threat to individuals, what would the agency do?

Dr. {Woodcock.} We talk to the company and ask them to do a recall or they may have instituted a recall themselves. We determine--we do a risk assessment, which we call Health Hazard Evaluation, and we determine the level of possible harm, and if it is a class I recall, then we have to decide should it go down to the patient level and be pulled out of the hands of the patients and then we do-- the company is supposed to be in charge of that but we audit that, the effectiveness, to make sure it is happening, and if it is a really bad problem, we may collaborate with the CDC or the public health departments in the States, you know, to make

sure this all happens.

Mr. {Murphy.} Okay. Let me ask something. A witness on our second panel, Walter Berghahn, notes in his testimony there has been ``a tremendous amount of effort expended in the last 10 years to tighten up and secure the supply chain. Those efforts certainly have closed many of the cracks and yet counterfeits still appear, and the FDA has opened more investigations in the last few years than ever before, more than 70 instances in 2010 alone.'' What do you attribute to these increased investigations? Is it that the FDA is getting better at it or the problem is getting worse?

Dr. {Woodcock.} Always hard to know, right? I think the problem is getting worse. We know from our colleagues around the world that in some parts of the world, 50 percent of the drug supply is counterfeit, but those folks in that part of the world don't pay a lot for their drugs, so our market is ideal because the drugs are expensive and you get a lot of money for them. And so we see more professional criminals getting involved, you know, racketeering, very high-level criminal elements, you know, conspiring to do this and penetrate the U.S. drug supply because there is a lot of

money to be made.

Mr. {Murphy.} We hear a lot about people who offer drugs online. Your recommendations on whether or not people should purchase anything when they go to a website and they say, oh, here is my prescription, I will just get it from there, your recommendation is should they or should they not purchase from those?

Dr. {Woodcock.} There is a program called VIPPS, which offers certified online pharmacies. Certainly some of the pharmacies are fine. Many of them, you know, we have looked, we have ordered, we have done this. You can get counterfeit drugs very easily or substandard drugs ordering from an online pharmacy that you don't know anything about.

Mr. {Murphy.} So make sure you know who that online pharmacy is. Finally, let me ask you this, and this relates to what I was just asking about too. Could this legislation eventually lead to less drug shortages or more because you are watching more closely? What do you think the outcome will be?

Dr. {Woodcock.} I don't think it will have a huge impact on drug shortages, frankly. I think that problem, as

we discussed earlier, has other root causes other than-- obviously the existence of shortages is another temptation for people to introduce counterfeit because people are desperate to get these medicines and they will pay a lot for them. But I don't that is the root cause of shortages.

Mr. {Murphy.} Thank you very much. Yield back, Mr. Chairman.

Mr. {Pitts.} The chair thanks the gentleman and now recognizes the gentlelady from Florida, Ms. Castor, for 5 minutes for questions.

Ms. {Castor.} Thank you, Mr. Chairman, and I want to thank my colleague, Congressman Matheson, for bringing the discussion draft to us, and welcome.

Dr. {Woodcock.} Thank you.

Ms. {Castor.} Dr. Woodcock, a critical part of an effective drug supply chain is the ability to secure a stable supply of medically necessary drugs, and I know this isn't a hearing on drug shortages but there is a very serious issue and I feel compelled to ask you about it, and that is the critical shortages involved with babies in the NICUs right now, the neonatal intensive care units in children's

hospitals in NICUs all across the country. We are talking about the calcium, zinc trace elements, magnesium. I have been advised by some children's hospitals that they have less than 2 weeks of nutrients left, and this is already impacting their ability to provide the top standard of care for the most vulnerable of patients. I do understand that you have been very aggressive in tackling this problem along with your drug shortage professional staff, the children's hospitals and the manufacturers, but it is so serious now that a medical director at one children's hospital is calling is the worst crisis he has ever seen in 30 years. What is happening on this now and what is the outlook here over the coming months?

Dr. {Woodcock.} Well, we have worked with one manufacturer to allow them to ship product along with filters to filter out the product that is precipitating, because you can't give particles in IV fluids. It can embolize into the lungs. So that should provide some of the products. We are also working with manufacturers outside the United States to make sure their product is okay and bring it into the country. We recognize this is a critical issue and it is

reaching a critical stage, and we need to get product out there for these babies. We understand that.

Ms. {Castor.} So what is your time frame? Because they are saying they only have the product for the remaining 2 weeks, and what is happening is there are professionals are calling all over the country trying to find the elements that they need. Are they going to be able to see some relief here over the next week or two?

Dr. {Woodcock.} We hope so. As I said, some of these products are being shipped now with filters, all right, then others we negotiating on importing some of those other elements into the country, and once we can give the green light that we are assured of the safety, then they can be made available pretty rapidly.

Ms. {Castor.} Okay. That is the short-term solution. What is the longer-term answer?

Dr. {Woodcock.} The long-term solution appears to be some structural problems, as we talked about earlier, in how these drugs are manufactured and delivered to patients and the lack of a robust supply. So if one manufacturer goes down in the United States, they may be the sole source of

some of these life-maintaining products, and that is a really bad situation. It is sort of outside of the scope of FDA, though, to figure out how to have more manufacturers.

Ms. {Castor.} And drug shortages in general, have you noticed a ramp-up in counterfeits that try to fill that void in the market over the past few years?

Dr. {Woodcock.} In some cases people, unscrupulous people, exploit the existence of a shortage to try to introduce substandard products.

Ms. {Castor.} Which particular areas have you seen that?

Dr. {Woodcock.} We would have to get back to you on that as far as all the details.

Ms. {Castor.} Okay. Thank you very much. I yield back.

Mr. {Pitts.} The chair thanks the gentlelady and now recognizes the gentleman from Utah, Mr. Matheson, 5 minutes for questions.

Mr. {Matheson.} Well, thank you, Mr. Chairman. You know, this is an issue that a lot of us have been working on for a number of years, and I want to acknowledge some of the

colleagues, Congressman Boulier and Congressman Bilbray, who both worked on this issue, and then I am pleased to be working with Mr. Latta. And I think this year we have an opportunity to really get something done, and I think we should all embrace that opportunity to try to work together. We put out a discussion draft. This is not a bill. It is an opportunity for us to really start to dig into this issue and have a substantive discussion, and I hope that is what we do, and this hearing is the first good step in that process.

And I really want to thank Dr. Woodcock, who has spent a lot of time on this issue, has been very open, has talked to me on the phone about this issue before and been engaged for a long time on it, and I know you have a strong desire to come up with a national standard that sets the rules for everybody. I think there is a need for preemption. I heard some questions earlier concerned about timing of preemption but I think we all know we need one set of rules in this country and not 50 different State rules, and I think you would acknowledge that, but I do appreciate all you have done. You put your own time in and your staff in offering resources on this.

In your testimony, you describe several situations or instances of counterfeit drugs finding their way into the supply chain. Many have been reported in the press reports. Can you describe for us how the product was able to really get in the supply chain, and you can talk about the emerging level of sophistication that the bad actors are deploying right now to do this?

Mr. {Woodcock.} Yes. We see a range of sophistication, and of course, the ones we are most worried about are those who are actually able to copy, really make a counterfeit. It looks like the authentic product. It has the label of the authentic product and yet it isn't. It may often have nothing in there, or we have had that had regular water, which is very dangerous to just give to people, say, intravenously. So they are introduced at some point in the distribution chain. It may be a secondary distributor level. It may be the pharmacy level. It may be somewhere in between there. It may be where something is shipped to a clinic and they buy from a distributor who actually probably due to perhaps the amount of oversight that we should have of some these licensed distributors, they are sort of the launderers.

They launder these products and then put them into a legitimate chain, send them out to, say, cancer clinics and then people use those drugs that are not effective.

Mr. {Matheson.} And it is safe to say with over a $300 billion annual prescription drug market in the United States, this is pretty attractive.

Dr. {Woodcock.} That is right.

Mr. {Matheson.} The reason I ask this, I know this sounds obvious to everybody but this is why we are doing this. I mean, our current system is not necessarily structured where it can best mitigate this challenge of counterfeiters, and I think there are a lot of important issues, a lot of important details in this discussion draft, but I think it is important we all acknowledge why we need a national standard, why we have to do something better than we have now because the bad guys are getting smarter, more aggressive and there is just too much money on the table for them not to want to do some bad things.

One other question, and then I will let you go. You touched on this a little perhaps in other questions but can you walk us through how moving forward with a robust track-

and-trace system would complement the work that this committee undertook last year in the latest version of PDUFA, how that is going to complement what that bill already gave you some authority to do?

Dr. {Woodcock.} Absolutely. There are two sides to the whole chain of medicines. One is the supply chain where you get all the components, maybe the IV bags, the active pharmaceutical ingredient and all other components. They go into the manufacturer. That is one area where the Innovation and Safety Act really addressed that supply chain and tightened up some big loopholes that existed. Now this is a distribution chain, okay, the manufacturer makes the product, but then as I described, they send it out all over through a chain of distributors and so forth down to the pharmacy or clinic or hospital level, and that is the chain where there are big loopholes still where these fake products can be inserted or we just don't know where the products are going, and so once we have an approach and a goal laid out for this distribution chain side, then we will have a very intact system that we can have much more confidence in.

