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IMPROVING PREDICTABILITY AND TRANSPARENCY

IN DEA AND FDA REGULATION

MONDAY, APRIL 7, 2014

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 3:01 p.m., in Room 2123, Rayburn House Office Building, Hon. Joseph R. Pitts [chairman of the subcommittee] presiding.

Present: Representatives Pitts, Burgess, Whitfield, Shimkus, Murphy, Blackburn, Lance, Griffith, Bilirakis, Ellmers, Upton (ex officio), Pallone, Dingell, Green, Barrow, and Waxman (ex officio).

Staff Present: Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Noelle Clemente, Press Secretary; Paul

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Edattel, Professional Staff Member, Health; Sydne Harwick, Legislative Clerk; Robert Horne, Professional Staff Member, Health; Carly McWilliams, Professional Staff Member, Health; Heidi Stirrup, Health Policy Coordinator; John Stone, Counsel, Health; Ziky Ababiya, Minority Staff Assistant; Eric Flamm, Minority FDA Detailee; Elizabeth Letter, Minority Press Secretary; Karen Lightfoot, Minority Communications Director and Senior Policy Advisor; and Karen Nelson, Minority Deputy Committee Staff Director of Health.

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Mr. Pitts. The subcommittee will come to order.

The chair will recognize himself for an opening statement.

Today's legislative hearing focuses on three bills designed to improve the predictability and transparency in Drug Enforcement Administration and Food and Drug Administration regulation.

H.R. 4069, the Ensuring Patient Access and Effective Drug Enforcement Act, introduced by Representatives Marino and Blackburn will facilitate greater collaboration between industry stakeholders and regulators in an effort to combat our Nation's prescription drug abuse epidemic.

[The information follows:]

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Mr. Pitts. H.R. 4250, the Sunscreen Innovation Act, introduced by Representatives Whitfield and Dingell, seeks to expedite the FDA's approval process for active ingredients in sunscreens that have long been approved for use in places like Europe, Canada and other countries to ensure that U.S. consumers have access to the safest, most effective sunscreens available.

[The information follows:]

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Mr. Pitts. And H.R. 4299, the Improving Regulatory Transparency For New Medical Therapies Act, which Ranking Member Pallone and I introduced.

[The information follows:]

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Mr. Pitts. Mr. Pallone and I introduced H.R. 4299, which seeks to improve the transparency and consistency of DEA's scheduling of new FDA approved drugs under the Controlled Substances Act, CSA, and its registration process for manufacturing controlled substances for use in clinical trials. Ultimately, this will allow new and innovative treatments to get to patients who desperately need them faster. It now takes on average well over a billion dollars and 14 years from the time a drug is discovered to the time of approval.

This committee has taken steps to provide more transparency and consistency in the drug approval process through the Prescription Drug User Fee Program and a commitment to review goals imbedded in the PDUFA agreements. However, drugs that contain substances that have not been previously marketed in the United States and that have abuse potential must also be scheduled under the CSA by the DEA before they can begin marketing their product. But under the CSA, there is no deadline for the DEA to make a scheduling decision, and the delays in DEA decisions have increased nearly fivefold since the year 2000. This lack of predictability in the timing of DEA's scheduling decisions leads to unnecessary uncertainty in the drug development process and needless delays in patients' access to new therapies.

H.R. 4299 simply requires the DEA to issue an interim final rule 45 days after it receives FDA's scheduling recommendation for a new drug, allowing patients access to new therapies 45 days after FDA

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approval. DEA would retain its authority to subsequently transfer the drug between schedules under the Section 201 of the CSA.

This bill also establishes a timeline for DEA to grant approval of manufacturers' applications to register controlled substances not yet approved by FDA to be used in clinical trials, allowing companies to properly plan clinical trial schedules for prospective new therapies. This provision will get products to the market faster because innovators will be able to get clinical trials under way in a timely and predictable way, which is critical to drug developers and patients alike.