Mr. {Matheson.} Thanks. Mr. Chairman, I yield back.

Mr. {Pitts.} The chair thanks the gentleman. That concludes the questions from the members. I am sure they will have some follow-up questions, some other questions. We will send those and ask that you please promptly.

Dr. {Woodcock.} We will be delighted to work with you.

Mr. {Pitts.} Thank you very much, Dr. Woodcock, for your testimony.

That concludes the first panel. We will ask the staff to set up for the second panel. We have seven witnesses. We will take a 2-minute break while they set up.

[Recess.]

Mr. {Pitts.} The subcommittee will reconvene. On our second panel today, we have seven witnesses, and I will introduce them in order of their presentations. First, Ms. Elizabeth Gallenagh, Vice President of Government Affairs and General Counsel, Healthcare Distribution management Association. Then Christine Simmon, Senior Vice President of Policy and strategic Alliances, Generic Pharmaceutical Association. Then Mr. Michael Rose, Vice President of Supply Chain Management, Johnson and Johnson Health Care Systems. Then Dr. Tim Davis, owner, Beaver Health Mart Pharmacy on

behalf of the National Community Pharmacists Association. Then Mr. Allan Coukell, Director of the Medical Programs of the Pew Charitable Trust. Then Dr. Carman Catizone, Executive Director, National Association of Boards of Pharmacy. And finally, Mr. Walter Berghahn, President of Smarter Meds for Life and Executive Director of the Healthcare Compliance Packaging Council.

Thank you all for coming. You will each be given 5 minutes to summarize your testimony. Your written testimony will be placed in the record.

Ms. Gallenagh, we will start with you. You are recognized for 5 minutes.

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^STATEMENTS OF ELIZABETH GALLENAGH, J.D., VICE PRESIDENT OF GOVERNMENT AFFAIRS AND GENERAL COUNSEL, HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION; CHRISTINE M. SIMMON, SENIOR VICE PRESIDENT, POLICY AND STRATEGIC ALLIANCES, GENERIC PHARMACEUTICAL ASSOCIATION; MICHAEL ROSE, VICE PRESIDENT, SUPPLY CHAIN VISIBILITY, JOHNSON AND JOHNSON HEALTH CARE SYSTEMS, INC.; TIM DAVIS, R.PH., BEAVER HEALTH MART PHARMACY, ON BEHALF OF NATIONAL COMMUNITY PHARMACISTS; ALLAN COUKELL, DEPUTY DIRECTOR, MEDICAL PROGRAMS, THE PEW CHARITABLE TRUSTS; CARMEN A. CATIZONE, R.PH., D.PH; AND WALTER BERGHAHN, EXECUTIVE DIRECTOR, HEALTH CARE COMPLIANCE PACKAGING COUNCIL

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^STATEMENT OF ELIZABETH GALLENAGH

} Ms. {Gallenagh.} Good morning, Chairman Pitts, Ranking Member Pallone and members of the subcommittee. I am Liz Gallenagh, Vice President, Government Affairs, and General Counsel at HDMA. Thank you for this opportunity to inform you about the critically important issue of prescription drug

pedigree, traceability and supply chain safety. I would also like to thank Chairman Upton, Congressman Latta and Congressman Matheson for their leadership in this area as well as the hard work and dedication of their staff.

The pharmaceutical distribution industry's primary mission is to operate the safest, most secure and efficient supply chain in the world. As part of this mission, HDMA's members work to eliminate counterfeit and diverted medicines by capitalizing on the technological innovation and constant improvements in efficiency that are the foundation of our industry.

Today, on behalf of our 33 members, I am here to express HDMA's strong support for a national, uniform approach to pedigree and the traceability of medicines throughout the supply chain. I will speak with more detail later in my testimony, but I want to state that we support the core elements of the Latta-Matheson proposal and look forward to working with you and your Senate colleagues on the final bill.

HDMA believes that any reform and modernization of the supply chain should raise national wholesaler standards and

include a new federal ceiling for pedigree and traceability requirements to improve safety and uniform and establish the foundation for longer-term electronic solutions such as unit-level serialization and product tracing. In addition to fundamentally addressing counterfeit and diverted medicines, a national approach may be a useful tool in discouraging gray market activities associated with drug products in short supply. More importantly, it will put the United States on par with other countries around the world that are currently beginning to engage in serialization and traceability efforts.

After many years of debate, it appears that we finally may have an opportunity to enact federal legislation in this area. This is in large part due to a broad consensus among supply chain partners as well as growing support from Members of Congress. While Congress, FDA and industry have been working at this diligently for several years, it is critical that Congress act now due to the uncertainties faced by the industry, the need for uniformity across the supply chain and to ensure patient safety.

Basic guidelines for pedigree were set forth 25 years

ago with the enactment of the federal PDMA. Since that time, activity at the State level has varied with some enacting very complex laws and others never going further than the original guidelines. Based on our experience, the complexities of dealing with multiple approaches in the States will only get worse if we fail to solve this problem now at the national level.

Since Florida's first foray into raising pedigree and licensure standards in 2003, we have seen dramatic variations across the country. This variation has occurred despite HDMA's attempts to work in every State along with fellow stakeholders to achieve more uniformity. Today, for example, 29 States have acted beyond the federal PDMA standards. The States of Florida and California are viewed as leaders in this area. However, they take completely different approaches, California being the most complex and forward-looking with track-and-trace and electronic pedigree implementation beginning in 2015, and Florida being the most stringent today in terms of what is happening in the supply chain with pedigree requirements.

This patchwork not only creates operational challenges

but also leaves openings for bad actors shopping for more lenient State rules, openings that could mean the difference between a fake or diverted medicine being dispensed to an innocent patient in need of important treatment. Because of this State-by-State variation, we believe pedigree and traceability should be under the purview of Congress and the FDA.

We have been a leader in this field and we are dedicated to working with supply chain partners and stakeholders on a consensus approach to pharmaceutical traceability. We are an active member also of PDSA, the Pharmaceutical Distribution Security Alliance.

The bipartisan discussion draft released by the committee this week achieves these goals and captures the core consensus elements that will significantly improve the integrity and safety of the supply chain. Specifically, the proposal does include national requirements for wholesaler licensing while preserving a critically important role for the States; uniform direct purchase and standard pedigree options; eliminating the current 50-State patchwork, manufacturer serialization at the unit level and case level,

enabling unique identification of prescription drug products for the first time in the United States; the development of electronic systems and processes to facilitate traceability and transaction data exchange to provide additional efficiency and safety benefits within the supply chain, and appropriate transition times and development phases for the migration to traceability for each segment.

There is no single element that will protect the supply chain from every threat but rather a comprehensive solution should incorporate each of these elements. We applaud your work and urge the committee to advance this important issue this year. Now is the time for Congress to act to bring cohesion and consistency to our national drug supply chain.

[The prepared statement of Ms. Gallenagh follows:]

********** INSERT 2 **********

Mr. {Pitts.} The chair thanks the gentlelady and now recognizes Ms. Simmon for 5 minutes for an opening statement.

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^STATEMENT OF CHRISTINE M. SIMMON

} Ms. {Simmon.} Thank you. Good morning, Chairman Pitts, Ranking Member Pallone and members of the subcommittee. Thank you for inviting me to testify here today on the important topic of securing our Nation's pharmaceutical supply chain. I am Christine Simmon, Senior Vice President of Policy at the Generic Pharmaceutical Association. We represent the finished-dose generic drug manufacturers and bulk pharmaceuticals and suppliers to the industry.

For the past year, the effort to develop a national solution to securing the supply chain received strong support from key members in both the House and Senate but unfortunately was not enacted into law. We applaud this committee for taking up this issue today, and we recognize and appreciate the dedicated attention to this issue and leadership by Congressmen Latta and Matheson.

GPhA believes that every patient in America deserves a safe, secure prescription drug supply. For many years, GPhA has worked closely with multiple stakeholders across the

supply chain to ensure just that. As the makers of 80 percent of scripts dispensed in the United States, our industry is deeply committed to preventing and detecting the distribution and sale of counterfeit and adulterated medicines. We strongly supported last Congress's historic Generic Drug User Fee Act, which recognizes that while providing earlier access to medicines is critical, FDA's central mission is ensuring drug safety. We applaud the efforts of this committee in enacting the user fee program into law.

GPhA is a member of the Pharmaceutical Distribution Security Alliance along with many others in the supply chain and including others at this table. The group's primary goal is to ensure patients have uninterrupted access to safe, authentic FDA-approved medicine. So today I am going to share with you our support for a system build on three core principles: a uniform federal standard, technical requirements that support achievability, and a building block approach to ensuring orderly implementation and avoid unintended consequences.

It is vital to ensure that any supply chain security

system put in place is practical, focused and uniform across the country. California's drug pedigree model that will be effective in 2015 would require implementation of full electronic track-and-trace capabilities where the entire distribution history and location of every unit in the supply chain can be determined at any time. At present, the technology to support such a system is unproven and the costs associated would be billions. Any attempt to hastily implement such a system could lead to confusion in the supply chain, aggravate product shortages and dramatically increase costs for all prescriptions including generic medicines.