H.R. 4299 requires that if the DEA has not made a final decision on whether to approve a registration application for products in the investigational new drug, IND, phase within 180 days of submission of the application, then the DEA shall provide notice to the applicant on the outstanding issues that must be resolved in order to reach a final decision and an estimated date on which a final decision on the registration application will be made.

Such a solution does not force the DEA to make a particular decision but will provide transparency to the process so companies can better plan when regulatory decisions will be made.

I would like to thank all of our witnesses for being here today. I look forward to having a constructive discussion on these legislative proposals. These bills touch on very important issues for this

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committee, and they offer an excellent starting point for finding solutions.

I yield back the balance of my time and, at this point, recognize the ranking member, Mr. Pallone, 5 minutes for an opening statement.

[The prepared statement of Mr. Pitts follows:]

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Mr. Pallone. Thank you, Chairman Pitts.

Today's important hearing will examine a number of bills that aim to provide predictability and transparency for medicines and other products.

This committee has an important balancing act it must play. As prescription drug abuse threatens the safety and health of too many people in this country, we must find ways to combat this growing public health epidemic. At the same time as we examine different policies to address this issue, we must also ensure patient access to necessary medications. We all agree that the Federal Drug Administration, the FDA, and the Drug Enforcement Agency, the DEA, have critical missions.

FDA ensures that innovative medicines and other products are safe and effective, while the DEA safeguards our communities from illegal and diverted drugs. Once the FDA approves a drug, the DEA's role is to utilize the scheduling process under the Controlled Substances Act, which helps them to keep the medicine in the hands of those who need them and away from criminals and abusers who aim to break the law or, in some unfortunate cases, abuse these drugs.

While both agencies typically work independently, it is important that their authorities and actions work in a complimentary way. There is no question that DEA has an important role in combatting drug abuse, but there must be some recognition by DEA of the legitimate therapies that improve the public health.

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One of the bills under consideration today is one that I am proud to sponsor with Chairman Pitts. H.R. 4299, the Improving Regulatory Transparency For New Medical Therapies Act, aims to improve the DEA's scheduling process for new FDA approved drugs under the Controlled Substances Act and the registration process for the use of controlled substances in clinical trials. In recent years, this committee has worked successfully to improve review of new medications. Without weakening FDA oversight, we have given manufacturers and patient groups a more predictable process allowing patients to get timely access to the latest innovation therapies available.

But unfortunately, when a medicine has abuse potential, the DEA's authorities under the Controlled Substances Act are hindering this progress. Specifically the draft bill would require DEA to make a final determination 45 days after receiving FDA's scheduling recommendation for a new drug. Additionally, it would generate more transparency in the application process for clinical trials by requiring the DEA make a final determination within 180 days or provide the applicant with details about what outstanding issues remain unresolved. I hope we can better understand today what is happening at the DEA and find ways to address it.

In addition today, we will examine H.R. 4069, the Ensuring Patient Access and Effective Drug Enforcement Act, introduced by Representatives Blackburn and Marino. The bill aims to improve and

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better coordinate enforcement efforts within the drug supply chain regarding prescription drug diversion and abuse. It also aims to curtail unnecessary supply chain disruptions that may be affecting patient access to needed medications.

And lastly, we will hear from our witnesses about H.R. 4250, the Sunscreen Innovation Act, introduced by Representatives Whitfield and Dingell. Skin cancer is the most common cancer in the U.S., and one in five Americans will develop skin cancer in their lifetime. Research has shown that sunscreen helps reduce the risk of skin cancer and is essential to protecting the public. However, to date, the FDA has not approved a new sunscreen ingredient in nearly two decades. This is a real issue that needs to be addressed, and I am hopeful we can all work together to establish a process that promotes the timely review of sunscreen ingredients while ensuring consumer safety and product efficacy.

So I want to thank all of our witnesses here today.

Dr. Woodcock, I don't know is this the second time in 2 weeks, and I look forward to your comments.

I would like to yield the remainder of my time to Mr. Dingell, who is the lead sponsor, Democratic sponsor, of H.R. 4205.

[The prepared statement of Mr. Pallone follows:]

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Mr. Dingell. Mr. Chairman, I thank the gentleman, and I thank you and commend you for this hearing.

I am particularly grateful to the gentleman from New Jersey for his courtesy to me. I ask unanimous consent that my remarks be extended in the record.

And I would like to address H.R. 4250 and particularly with my concerns as they might exist with regard to Food and Drug. There is no reason why a piece of legislation like this is necessary after 10 years, and why it is that the Congress of the United States has not received the counsel of Food and Drug, that they have had need of legislation of this kind to address a serious problem like skin cancer. This is a great shame indeed. It is the kind of thing that causes distress on the part of the public, puts the public at risk, and puts them at risk of a particularly deadly form of cancer, which is one of the most frequently achieved levels of cancer and kinds of cancer in our society.

Food and Drug did not come up here to talk to us about it. We think that this is legislation, which was crafted somewhat with and somewhat without the assistance of the Food and Drug Administration, but it would have been so much better had Food and Drug come up here with the legislation earlier on.

I want to thank you for holding this hearing, Mr. Chairman.

And I want to particularly thank my good friend Mr. Whitfield for

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his leadership and responsibility in this matter. I hope that we are going to have supportive testimony from Food and Drug and that the Food and Drug Administration will not let this kind of thing happen again.

Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Dingell follows:]

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Mr. Pitts. I now recognize the chairman of the full committee, Mr. Upton, for an opening statement.

The Chairman. Thank you, Mr. Chairman.

Today the subcommittee will hear testimony on what I think will be three bipartisan bills that address important problems facing the nation. First, Chairman Pitts and Ranking Member Pallone are collaborating on H.R. 4299, the Improving Regulatory Transparency for New Medical Therapies Act. Their bill would provide more certainty among the Drug Enforcement Administration's review of scheduling decisions for new drug products.

Second, Vice Chair of the Committee Marsha Blackburn is working with Representative Marino on H.R. 4069, the Ensuring Patient Access and Effective Drug Enforcement Act. This bill establishes a collaborative and coordinated approach to the prescription drug abuse crisis that certainly is plaguing our local communities across the country. And finally, we are going to be discussing H.R. 4250, which is cosponsored by Ed Whitfield and Mr. Dingell. Everyone does seem to agree that the current system for approving sunscreen ingredients is broken. It is long overdue that we find a solution to the current backlog of sunscreen ingredients pending at the FDA, and this bill does it. I want to commend my colleagues for working together to develop these legislative solutions. We have had a strong record of bipartisan success this Congress in our work to improve public health, and these

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bills further that effort.

And I yield the balance of my time to Ms. Blackburn.

[The prepared statement of The Chairman follows:]

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Mrs. Blackburn. I thank the chairman for yielding, and Mr. Pitts for the hearing.

And, yes, I have worked with Congressman Marino; 4069 is a piece of legislation that we have put some effort into to come up with the Ensuring Patient Access and Effective Drug Enforcement Act. And there is a necessity to clarify a couple of definitions and provide some certainty and some consistency. We will talk more about that.

And Mr. Chairman, I would like to submit my full statement to the record.

Mr. Pitts. Without objection.

Mrs. Blackburn. And also three letters of support for our legislation, one from FedEx, another National Association of Chain Drugstores, and then also the Alliance to Prevent Abuse of Medications.

Mr. Pitts. Without objection, so ordered.

[The information follows:]

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Mrs. Blackburn. And I appreciate that so much.

Congressman Marino and I are working to clarify the two phrases consistent with public health and safety and how that corresponds to substantial relationship to preventing diversion and abuse of controlled substances and further define imminent danger by providing clarification and harmonizing the CSA with other statutes using the imminent danger standard, such as the Federal Mines Safety and Health Act. And these definitions do matter. We all realize that.

We are also interested in moving forward with the prescription drug abuse working group, which would give government, public policy, and industry the ability to collaborate and provide recommendations to Congress on initiatives to reduce prescription drug diversion and abuse.