In contrast, GPhA believes that a building block enables the industry to attain interoperability in achievable steps all the while applying the knowledge and experience gained over time to refine the model. While the generic industry is still reviewing recently released drafts, many elements are consistent with our proposed approach.

Specifically, as outlined in phase I of the Latta-Matheson discussion draft, generic manufacturers have committed to identifying individual saleable units of medicine with labels and maintaining and managing data in

their systems that would associate the identifiers on individual bottles of medicine with the lot numbers of the products. Verification that a specific unit was serialized by a manufacturer within a given production lot can provide information and security that is a major step forward from current practices. The system would help identify and prevent the introduction of suspect product through full lot traceability and allow regulatory authorities to validate the unique identifier of a product at the unit level.

The stepped approach in the House draft would provide immediate measures to increase supply chain security. The system established under the proposals will improve the efficiency and effectiveness of drug recalls and returns. In planning for the future, it would provide critical building blocks that can be expanded as public health threat standards and technologies evolve.

Because American consumers today expect the convenience and simplicity inherent in the digital transfer of information, GPhA strongly supports the e-labeling requirement in the discussion draft to provide more standardized electronic prescription drug information that

would increase patient safety and provide significant quality improvements and cost reductions through a more accurate, cost-effective and sustainable alternative to paper inserts.

In conclusion, Mr. Chairman, GPhA and the industry share the concerns of the committee with regard to maintaining the security of our country's drug supply. The development of a uniform national system is needed to give regulatory authorities another tool for enforcement, make it more difficult for criminals to breach the supply chain, and enhance the ability of the supply chain to respond quickly when a breach has occurred. We believe the model proposed by the House includes many elements to achieve these goals. We look forward to working together with Congress to develop a consensus measure on this important issue that can be enacted into law.

Thank you, and I would be happy to answer any questions you may have.

[The prepared statement of Ms. Simmon follows:]

********** INSERT 3 **********

Mr. {Pitts.} The chair thanks the gentlelady and now the chair recognizes Mr. Rose for 5 minutes for an opening statement. Please speak into the microphone.

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^STATEMENT OF MICHAEL ROSE

} Mr. {Rose.} Thank you for your introduction, Mr. Chairman, and thank you, Mr. Pallone. I work for and am representing Johnson and Johnson Health Care Systems Inc. Johnson and Johnson Health Care Systems Inc. is the principle supply chain commercial entity within the Johnson and Johnson family of companies in the United States.

Securing our Nation's supply chain is an important concern for our company. We believe it is vital for the patients who use our products receive our genuine products. We have already taken steps to secure our supply chain and protect our products. As a member of PhRMA and BIO and a participant in PDSA, I will share with you our perspectives on serialization and track-and-trace, our serialization experience and views on the draft legislation.

Serialization regulations have become increasingly common across many countries including the European Union, Turkey, Argentina, China, India and Brazil. In the United States, the California law requires manufacturers to

serialize and pedigree all pharmaceutical products sold in the State of California 50 percent of our products by January 1, 2015, and the remaining 50 percent by January 1, 2016. Additionally, more than 50 percent of the States have pedigree laws with varying approaches, that is, some require electronic pedigrees, others use paper. Some start the pedigree at the primary distributors, others will start it with the secondary wholesaler, et cetera. This patchwork quilt of regulations leaves us with a complicated, inefficient regulatory landscape creating unforeseen gaps where bad actors can introduce illicit drugs into the legitimate supply chain, thereby placing our citizens at risk of counterfeit medicines.

While the risk of encountering counterfeit medicines may be small within the legitimate domestic supply chain, when a patient receives a counterfeit medicine, the effects can be extremely dangerous, have long-lasting impact and can even be life-threatening. Our company believes that federal serialization and track-and-trace legislation is necessary to properly secure our pharmaceutical supply chain by eliminating varying and conflicting State regulations.

Federal legislation should help close the gaps where illicit drugs enter the U.S. supply chain as well as provide additional mechanisms to help authenticate the legitimacy of medicines distributed and dispensed within the United States to help protect the patients who use our medicines.

Next I would like to share our company's domestic serialization experience. We are preparing our packaging sites, distribution centers, business and information technology systems to serialize and track and trace our products so that we can comply with the California e-pedigree law. Here is an example of the first product that we have serialized for the U.S. market. This product is Prezista 600-milligram tablets. For your reference, I have attached a label of serialized Prezista 600 milligrams to my testimony.

Let me draw your attention to the product license plate on the side of the label. This space is similar to the prescription drug product identifier prescribed in the House bill. We provide both machine and human readable forms for easy and accurate identification. Similarly, we apply a standard serialized barcode to every homogenous case to facilitate handling during distribution. This identification

space complies with both the FDA's serial number identifier guidance and the widely adopted international standards developed by GS-1.

Additionally, we are establishing processes to exchange serialized data with the distributors who distribute our products and with the pharmacies that dispense our medicines to patients who need them. We are required to provide this information to the distributors and pharmacies so that they can use it to help verify both the authenticity of the package as well as the transactions related to the product.

Bottom line: While it is complicated work and a lot still remains, we are doing our part to comply with the California law. However, if any States were to adopt slightly different regulations, the inconsistencies could compromise the integrity of the supply chain, hence supporting the need for federal action now to secure our national security chain.

Lastly, I would like to comment on the proposed legislation. In 2011, our company along with several other PhRMA and BIO members and other supply chain participants helped form PDSA. PDSA's mission is to help enact a federal

policy proposal for one unified national system enhancing the security of the domestic supply chain for patients and to define a migratory implementation pathway.

Johnson and Johnson Health Care Systems supports Representatives Latta and Matheson for tackling this important issue and making progress on a legislative solution. This legislation incorporates many of PDSA's proposed provisions including a uniform national standard with a phased implementation. It is vitally important that both government and the private sector work together to protect our national drug supply in a manner that makes sense. We believe this legislation will help us secure the domestic pharmaceutical supply chain by providing additional protection to our citizens, patients who depend on the integrity of our medicines to treat their diseases and life-threatening conditions from counterfeit medicines. Johnson and Johnson Health Care Systems' commitment to patient safety is unwavering. We look forward to Congress's enactment of this legislation and we are committed to work with Congress, the FDA and our supply chain stakeholders to implement it successfully. Again, thank you for the opportunity to

provide this testimony to the committee.

Before concluding my remarks, I would like to recognize Steve Drucker, an industry colleague from Merck, who passed away last week. We will miss Steve's immense contributions, commitment to patient safety and especially his humorous insights. Our thoughts and prayers go out to Steve's family, especially his wife Ann and the entire Merck team.

[The prepared statement of Mr. Rose follows:]

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Mr. {Pitts.} The chair thanks the gentleman. Dr. Davis, you are recognized for 5 minutes for an opening statement.

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^STATEMENT OF TIM DAVIS

} Mr. {Davis.} Chairman Pitts, Ranking Member Pallone and members of the committee, thank you for conducting this hearing and for providing me the opportunity to share my perspective as an independent pharmacist and small business owner on the issue of securing the pharmaceutical supply chain. My name is Tim Davis of Beaver County, Pennsylvania, and I am the owner of Beaver Health Mart Pharmacy and have been a practicing pharmacist for over a dozen years. I am here today representing the National Community Pharmacists Association, which represents the pharmacist owners and employees of more than 23,000 independent community pharmacies in America. Our pharmacies provide over 40 percent of all community-based prescriptions.

It is my belief that the United States pharmaceutical supply chain is largely safe and secure. Most pharmacists today have a heightened awareness of counterfeit or diverted drugs and therefore recognize the critical importance of purchasing medications only from trusted trading partners.

In addition, pharmacists as part of our training and daily practice carefully examine both drug packaging and the drug itself to be sure there are no suspicious anomalies.

It has been my observation, though, that certain types of prescription medications tend to be the target of counterfeiters. Relatively expensive drugs that can be easily produced and readily sold entice these bad actors. Some drugs that I have personally seen are lifestyle drugs, such as Viagra, and very costly injectable medications such as Procrit or more recently Avastin.

In response to concerns about the safety of prescription medications in the United States, over half of the States have passed drug pedigree laws that require drug products that move outside of normal distribution to be accompanied by a record of prior transactions. However, the differences in each State's laws has created a patchwork of activities across the United States. As a result, there have been past discussions about the practicality of a system that would track prescription drugs at the individual unit level. Pharmacists have had significant concerns about any system that would require each individual unit of medication to be

electronically scanned upon arrival in a pharmacy due to the capital, time and labor costs associated with such a system. Presently, the technologies required to implement such a system are not fully developed, designed or scaled to be feasible or affordable for use in individual community pharmacies.

Of great concern is the California e-pedigree law that will begin to be implemented in 2015 that will require the electronic tracking and tracing of all drug packages in real time. This well-intentioned system will require each individual participant in the supply chain to scan each individual item to capture the transaction information. With each successive distribution, the e-pedigree must be updated with the newest transaction data as it makes its way to our pharmacies. In short, our pharmacies will have the unenviable task of maintaining all drug pedigree data for all distributions and must be able to access it on demand. The cost of compliance with this law will be extremely high when factoring in both initial implementation and ongoing expenses necessary to maintain and access the data. Imposing these challenges, particularly on community pharmacies, is not

logical at a time when the Nation is focused on trying to reduce health care costs.

All of these factors bring us to a place in which we need a uniform federal framework to provide further assurances of supply chain security and that could be used to assist federal regulators in instances of drug recalls or inquiries. We need a reasonable, commonsense federal approach that will strike the appropriate balance between enhanced patient safety and minimizing unreasonable burdens on supply chain stakeholders, particularly small business pharmacies like myself.

NCPA is a member of the Pharmaceutical Distribution Security Alliance, a working group comprised of representatives of all sectors of the pharmaceutical supply chain, which has been collaborating over the past year and a half to address supply chain security issues. This group has reached a consensus around a number of topics. One is that of establishing national requirements for wholesaler licensure standards. Raising the standards for wholesaler licensure in a uniform fashion would provide the community pharmacist with an additional layer of confidence in the

integrity of the medications purchased. The second concept is that of attaching a unique identifier to prescription drugs at the unit and case levels. Products would be identified with a two-dimensional matrix barcode including the serial number, lot number and expiration date. The PDSA coalition has also built consensus around being able to use the serialized identifier information to track products at the lot level. NCPA is pleased to note the inclusion of national wholesaler licensure standards, product serialization and lot-level tracking in both the recently released House discussion draft and the Senate draft. NCPA believes that the proposed lot-level system is one that could be built upon at some point in the future.

Community pharmacists take very seriously our role in ensuring the safety of medications that we personally dispense to our patients and we remain committed to working with our colleagues in the supply chain as well as with State and federal authorities to make any needed improvements. Moving forward, it is essential that all stakeholders make a concerted effort to keep the lines of communication open so that consumers can continue to trust the integrity of the

medications that we all so depend on.

Thank you.

[The prepared statement of Mr. Davis follows:]

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Mr. {Pitts.} The chair thanks the gentleman. Mr. Coukell, you are recognized for 5 minutes for an opening statement.

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^STATEMENT OF ALLAN COUKELL

} Mr. {Coukell.} Chairman Pitts, Ranking Member Pallone and members of the committee, thank you for the opportunity to testify. My name is Allan Coukell. I direct drug and medicine device work at The Pew Charitable Trusts, an independent research and public policy organization.

Pew supports the creation of a strong national system to protect American patients from the risks of counterfeit, stolen and diverted drugs. We do so based on our analysis of the risks to the supply chain and the feasibility of solutions. The principles that I will outline today are supported by other consumer, patient, public health and industry stakeholders, and I ask that a number of statements be included in the record with my written testimony.

There is general agreement on the need for a national system and how it would work. Manufacturers would put a unique serial number on each package of drugs. The drugs would be tracked as they pass from hand to hand through the complex distribution system and they could be checked to be

sure they are authentic. This approach would bring the United States into line with other countries and individual States. Providing it creates a meaningful advance in safety, a single national system would be preferable to the current patchwork of State laws.

A recent example demonstrates how verifying a serial number on a drug package could have prevented a significant crime and risk to patients. Last year, the U.S. Attorney in New York charged 48 people in a large-scale diversion scheme to buy half a billion dollars worth of medicines from patients on the street, repackage them, sometimes with fake labels, and sell them back into distribution through licensed wholesalers who in turn sold the drug to pharmacies. This massive criminal recycling of government-subsidized drugs--similar schemes are well documented in other States--could be prevented if the drug package had a serial number and the serial number was retired after the drugs reached the pharmacy. This requires that pharmacies and wholesalers purchasing the drugs check that serial number. Without checking, the same serial, real or fake, could be sold again and again without detection.

Manufacturers are already making investments in drug serialization. To justify the expense and the preemption of strong State laws, it is essential that any federal law achieve the following within a reasonable time frame: Participation of all members of the supply chain. We need traceability of drugs at the package level, not merely by lot, which can include thousands or tens of thousands of bottles, and routine checking of serial numbers. In a soon-to-be-released Pew Booz Allen Hamilton report, supply chain stakeholders overwhelmingly said that all sectors, manufacturers, distributors and pharmacies, need to participate in a national system without exception.

The technology is feasible, and package-level serialization and verification already exist or soon will in China, Brazil, Turkey, Italy and across the EU. A system that does not track drugs by the unit level would fail to catch unsafe drugs in many scenarios. Take the example of a narcotic or any drug in shortage that is sold illegally or in the gray market. Without unit-level traceability, neither the purchaser nor an investigator would have any way to know who had sold that product or where it had come from.

Today, some companies are required to track a drug's transaction history through paper pedigree. An electronic system would be a welcome replacement, but Congress should certainly not replace pedigrees, which are used by regulators and law enforcement, with a structure that does less to capture the chain of custody than today's systems. Regular checking of drug serial numbers by supply chain partners is a powerful way to ensure that illegitimate products do not enter distribution. Take, for example, a truckload of insulin, 129,000 refrigerated vials, that was stolen from a highway rest stop a few years ago. After several months, some of that drug showed up on the shelves of chain drugstores in Texas, Georgia and Kentucky, having been handled by licensed wholesalers in at least two other States. Nobody knows how much of that product was resold but only 2 percent of it was recovered. We need a system that can flag suspect of illegitimate and flag it automatically.

Recognizing the danger, some companies have already taken steps. For example, the pharmaceutical company EMD Serono, after its human growth hormone was counterfeited, put in place a secure distribution program with unique serial

numbers on each vial that are checked by the dispensing pharmacy. The core of that program shows how a national system can work.

Mr. Chairman, I thank you for this hearing and for your commitment to this issue. The discussion draft released by this committee a few days ago acknowledges the risks I have been describing. We urge you now to refine it to achieve the meaningful protections called for by patient, consumer and public health groups and the others I have mentioned. Indeed, we urge you to return to the bipartisan, bicameral, two-phrase framework that you and your office and others on this committee have spent much of the past year developing, an approach that every organization represented on this panel has supported. It has been 25 years since PDMA. The California law will begin to be implemented in 2 years. The opportunity for a federal system now is great. We would like to work with this committee to improve this proposal to achieve a strong national system that achieves what it must: meaningful protections for patients.

Thank you, and I would welcome your questions.

[The prepared statement of Mr. Coukell follows:]

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Mr. {Pitts.} The chair thanks the gentleman. Dr. Catizone, you are recognized for 5 minutes for an opening statement.

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^STATEMENT OF CARMEN A. CATIZONE

} Mr. {Catizone.} Chairman Pitts, Ranking Member Pallone and members of the subcommittee, I thank you for the opportunity to be here today. The National Association Boards of Pharmacy founded in 1904 and based in Illinois appreciates the chance to share with you comments and input from the States who are currently responsible for regulating this particular situation.

The issues before the committee are not new. In fact, the timeline in trying to secure our Nation's prescription drug supply extends far back than we care to admit. The activities that have ensued since the enactment of the PDMA some 25 years ago can best be characterized by two words: proposed and delayed. The language found throughout multiple Federal Register notices since the implementation of the PDMA read similarly over and over. The proposals presented by the FDA and supported by the States were continuously delayed and defeated by pressure from the industry.

As some of you may be aware, NABP is intimately involved

in the oversight of wholesale distributors; as a result, our verified, accredited wholesale distributors program. To date, we have surveyed and accredited 552 wholesale distributors across the United States. We have observed firsthand and reported to the applicable State and federal authorities breaches in and compromises to the prescription drug supply chain. These breaches and compromises include the lack of a pedigree, the lack of complete information, the absence of any documentation, pedigrees or other transaction documents that indicate a product passed through multiple entities, some licensed and others not, multiple wholesaler companies located in a one-room business office in a strip mall claiming some form of common ownership, wholesalers receiving and storing products under conditions that render the medications adulterated or contaminated, and wholesalers and pharmacies establishing as their sole business model the purchase and sale of shortage drugs and inflating the price of these products by a thousandfold, an unconscionable action when it comes to drugs that are needed by patients suffering from life-threatening diseases such as cancer.

The States are both the frontline and last defense in

the prescription supply chain. Together with NABP, they have forged an effective public-private partnership. That partnership was recognized by the Institute of Medicine in its report ``Countering the Problem of Falsified and Substandard Drugs.'' The report notes that crime and corruption drive the business of falsified medicines and that medicines can change hands many times in myriad countries before they reach patients.

One of the primary recommendations of the IOM that is critical to the considerations before this committee and bears noting this afternoon was a recommendation they made in regard to NABP, and I quote: ``The IOM committee calls for strengthening the drug distribution system in order to improve the quality of medicine and protect consumers. Top among its priorities is restricting the U.S. wholesale market to firms vetted by the National Association of Boards of Pharmacy. This action would tighten the American drug distribution chain and build momentum for better controls on drug wholesalers in developing countries.''