This is an issue that has grown to epidemic proportions in our country, and we had about 27,000 unintentional drug overdose deaths which occurred in the U.S. during 2007 and a number that has increased fivefold since 1990.

At this time, I yield the balance of my time to Mr. Whitfield.

[The prepared statement of Mrs. Blackburn follows:]

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Mr. Whitfield. Thank you very much.

FDA has not expanded its approval list of sunscreen ingredients since 1999, even though many innovative products have been used safely for years abroad. In fact, there are eight pending applications, all of which have been used in other parts of the world. Some of them have been under the process of being scrutinized for 12 years.

That is why we have introduced the Sunscreen Innovation Act, Mr. Dingell and others, and we look forward to working with FDA because we need to pass legislation to make sure that this process is speeded up in some way, and I yield the balance of the time to the gentleman from Texas, Mr. Burgess.

[The prepared statement of Mr. Whitfield follows:]

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Dr. Burgess. I thank the gentleman for yielding the time.

Glad to have both the FDA and the DEA here today. Time is short. Let me confine my observations to the Drug Enforcement Administration. I am hearing that manufacturers and distributors are having a difficult time working with your agency. They say the relationship is not collaborative. It is one where intimidation and lack of communication is all too common. I am willing to work with anyone to close loopholes to target bad actors and even propose policies that might raise the ire of those in my party, but I will not sit by while patients cannot access lawfully prescribed medication. No doctor, no wholesaler, no pharmacist, should live in fear that in their attempt to alleviate human suffering, they are likely to be put out of business.

I understand your mission, but I want to know that you have a strong voice for patients, for providers, and I want you to know the effect that you have. It is necessary to enter conversations on everything from the scheduling of certain drugs to prescribing drug abuse with an interactive perspective.

No one should stand down in the face of bullying, aggressive and narrow-minded tactics.

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

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Dr. Burgess follows:]

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Mr. Pitts. I will now recognize the ranking member, Mr. Waxman, for 5 minutes of opening statement.

Mr. Waxman. Thank you, Chairman Pitts, for holding this hearing today.

Today's hearing focuses on three bills, all addressing important issues. Mr. Marino and Mrs. Blackburn's bill, H.R. 4069, makes changes to the Controlled Substances Act that will help drug distributors and others work with the DEA to keep controlled substance prescription drugs out of the hands of drug abusers. It also will help them avoid inappropriately limiting legitimate access to these same drugs by patients who need them. Achieving that balance is a difficult challenge. I will be interested to learn DEA's views on the bill.

Mr. Pitts and Mr. Pallone's bill, H.R. 4299, would speed up DEA decisions on scheduling new FDA approved drugs containing controlled substances so they could get to patients more quickly. It also would speed up the DEA registration process, allowing the manufacture and distribution of controlled substances for use only in clinical trials. It is aiming to address a problem faced by those with epilepsy and other patients, the delay in getting a new FDA approved controlled substance medication to patients in need. I think their bill could make a significant contribution to solving this problem, and I applaud them for introducing it.

DEA's mission and focus is combatting drug abuse. I applaud its

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work in that area. At the same time, we need to find a way for new FDA-approved controlled substance medicines to get to patients who need them more quickly, and I hope DEA shares that goal and will work with the committee to achieve it.

Mr. Whitfield and Mr. Dingell's bill, H.R. 4250, aims to speed up FDA's regulatory decisions on sunscreens that have been marketed in other countries for at least 5 years. Sunscreens are an important tool in lowering the risk of skin cancer. Skin cancer is the most common cancer in the United States, and its incidence continues to grow. Melanoma, the deadliest kind, kills over 9,000 Americans a year. One way to prevent skin cancer is to minimize exposure to UV rays.

I have had a long interest in this issue. I have been working with Chairman Upton to protect teenagers from the dangers of sun lamps. Getting better sunscreens to market and increasing sunscreen use is another critical element in the fight against skin cancer. We need a regulatory system that enables safe and effective sunscreens to make it to the market in a reasonable amount of time. Under our current system, sunscreen applications have been languishing for 5 to 10 years. I don't think anyone could call that a reasonable amount of time.

Mr. Whitfield and Mr. Dingell, working with the PASS Coalition, have made a good faith effort to come up with a bill that would help FDA reach decisions in a timely fashion on such sunscreen applications. I strongly support those efforts. However, I do have concerns with

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a number of elements of the bill, most notably the bill effectively cedes FDA's jurisdiction to an advisory committee. If the advisory committee recommends approval, the approval goes into effect, unless FDA rejects it within 45 days, and even then, the burden is on FDA to justify its decision not to accept the recommendation. I think this would be a bad precedent.

I applaud the bill's sponsors and the PASS Coalition for working on this issue and developing a bill for us to consider. That alone is a step forward. I share the goal of having an FDA review process that enables safe and effective sunscreens to get to market as quickly as possible. I recognize that the current system does not achieve that goal. I hope FDA will commit to work with the committee and with the coalition and other stakeholders to reach that goal.

I look forward to the hearing today and, while I may not be here all of the time, to reviewing the testimony from our witnesses.

Thank you, Mr. Chairman. I would be happy to yield my time if anybody seeks it. If not, I yield it back.

Mr. Pitts. The chair thanks the gentleman.

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[The prepared statement of Mr. Waxman follows:]

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Mr. Pitts. That concludes the opening statements. All members' written opening statements will be submitted for the record.

We have two panels before us today. On our first panel we have Dr. Janet Woodcock, director, Center for Drug Evaluation and Research of the U.S. Food and Drug Administration.

Thank you again for coming to the subcommittee.

And Dr. Joseph Rannazzisi, deputy assistant administrator, Office of Diversion Control, Drug Enforcement Administration.

Your written testimony will be made part of the record. You will be each given 5 minutes to summarize. Thank you for coming today.

And Dr. Woodcock, you are recognized for 5 minutes for your opening statement.

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STATEMENTS OF JANET WOODCOCK, M.D., DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION; AND JOSEPH T. RANNAZZISI, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION

STATEMENT OF JANET WOODCOCK, M.D.

Dr. Woodcock. Thank you and good afternoon.

I am Janet Woodcock, director of the Center for Drug Evaluation and Research at FDA, and thank you for the opportunity to discuss important issues concerning sunscreen products.

Now, as you know, manufacturers must have an approved new drug or abbreviated new drug application before they can market a drug in the United States, unless they have a drug that complies with an over-the-counter monograph. The monograph is a regulation that describes the conditions OTC drugs must meet. This allows these monograph products to be offered in many different configurations to the public without filing different applications. And this has been a very successful program. There are over 100,000 products out there, OTC products out there, it is estimated, that are monograph products. And most sunscreens are marketed in the U.S. under the sunscreen monograph.

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Now, the FDA must conclude that an ingredient is generally recognized as safe and effective for the condition of use if it is going to be put into a monograph. But the real world conditions of use and what is scientifically considered safe and effective can change over time. And by over time, I mean over decades of time. And in the 1970s, when examination of sunscreens began in the OTC drug review, they were used primarily on a seasonal basis to prevent sunburn. That is what sunscreens were thought to be for back in the day. And the Sunscreen Advisory Panel thought people would be exposed to these sunscreen active ingredients in modest amounts and for short intermittent time periods. And also the ingredients weren't thought to get below the skin, so systemic exposure to these drugs was not a concern. This was before we had all the transdermal skin products that we have now -- we realize for a hypertension and so forth -- that are delivered through the skin. The advisory panel safety evaluation focused on ensuring that sunscreen products caused minimal skin irritation and sensitivity and then, on their efficacy, just that they prevented sunburn.

Today people are urged to apply sunscreen in generous amounts and to reapply it frequently and to use it year round, resulting in exposure to the products that is massively greater than what was contemplated originally in the monograph. In addition, sunscreens are applied all over babies and children repeatedly as well to prevent them from the deleterious effects of the sun.