NABP supports the implementation of a national system for the oversight and regulation of prescription drug supply

chain provided such system is comprehensive and does not discard the protections already in place and ready for implementation by the States, particularly California. It should take into account the existing and successful public-private partnership established between the States and NABP endorsed by the Institute of Medicine and operating effectively at no cost to the American taxpayers. NABP calls for no further delays. The time has long passed for the continued delay in addressing and resolving the challenges confronting our Nation's prescription drug chain. NABP requests that all participants in the supply chain be accountable. Exemptions should not be granted to pharmacies. NABP supports the tracking and traceability of products to the package level and made operational in 2015 and 2016 in order not to retreat on advances made by California and the timeline already committed to by a growing number of the industry. NABP supports pharmacies and wholesale distributors being required to append and pass pedigrees or other equivalent transaction documents within the next 2 to 4 years, and NABP supports providing the Food and Drug Administration with the full scope of authority and resources

needed to implement and enforce a national system.

We thank you for the opportunity.

[The prepared statement of Mr. Catizone follows:]

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Mr. {Pitts.} The chair thanks the gentleman. Mr. Berghahn, you are recognized for 5 minutes for an opening statement.

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^STATEMENT OF WALTER BERGHAHN

} Mr. {Berghahn.} Thank you, and good afternoon. Chairman Pitts, Ranking Member Pallone and members of the committee, I appreciate the opportunity to be here and share my perspective on this matter. My name is Walter Berghahn. I am the Executive Director of the Healthcare Compliance Packaging Council, a trade association dedicated to improving medication adherence and patient safety through broad adoption of innovative packaging. The HCPC represents packaging material and machinery suppliers as well as contract packagers. The members serve as pharmaceutical manufacturers and pharmacy both institutional and retail. The HCPC supports California's SB 1307 and the work of this committee, recognizing that we share the common goal of a secure supply chain.

The U.S. pharmaceutical supply chain is primarily safe. Drugs are produced, packaged and shipped according to FDA guidelines. They travel through a complex supply chain and arrive at the appropriate pharmacy, hospital and nursing home

mostly without incident. That sounds wonderful, but that is not why we are here today. We are here because there are many groups intent on selling counterfeit or gray market drugs into the U.S. supply chain despite a tremendous effort over the last 10 years to secure the supply chain. Counterfeits are still appearing. The FDA has opened more investigations in recent years than ever before, more than 70 incidents in 2010 alone.

Some suggest that the cost to fix it is too high and the supply chain is safe enough. I am betting that those people have never had a family member ingest or inject a counterfeit medication and suffer the health consequences.

It has been suggested that serialization and barcoding technology is not mature or scalable enough for this task, and yet barcoding has been used since the 1970s. It is found in every store and pharmacy in America. Two-dimensional barcoding required for serialization is newer but well established. The Department of Defense issued a paper in 2005 outlining their use and implementation of 2D barcoding for tracking valuable items in both forward and reverse logistics. Every day, tens of millions of packages are

tracked by FedEx and UPS utilizing serialized barcodes. Every day, 1-1/2 million U.S. air travelers board planes using 2D serialized barcodes. I am not suggesting the process will be easy for pharmaceuticals but the technologies employed are proven and they are widespread.

California led the way on serialization with SB 1307 with initial targets in 2007 and subsequent delays allowing industry time to comply. I am sure you are familiar with the timeline. Pharmacy would be the last to comply in July of 2017, a full 4 years from today. The HCPC hopes that the federal legislation will support SB 1307 and not undermine its progress.

The packaging machinery industry is prepared to help meet these deadlines. Systems ranging from manual to fully automated exist which apply, verify and aggregate 2D barcoded containers to cases. Companies such as Systech, Optel, Seidenader, Omega and numerous others are delivering these systems to branded and generic pharmaceutical manufacturers today. Dozens of systems have been installed in the United States in anticipation of California's deadlines. Hundreds more are being planned, ordered and constructed now. A

larger number of systems have already been deployed globally to meet international requirements for serialization in countries like China, Brazil, Turkey, India and a large portion of the EU.

All this work does wonders for securing the normal supply chain but we would be remiss if we didn't consider the many documented problems occurring outside normal channels. So how do we detect those instances? In my opinion, the best way would be to provide prescriptions the way most of the world does: in the manufacturer's original container. This would accomplish two things. It thwarts the introduction of counterfeit products in pharmacy as well as dispensing of outdated and returned product, all unfortunately well documented. Secondly, it would allow the insurance industry to mandate the use of a serial ID for reimbursement, not simply the NDC number. This practice would greatly reduce prescription fraud. The government via CMS and the Veterans Administration is the largest payer in the United States and would see the largest benefit from this practice.

This is relevant because even the physicians cited in the recent Avastin counterfeit case in California need to

submit for reimbursement. Today, all they need is a valid NDC number. In the future, requiring a serial number for reimbursement could block illegally purchased items from being distributed. California has documented cases where pharmacists have illegally purchased product over the Internet and dispensed them in pharmacies, submitting for reimbursement with a legitimate NDC. Could lot-level tracking have stopped this?

In conclusion, I would like to address one of the major differences between the proposed methodologies being considered. The debate is item-level tracking versus lot-level tracking. To be sure, lot-level tracking is less cumbersome on industry players but one must question its effectiveness. Lot-level tracking will provide tools for evaluating what happened, why a counterfeit drug got in the supply chain. Item-level track-and-trace will prevent it. The difference is staggering: prevention versus detection after the fact. I would hope that in considering which path to pursue, members will look at past instances of counterfeiting and ask a simple question: would lot-level tracking have prevented this product from entering the supply

chain?

Thank you for the chance to contribute to this.

[The prepared statement of Mr. Berghahn follows:]

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Mr. {Pitts.} The chair thanks the gentleman. That concludes the opening statement of our second panel. At this time I would like to request unanimous consent to place a statement from the National Association of Chain Drugstores into the record. Without objection, so ordered.

[The information follows:]

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Mr. {Pitts.} You have a UC request?

Mr. {Pallone.} Mr. Chairman, I would ask unanimous consent to enter into the record a letter from EMD Serono.

Mr. {Pitts.} Without objection, so ordered.

[The information follows:]

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Mr. {Pitts.} All right. I will begin the questioning and recognize myself 5 minutes for that purpose.

I will start with Ms. Gallenagh. Talk a little bit about the California model. Would the California model work on a national level? Would you describe some of the consequences for patients and industry and others? We will go down the line and start with you, Ms. Gallenagh.

Ms. {Gallenagh.} Sure. Based on what we know right now, a lot depends on the time frames that would be set forth on a national level. The California dates currently, in my opinion, would not be practical for a national model. Additionally, there is a piece of the California law that is providing to be particularly difficult in piloting, and that is the electronic pedigree portion of the law that also goes along with full track and trace of product electronically throughout the supply chain. And these are right now, based on what we are learning through experimenting with the processes and the technology very difficult for industry.

Mr. {Pitts.} Ms. Simmon?

Ms. {Simmon.} Thank you. Yes, we would echo that. You

know, some of the necessary technology, speaking from a manufacturer's point of view, just isn't really there yet. Aggregation of units to cases and pallets is not ready to be deployed with a high level of accuracy for the data that would be required, and some of the interoperability standards for the data are not yet solved. With the compliance dates only 2 years ago, you know, we feel that is moving too quickly to avoid some unintended consequences.

Mr. {Pitts.} Mr. Rose, would you comment on the consequences for industry and patients?

Mr. {Rose.} Consequences on patients?

Mr. {Pitts.} Both industry and patients.

Mr. {Rose.} Okay. For industry, you know, we brought a sample of our product where we have applied the 2D data matrix code with a serial number on it.

Mr. {Pitts.} And would you point out what you said in the testimony?

Mr. {Rose.} Right here we have the 2D data matrix code, and then here we have human readable format where we have put the serial number in there as well as the product code and expiration date and lot, and you can read it human readable

or via machinery. This took a lot of work to get going. The next phase we are working on right now is exchanging data with our trading partners. Those standards don't exist. We don't have guidance from California on those data standards, and we are missing those. That is very important to have for us to be fully compliant with the California law. So to achieve this date, we need those standards to be put in place but then also we have to put those systems in place to be able to exchange that data with our trading partners.

Mr. {Pitts.} Dr. Davis, would you care to comment?

Mr. {Davis.} I think that from a community pharmacist's perspective that it would be relatively difficult for us to comply nationwide because of a couple of reasons. One would be the ability to absorb and to maintain the costs associated with the system, and two, to access and be able to implement the technologies surrounding it. This is something external to all of our current processes in the field of pharmacy, and we don't want to necessarily lose the relationships and patient care experiences that we have currently in place in lieu of trying to comply by another national standard.

Mr. {Pitts.} Now, I posed several of these questions to

FDA earlier today, and I would like to get the opinion of actors on the ground working to manufacture and distribute and dispense our Nation's drug supply, so if you will please respond. Will national uniformity increase the security of the supply chain and improve patient safety, Ms. Gallenagh?

Ms. {Gallenagh.} Yes.

Mr. {Pitts.} Ms. Simmon?

Ms. {Simmon.} Yes, it would.

Mr. {Pitts.} Mr. Rose?

Mr. {Rose.} Yes, it would.

Mr. {Pitts.} Dr. Davis?

Mr. {Davis.} Yes.

Mr. {Pitts.} What about, is it important to preserve the States' ability to license and enforce national standards?

Ms. {Gallenagh.} I would say yes, it is important so that they have a role to partner with FDA.

Mr. {Pitts.} Ms. Simmon?

Ms. {Simmon.} Yes, we would agree as well.

Mr. {Rose.} Yes, we would agree as well.