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There is increasing evidence, though, that some sunscreen ingredients are absorbed through the skin, and that leads to systemic exposures that are chronic, that have not previously been understood or anticipated. This shift in sunscreen use, together with advances in scientific understanding and our own safety evaluation methods have raised questions about what is needed to assure sunscreen safety.

FDA has undertaken major actions on important sunscreen issues in the last several years. We have not been inactive. In 2011, we published a regulation that updated efficacy testing and sunscreen labels. This put on what people are used to now the broad spectrum claim that we urge people to use to protect against various types of UV, and also it put information in the label about preventing skin cancer and about decreasing skin aging, so important information about the use of these sunscreens.

We also issued a proposed rule with a maximum SPF value of 50 plus for all sunscreen monograph products, and we put an advance notice of proposed rulemaking about additional information on the safety and effectiveness of various dosage forms, like sprays, that raise new concerns about flammability, for example, and inhalation.

We have also been evaluating these Time and Extent Applications to add eight new ingredients to the sunscreen monograph. This process, established in 2002, provides a potential pathway for newer active ingredients. We recently sent sponsors letters on two of these

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applications, giving them feedback and noting that their record is insufficient to establish that they are safe for OTC sunscreen use.

We will be holding a public meeting later this year to further clarify our thinking about safety testing for all OTC sunscreen products. And given the expansion of sunscreen use and scientific advances since the OTC evaluation began, our evaluation must include potential endocrine or other effects from systemic absorption.

Now this process has taken too long. I agree with that, and we really recognize the entire OTC monograph process is outdated, and about 2 weeks ago, we had a public hearing to discuss ways we might be able to modernize the process.

In closing, the OTC monograph process that had historically been so successful is no longer really serving the needs of consumers, industry or the FDA. We have embarked on consideration of how to revise it to work in the current environment, and the problem with sunscreens is really a microcosm of the larger issues we have with the OTC monograph process. Thank you.

Mr. Pitts. The chair thanks the gentlelady.

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[The prepared statement of Ms. Woodcock follows:]

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Mr. Pitts. I now recognize Mr. Rannazzisi for 5 minutes for an opening statement.

STATEMENT OF JOSEPH T. RANNAZZISI

Mr. Rannazzisi. Thank you, sir.

Chairman Pitts, Ranking Member Pallone, distinguished members of the subcommittee, on behalf Administrator Michele Leonhart and the men and women of the Drug Enforcement Agency, thank you for the opportunity to discuss today the drug scheduling process and the registration and verification suspension process.

First, the DEA was not given the opportunity to comment when legislation that was pending before the subcommittee was drafted. The Department and the administration has not taken a position on the legislation. Therefore, I must emphasize that I am unable to discuss with you the specific details of the legislation.

The Controlled Substances Act provides the DEA with the authority to administratively control substances with abuse potential. As fully explored in my written testimony, generally, the complexity and length of time to complete the scheduling process depends on many variables. There are two important points I will emphasize.

With respect to newly approved medicines, the DEA initiates the scheduling process when it receives a recommendation from HHS. The

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DEA might receive the recommendation before or after the approval for marketing. One recent example I will share involves two similar medications that are indicated for epilepsy. The DEA completed the scheduling process in about the same time, 10 and 11 months from the time we received the recommendation. However, in one instance, we received the recommendation 5 months before the drug was marketed -- was approved for marketing. In the other instance, we received it 4 months after it was approved for marketing. The result was that one drug was controlled 6 months after market approval, and the other drug was controlled 14 months after market approval. The experience here is that the sooner DEA receives the recommendation to control, the closer to market approval a drug can be scheduled.

The next point also concerns timing. Patent holders of recently approved medicines have paid fees to expedite their products through the market approval process, but that is not the process when it comes to scheduling. Like most Federal law enforcement agencies, DEA must prioritize resources to meet the threats and to accomplish the mission. Any perceived delays to control newly approved drugs in the past 3 years must be viewed as part of a bigger picture.