Mr. {Davis.} Yes.

Mr. {Pitts.} Will product serialization increase the security of the supply chain and improve patient safety?

Ms. {Gallenagh.} Yes, absolutely.

Ms. {Simmon.} Yes, we definitely favor product serialization.

Mr. {Rose.} We agree with product standardization.

Mr. {Davis.} And we agree with it as well in a phased-in approach so that we can build our systems and our capabilities without compromising patient care as it stands today.

Mr. {Pitts.} All right. Will data exchange and systems between actors in the supply chain increase the security of our drug supply and improve patient safety?

Ms. {Gallenagh.} Yes.

Ms. {Simmon.} Yes, it would.

Mr. {Rose.} Yes, it would.

Mr. {Davis.} Yes, it would.

Mr. {Pitts.} And finally, would a national track-and-trace standard increase the efficacy of product recalls?

Ms. {Gallenagh.} Yes, it would.

Ms. {Simmon.} Yes, we believe it would.

Mr. {Rose.} Yes.

Mr. {Davis.} Yes, it would, sir.

Mr. {Pitts.} Thank you. I have gone over time. The chair recognizes the ranking member, Mr. Pallone, 5 minutes for questions.

Mr. {Pallone.} I just wanted to follow up on Mr. Pitts' question going down the line, a yes or no because I have other questions. So okay, 2 years you are saying isn't workable but what about 10 years? Can the issues that we referenced here, you know, track and trace, unit level, can they be worked out by then over 10 years? Yes or no, Ms. Gallenagh?

Ms. {Gallenagh.} I think that it is possible to get to a next step. I think that--

Mr. {Pallone.} I am trying to get a yes or no, though, because otherwise I am going to run out of time. Or if you don't want to say yes or no, you can say maybe.

Ms. {Gallenagh.} I would say maybe.

Mr. {Pallone.} All right. Ms. Simmon?

Ms. {Simmon.} I would say maybe if it is a stepwise approach.

Mr. {Pallone.} All right. Mr. Rose?

Mr. {Rose.} Yes, it would.

Mr. {Pallone.} Dr. Davis?

Mr. {Davis.} And I agree with the phased-in approach as well.

Mr. {Pallone.} Mr. Coukell?

Mr. {Coukell.} Can I make a very brief response, Mr. Pallone?

Mr. {Pallone.} Please.

Mr. {Coukell.} The question was asked earlier, would serialization--

Mr. {Pallone.} Yes, no or maybe. I am sorry.

Mr. {Coukell.} Yes.

Mr. {Pallone.} Okay. Dr. Catizone?

Mr. {Catizone.} Two answers. Based upon existing technology, yes. Based upon the history of the industry in this regard, 25 years has not been enough time so they will probably say 10 won't work either.

Mr. {Pallone.} All right. Mr. Berghahn?

Mr. {Berghahn.} Yes, I think it is possible.

Mr. {Pallone.} Okay. I mentioned in my statement, I

have a lot of concerns with the Republican bill. We spent many months engaged with members on a bipartisan, bicameral basis discussing and learning about the problems associated with the security of our drug distribution system, but to put it simply, the draft just doesn't reflect where we landed at the end of those discussions or anything close, in my opinion, and the House Republicans, as I said, didn't consult with us before putting the draft out so I am disappointed, to say the least. But I would like to hear from some of you--I can't do everybody--on what you think is lacking in the bill. So let me start with you, Mr. Rose. What important aspects of a track-and-trace system is lacking or need improvement in the House draft?

Mr. {Rose.} What we really need at this point in time is where are making our investments is a clear end game. We need to know where the goalpost is fixed. We have to--if we are making investments to put serialized numbers on our product and then also to exchange data, we want to make sure that the other parties in the supply chain are also using those numbers and using that information to verify the product and the accuracy and the veracity of that product and

then also the transactions associated with the product.

Mr. {Pallone.} All right. Same for you, Ms. Gallenagh.

Ms. {Gallenagh.} Yes, I think that is correct. In our opinion, once we have serialization, there are many things that are possible with this but the one thing that differs between the past drafts is to not get to a clearly defined place or year date certain for traceability. We do think, though, that the bill draft does lay out the foundation to get there. The core elements again, as we have mentioned, and beginning with serialization and lot traceability, we do think that those are important steps that have to be taken before you get to that end phase.

Mr. {Pallone.} Okay. Mr. Coukell?

Mr. {Coukell.} The current House draft immediately bans all State pedigree laws and doesn't replace them with anything for a period of many years, and it never gets to the second phase that we need to get to. It is like building a set of steps to your front door, building the first step now and having a plan to come back and put the second step on some time later.

Mr. {Pallone.} Dr. Catizone?

Mr. {Catizone.} All the points that were previously made except it should not preempt State laws at this point because if it does so, there is no protection for the consumer. Two, I am confused by the argument about clear standards. They are needed. In 1998, NABP offered to develop national standards. Some people sitting at the table said the industry would do that. It is 25 years later. We still don't have those standards so I am not sure the standards are the barrier. The standards can be built and done so I believe clear direction, no delays, an implementation timeline and standards should be developed as quickly as possible.

Mr. {Pallone.} Thank you. And finally, Mr. Berghahn?

Mr. {Berghahn.} Yes, I think one of the main concerns is the lack of the unit-level trace and the lack of requirements for people in the supply chain to use it. Without that, you really lose visibility on the product and you decrease safety.

Mr. {Pallone.} Well, thank you. I am sorry I couldn't get to all of you but my time is limited.

I just wanted to reiterate that I am disappointed in the

bill. The Senate released a draft last week that was an obvious attempt to address the views of Members on both sides of the aisle. It represents a compromise, and I regret that the House Republicans felt the need to sway so far from the good work that so many Members have put into this issue throughout the last year. So hopefully we can still come up with a good product. I yield back, Mr. Chairman.

Mr. {Pitts.} The chair thanks the gentleman and recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. {Griffith.} Thank you, Mr. Chairman.

Dr. Davis, as you may have heard earlier, I represent a rural area with a lot of community pharmacists, and I want to focus your questions in regard to the e-pedigree program in California. How familiar are you with that program?

Mr. {Davis.} I have a cursory understanding of the specifics of it but again, I understand the concerns of my colleagues in that State as well through discussions.

Mr. {Griffith.} Well, let us talk about that. Do you know how the small pharmacies, the small-town pharmacies in California are dealing with that?

Mr. {Davis.} We are still a few years away from pharmacies having to assume responsibility for their component of the program. But that being said, there are concerns surrounding the ability to absorb the costs and the labor associated with such a system.

Mr. {Griffith.} Now, I understand you are not facing that, but have your colleagues in California given you some idea of what those costs would be for a small-town pharmacy?

Mr. {Davis.} Well, they range. Our problem is, our margins continually shrink at this point, and we have less and less to work with and still maintain our practices as our communities expect them to be maintained. That being the case, the estimates from colleagues range anywhere from thousands of dollars to having to remove employees from their work staff to replace them with this process. So the clear projections aren't intact at this point but there is a significant impact that is going to either impact the profitability and the ability for that business to support its community, or the profitability of the business being able to support its current employee structure.

Mr. {Griffith.} And as a part of those concerns, are

there concerns that some of the small-town pharmacies won't be able to survive with this cost?

Mr. {Davis.} Well, and that is always a question. I would say 99 percent of our technology spent over the past decade has been to comply with regulations and maintain technology and processes to comply by State and federal regulations. That being said, we are worried that sooner or later our spend, our technology spend and our process spend, is going to outpace our ability to absorb it, and there will be doors that close unfortunately.

Mr. {Griffith.} Okay. So there is some concern that some of the pharmacies won't make it, and if that pharmacy happens to be in a small town and the next town over is on the other side of a mountain and 40 miles away, I am going to ask a question that I already know the answer to, but how does that impact the patient?

Mr. {Davis.} I come from a region very much like that, and what happens is, we see that patients are always trying to seek out the best care that they can at any given moment. That limits the patient's access to care and access to the best care that they can possibly get in their locations.

Mr. {Griffith.} And in many cases, it is not just getting, you know, the prescription filled, it is that trust that has been built up. Sometimes you have--in fact, my pharmacist is the son of the pharmacist that we used when I was a child, and that trust has built up and so a lot of times there is a certain element of, you know, do you think this is--am I doing the right thing heading down this direction or they will come in and they will just chitchat about what is going on in their health care, and particularly for senior citizens, they may be getting different prescriptions from different folks and sometimes having that resource is very valuable, is it not?

Mr. {Davis.} I agree, and most of my patients held me as a baby, so when I look them in the eye and I dispense medications or prescriptions to them, that is why this topic is so very valuable to me. I need to know that I am taking care of their families much like they took care of mine through patronage and loyalty. So making sure that we provide safe, secure and efficient medications for them on a regular basis is paramount. My dad always said always make the best decision for your patient and you have made the best

decision for your company, and we are trying to do that in this day and age with this particular topic as well.

Mr. {Griffith.} Yes, and I can't remember what the specifics were but I do know that in regard to one of my children, we went to get the prescription and the doctor looked at it and he said but isn't he also taking this, let me call your doc, and called the doc and they changed the prescription, and I think that is very valuable, and in rural areas, if you eliminate that community pharmacist, you have eliminated a valuable part of that tool. And so that is why I think it is proper that we move forward with a plan but also that we do it in a way that the community pharmacists don't get left out of the formula.

Mr. {Davis.} Thank you, sir.

Mr. {Griffith.} I appreciate it, and yield back my time.

Mr. {Pitts.} The chair thanks the gentleman and now recognizes the gentlelady from California, Ms. Capps, 5 minutes for questions.

Mrs. {Capps.} Thank you, Mr. Chairman.

Dr. Catizone, I would like to ask you about the role

wholesale distributors play in the integrity of the drug distribution supply chain. I know that FDA has stated in its reports on counterfeit drugs that counterfeit drugs are most likely to be introduced as a part of a supply chain that involves multiple wholesaler. That is correct, right?

Mr. {Catizone.} Yes.

Mrs. {Capps.} Because of widespread abuses in the early 2000s, many States have tightened their licensure requirements. I believe Florida and California have especially strong licensure requirements, which they adopted to address specific problems that they had identified. However, there is, as you know, a wide variation in the rigor of different State requirements leaving many vulnerabilities in the system nationwide. My question is whether you agree that there is wide variation in State requirements for wholesale licensing and what has been the public health effect of these varying State requirements?

Mr. {Catizone.} There is variation but not as wide as I think people have reported. As an explanation, the primary wholesaler since the PDMA have done an outstanding job of cleaning up the industry and making sure the supply chain has

its integrity and validity. We have seen problems with secondary wholesalers and pharmacies entering the picture. The patchwork among the States is being equalized through the accreditation program that we have, which has become a de facto national standard, and for States waiting to see what happens with California. If California moves forward, other States would follow suit and that would become a national standard across the board.

Mrs. {Capps.} Okay. Given these differences, you say they are not as wide as we have been led to expect. Do you see any role for the FDA in setting federal standards for wholesale?

Mr. {Catizone.} Yes. What we talked about earlier, the need for standards, the FDA's role is critical to this process because the States have tried to put together a patchwork and we need that overseeing nationally.

Mrs. {Capps.} I get you. So thank you. And now I would like to get your views on the wholesale distributor licensing provisions of the House bill. It does require FDA to set licensure standards for all wholesale distributors. It also requires wholesale distributors to report annually to

the FDA their name, address, dates in which they are licensed and any disciplinary actions that have been taken against them. The FDA would be required to publicly post the names of all wholesale distributors and the States in which they are licensed on their web page. However, the public would not be able to see the disciplinary actions that have been taken against any wholesalers that are on this site. In other words, that is not required in the bill. States would also be prohibited from having any licensure requirement except those established by FDA. Essentially, the new FDA standards could be seen as both a floor and a ceiling. Coming from a State like California with strong licensure standards, naturally I am concerned about that. So my question to you is whether you believe it is appropriate or necessary for the bill to prevent States from establishing or maintaining stricter standards or additional requirements to address local problems a particular State may have experienced. In other words, is this going to prevent kind of individual States from addressing their own situations? Is there any public health benefit to the kind of system being described?

Mr. {Catizone.} The answer is yes, it will prevent, and we are sympathetic to the industry establishing some sort of uniform process, so we would support that, but the States need the discretion to act where there is a significant occurrence within their State, and we believe the bill would address that and even allow the States to be included in discussion. That would be critical.

In regard to the posting of information in response to the compounding issue, we will soon provide a listing of all the pharmacies in the United States, where they are licensed, what disciplinary action has been taken and whether or not they have been inspected. We can put that same system in place for wholesalers that we have accredited as well at no charge for the public.

Mrs. {Capps.} Thank you very much. I just have a few seconds, but Mr. Coukell, could you give us your opinion on these provisions in the House bill? I know it is going to be brief.

Mr. {Coukell.} In the interest of time, I will second what Dr. Catizone said. We think national standards are very desirable. There is an important role for FDA to play there

but we don't want to tie the hands of States at being able to respond to local conditions.

Mrs. {Capps.} I see a couple of heads nodding. Is this shared by anybody else on the panel? Could you indicate?

Mr. {Davis.} We agree as well. National standards, I think, would make it easier for pharmacists to be able to access and purchase and manage prescription products throughout the United States with some conformity.

Mrs. {Capps.} Thank you. Mr. Chairman, I yield back.

Mr. {Pitts.} The chair thanks the gentlelady and now recognizes the gentleman from New Jersey, Mr. Lance, 5 minutes for questions.

Mr. {Lance.} Thank you very much, Mr. Chairman.

To Mr. Rose from J&J, I think New York recently proposed supply chain security legislation similar to standards in California. New York is obviously our neighboring State in New Jersey, and in fact, many pharmaceutical companies in the district I serve have employees from New York. If the California law were fully enacted and if New York follows suit we will have two highly populated States on opposite sides of the country requiring a varying degree of standard

by which the entire industry from the manufacturer all the way to pharmacists must comply. You cite in your testimony a patchwork quilt of regulations, and I am interested in knowing how exactly would establishing a uniform tracking system ensure patient safety.

Mr. {Rose.} Thank you for that question. What it would do is, it would give us security through the whole Nation. These labels that we are putting on our product, this product is sold throughout the State, or throughout the country, and we are talking about interstate commerce here. When we manufacture it, we don't manufacture for New York or California or Florida.

Mr. {Lance.} You do it for the entire Nation.

Mr. {Rose.} The entire Nation, and so as a result, we have this system in place. The entire Nation would benefit from this. All the citizens throughout the Nation would benefit from this system. It would provide a veil and umbrella over top of the supply chain, ensuring that we would keep counterfeit products out of the supply chain. It would give us another level of mechanism, another layer which we could prevent counterfeits from getting in the supply chain

throughout the Nation.

Mr. {Lance.} Thank you. Your testimony reflects a strong commitment to patient safety. How often are products compromised? Under the current system if a product is compromised, how is the manufacturer, J&J or others, alerted to an issue, and how do you address the problem?

Mr. {Rose.} We are alerted to it in many ways. We may have received a call from a patient. We may hear from a doctor or a pharmacist. We have mechanisms in which we handle those calls, and we receive it and then we do an investigation of whether or not that is a counterfeit product or not. So we have mechanisms which we put in place to verify the authenticity of that product and then determine what the next steps might be.

Mr. {Lance.} Thank you. Would anyone else on the panel like to comment on my questions? Yes, sir.

Mr. {Coukell.} Just briefly. I don't think we know how common it is. There was a story in the newspaper this week. It was a tiny story--I think it maybe only ran in Chicago--about a pharmacist who had bought counterfeit drugs from China, I believe it was, and was dispensing them to patients

and had been caught doing that. We don't know how common that is, and that is not to tarnish the industry. You know, 99.99 percent of them are good guys and the supply is generally safe but how common are these problems? I don't think we know.

Mr. {Lance.} Would anyone else like to comment? Dr. Davis?

Mr. {Davis.} I think that again, the pharmaceutical industry, specifically, independent community pharmacists, rely on the rapport that we create with our patients, and it is very important for us to maintain that position. That being said, we take counterfeit medications, diverted medications and how we access and purchase medications in the industry very, very seriously. So that inherently adds a level of security that exists today.

Mr. {Lance.} Thank you. Dr. Davis, let me say that I come from a small town and from a small family law practice, and we rely on a family pharmacy in a small town, and I know that there are many across America who rely on the good work of family pharmacies across this great country.

Thank you, Mr. Chairman. I yield back the balance of my

time.

Mr. {Pitts.} The chair thanks the gentleman and now recognizes the gentleman from Utah, Mr. Matheson, 5 minutes for questions.

Mr. {Matheson.} Thanks, Mr. Chairman, and I do want to thank all the stakeholders, more than just for being here today but there has been a lot of stakeholder involvement for a long time on this issue. I appreciate everyone spending the time to try to come up with a solution.

I have said it in my earlier comments: I think we need a uniform standard in place, a national standard, and it is really for two things. It is to ensure integrity of the drug supply chain at a national level and also alleviate operational burdens. It also is to prevent counterfeit or diverted product from reaching consumers.

So my first question is to Ms. Gallenagh. I was wondering if you could--you mentioned both the concern about operational burdens for stakeholders and the problem with counterfeit product hitting the market. Can you describe for me the operational challenges that your member companies would face in delivering product to their downstream partners

across the country in a situation with no national standard and as different State laws go into effect?

Ms. {Gallenagh.} Absolutely. As you already know, HDMA members are primary wholesalers, so they purchase directly from the manufacturer in most cases and provide their products directly to the pharmacy and providers. The challenge with a 50-State approach, particularly when we start talking about not just pedigree but when we start talking about serialization and traceability really is the great unknown. If we are working on systems to be developed for California, for instance, that is one thing, but we operate national companies, much like the manufacturers. While we are not manufacturing product and we are not actually serializing that product, we will have to have the systems in place to be able to move it within our distribution networks, not just for the State of California but across the country. If we have a different standard for California than, for instance, in New York, which is also looking at this in their state legislature, then we have to segregate product according to region, and it makes it very difficult to know what types of systems we need to develop.

Mr. {Matheson.} Do you have thoughts or can you elaborate on how a bad actor might circumvent more stringent State laws to introduce an adulterated product into a supply chain that doesn't have the national standard?

Ms. {Gallenagh.} Sure. I think, you know, one of the problems with variation in State licensure was is one, the requirements. For example, some States don't choose to inspect wholesaler facilities when they are actually issuing licenses, and so then you end up with, you know, sort of fly-by-night actors or maybe substandard companies applying for and receiving licenses, and this has been shown to be a problem in States like Florida where when they did raise their licensure standards, they eliminated, you know, hundreds of bad actors and really not legitimate companies. I think that the other part of this, though, is also not just the variation in requirements but the variation in actually having to meet a standard bar, you know, one kind of uniform set of requirements so that a bad actor can't move to the next State and get a license there, for instance.

Mr. {Matheson.} Mr. Rose, in your testimony you described your company's experience with serialization of its

products. You know, this is something that has been included in this discussion draft. Can you discuss the role that serialization plays in strengthening the integrity of the drug supply chain both in the near-term impact it could have as well as the role it would play in the longer term?

Mr. {Rose.} Sure. In the near term, I think what it gives us is a capability that would be available in our product if we just looked at the discussion draft in its current form. You would have a serialized number on there that could then be verified, and that becomes important. I think what we would like to see as an end game is where every party in the supply chain is accountable for using that serial number and then also the information that is passed along with it. So we really believe that simple act of scanning that barcode becomes very, very important to help verify that package and ensure that it is the genuine package and then also the transactions that are associated with that package that can verify those transactions as well.

Mr. {Matheson.} Thanks. Mr. Chairman, I will yield back.

Mr. {Pitts.} The chair thanks the gentleman and now

recognizes the gentleman from Texas, Mr. Green, 5 minutes for questions.

Mr. {Green.} Thank you, Mr. Chairman. I got back just in time.

Mr. Coukell, I have some questions about the time frames set up in the House bill. As you know, it doesn't require much until about 5 years after the enactment. At that point it would only require manufacturers to serialize their product and to begin tracing their products by lot number, not unit level. I understand that actually getting a unit-level interoperable electronic system up and running, particularly on the federal level, will take some time and has many complications, but I am concerned the House bill doesn't start us on that path soon enough. In fact, it actually prohibits FDA from going forward with a unit-level electronic system in absence of new federal legislation. My question is, can you comment on this? And I am sure we can all agree that we want to ensure that industry has a reasonable amount of time to comply with whatever federal system we put in place but do we really need to wait until 2018 to even start on a lot-level non-electronic system?

Mr. {Coukell.} Thank you for that question, sir. We absolutely share that concern as well as the view that the appropriate approach is to phase this in in a reasonable time frame that is something between California and what is proposed in the House draft, and I think one of the big impediments to this whole area moving forward has been the lack of regulatory certainty. So leaving 10 years and still not having that certainty is likely to delay the field a very long time.

Mr. {Green.} Mr. Berghahn, do you have any thoughts on that too?

Mr. {Berghahn.} Well, I think that what would be important to consider is that many of the pharma manufacturers and the industry are already preparing today and putting systems in place to serialize an aggregate as we speak, and certainly allowing that to continue would be in the best interests of everyone. It doesn't mean that we are going to get to a national standard in anything resembling the timelines put in place in California but it certainly means that the basis is there. I mean, California is more than 10 percent of the population of the United States, so we

could say if we allowed it to continue as scheduled that by 2017 10 percent of the product in the U.S. supply chain would be serialized.

Mr. {Green.} Mr. Catizone, how about you on that question? I am sure we all agree but do you really need to wait until 2018 even to get started on a lot-level non-electronic system?

Mr. {Catizone.} No, I think that is too long of a delay. I agree with the prior comments but also the caution, if this law preempts all existing State laws, there will be no oversight of the distribution system and the problems that we are seeing now will increase significantly so the medications you receive and I receive and others receive will not be safe if the State laws are all preempted.

Mr. {Green.} Well, I hope that we can work together to ensure we don't have unnecessary delays in implementing a federal system. Although I know that California may have 10 percent, but for a fellow with my Texas accent, we might want to have our own. But I do think we need across State lines regulation as quick as possible. And again, like any other regulation, if you know it is going to happen, you can

capitalize it and prepare for it over a period of years and it looks like the bill may not be as aggressive as some of us would like. It sounds like some of the witnesses share it.

Thank you, Mr. Chairman. I will yield back my time.

Mr. {Pitts.} The chair thanks the gentleman and now recognizes the gentleman from Ohio, Mr. Latta, 5 minutes for questions.

Mr. {Latta.} Well, thank you very much, Mr. Chairman. Again, thank you very much for allowing me to participate in the hearing today. I really appreciate your willingness. And again, I want to thank the witnesses that are here today for their testimony today because we have to have input from everyone, which we have been doing for quite a while now, meeting with the stakeholders.

If I could start with Dr. Davis, and again, what we are looking at here, what we want is safety for the patients out there. We want to make sure that the supply chain is protected, that nothing is adulterated out there, and that when someone receives a medication, they know it is safe for them to take. And I think the chairman was talking about it a little bit earlier but if I could just ask you again, what

is your view of having this phased in over time instead of something happening overnight? And I know that Mr. Griffith and Mr. Lance also kind of alluded to that in their questioning, but if I could ask you?

Mr. {Davis.} Again, I think our concern is of the level of complexity that occurs at the patient-to-practitioner level. We have a lot of very specific business rule questions surrounding lot-level versus unit-level serialization and tracking. What would happen if a patient had a prescription that we prepared for them, they decided that it was too expensive and we had already removed it from the packaging and the ability for it to be traced any further? How do we get that back into our drug supply? How do we take processes such as that to make sure that our businesses remain profitable and don't waste dollars on unused inventory, unreturnable inventory? How do we access the information and utilize the information, and how do we insert those processes in our current practices?

We are kind of dependent--actually, not kind of. We are absolutely dependent on our technology vendors to provide us with the capabilities, and while we are wholeheartedly in to

continue working with our partners to create a system in the United States and to maintain the system, we want to make sure that it is built in an efficient, affordable manner for us to implement in our communities.

Mr. {Latta.} Thank you.

Mr. Rose, in your testimony, you state that this legislation incorporates many of PDSA's proposed provisions including a uniform national standard with a phased implementation. I am just kind of following up on that. How important is that phased implementation?

Mr. {Rose.} We believe the phased implementation is important. The California law in many regards goes from zero to 60 very quickly so you go from serialization to this interoperable system. We really believe what is important here is to make sure that we have an approach that allows parties in the supply chain to prepare properly, to adopt these systems. As Dr. Davis mentioned, the pharmacies have some work to do, so do the wholesalers and the manufacturers. We still have a lot of work to do, as I indicated in my testimony. We have to give people some time to put those systems in place and make sure, to work out the

interdependencies between the different stakeholders in the supply chain. That is where the real phased-in approach is really required is, how do we exchange data with the customers that we work with. It is very, very critical to do this, and it is not just the forward supply chain but it is also the reverse supply chain as well.

Mr. {Latta.} Let me follow up with that. In your estimation, has California given you and the industry the guidance it needs for that operational clarity on how that law is going to work?

Mr. {Rose.} We still are awaiting guidance on the interoperable system. Also, I think as I recall, and I will have to get back to you on this, but they have issued some guidance around grandfathering and I think they issued some guidance recently around inference, but we really do need to have much more guidance from them about their interoperable system, how that is going to work. That is a key piece right now.

Mr. {Latta.} And I could turn real briefly, and I do mean briefly, Ms. Gallenagh, I believe we all share the same goal of improving the safety and the efficiency of the drug

supply chain, as I mentioned earlier, that we want to make sure that everyone is safe out there. However, the argument has been made that what has been proposed to date doesn't go far enough to satisfy all the elements of a comprehensive system that some had envisioned. Could you in practical terms talk about how the elements of this proposal would create a platform upon which to build future technologies?

Ms. {Gallenagh.} Absolutely. I think the intent of the bill, first of all, starts with what we traditionally call an interim pedigree step, essentially a direct purchase option and a full pedigree option across the board so that would be uniform across the country. It sets higher licensure standards to close those gaps across the States, and I think what we are all forgetting here when we talk about looking for the perfect solution is that this draft requires serialization for all products at the unit level regardless of where they are in the United States. I think that that alone sets a great foundation for what the industry can do with the product and with the systems once they are built. The lot traceability as a phase-in I think absolutely also lets us know how to work with that product and the serial

numbers in a measured, responsible way and in a way that is practical for all of the supply chain partners.

Mr. {Latta.} Thank you very much, Mr. Chairman, and my time is expired and I yield back.

Mr. {Pitts.} The chair thanks the gentleman. That concludes the questions of our members. I am sure they will have additional follow-up questions, other questions, and we will send them to you. We ask that you please respond promptly.

I would like to thank all of the witnesses for appearing today, two excellent panels, a lot of good information, a very important issue as we move forward, and I remind members they have 10 business days to submit questions for the record. The members should submit their questions by the close of business on Thursday, May 9th.

Without objection, the subcommittee is adjourned.

[Whereupon, at 12:49 p.m., the Subcommittee was adjourned.]