In the 13 years from 1997 to 2010, the DEA controlled nine new pharmaceutical drugs and temporarily controlled four substances to avoid an imminent hazard to public safety, but in the last 3 years, DEA has controlled four new pharmaceutical drugs and 28 different

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synthetic drugs to avoid imminent hazard to public safety. To be sure, the additional responsibility to control 28 different synthetic drugs had an effect on the time to control new pharmaceuticals.

In 2010, designer drugs exploded in the retail market, resulting in serious injury and death across America. Faced with the responsibility to get these drugs off the retail shelves, the DEA had no choice but to control these substances as quickly as possible. The DEA acted to stop the imminent hazard these drugs caused, which in turn required significant resources.

Another use of DEA's administrative authorities to stop an imminent threat is the authority to immediately suspend a DEA registration. As a law enforcement agency with a regulatory function, the DEA has the authority to revoke a registration and also immediately suspend a registration that poses an imminent danger. In addition to revocation and immediate suspension, there are other nonpunitive actions available to DEA, including a letter of admonition or an informal hearing.

From 2007 to 2013, the DEA issued approximately 5,500 letters of admonition and held approximately 118 informal hearings. This fiscal year to date, DEA issued less than 20 orders to show cause and immediate suspensions combined. When the DEA issues a show cause order, the registrant is afforded the opportunity to present his case at a formal hearing in front of a neutral fact finder before any action may be taken.

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An immediate suspension is authorized during the pendency of the show cause proceeding and is effective immediately. Immediate suspensions are by law reserved for those entities that are in imminent danger to public health and safety.

. The DEA's administrative enforcement authorities are important tools in DEA's arsenal to ensure compliance, deter and prevent diversion, and ensure that every registration is within the public interest. Without these administrative tools, civil and criminal sanctions would increase, and it would be tremendously more difficult to protect the public health and safety from the diversion of pharmaceutically controlled substances.

In closing, I would like to comment on other testimony that the subcommittee would hear today. Some of the witnesses may assume to advocate on behalf of DEA, representing that they believe new legislation will help DEA. I encourage you to look beyond the self-interested statements of witnesses who are here to lobby you to protect their paying clients, present and future, from administrative sanction.

The DEA has a responsibility to maintain the closed system of distribution established by the Controlled Substances Act. As such, the DEA's sole interest is protecting the public from harm. That is what the administrative and regulatory process is for. That is what we do best: Keeping industry in compliance and protecting the public

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health and safety.

I appreciate the invitation to appear today and look forward to your questions. Thank you.

Mr. Pitts. The chairs thanks the gentleman.

[The prepared statement of Mr. Rannazzisi follows:]

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Mr. Pitts. We will now go to questioning. I will recognize myself for 5 minutes for that purpose.

Dr. Woodcock, with respect to scheduling of controlled substances, would you elaborate on what types of data FDA uses in conducting its analysis for a new molecular entity prior to sending the agency's recommendation to DEA, and what is the purpose of this evaluation? Do the scientists at FDA do everything they can to make this evaluation as comprehensive and accurate as possible?

Dr. Woodcock. Certainly. Well, the FDA and our partner, we work with NIDA, are trying to predict, based on what data we have, how abusable, how attractive, a drug may be once it is out on the market for abuse and addiction. We use everything from the structural knowledge of the drug to animal studies, and there are animal studies that can look at whether the animals find the drug attractive, to actual human studies, likability studies, where we ask experienced humans what they think of the effects of the drug, and that is very illuminating.

We put all that information together plus epidemiology on similar and related substances, and basically, we do what is called an eight factor analysis, and we put all those factors together into an analysis.

Mr. Pitts. Thank you.

Mr. Rannazzisi, what is the average time it takes DEA to schedule a new molecular entity after your agency receives FDA's recommendation?

Mr. Rannazzisi. I don't know what the average time is, but it

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is very product specific. It depends on when we receive the recommendation. See, in some products, we receive the recommendation way before approval, so we could go ahead and start our eight factor because like my colleague, we have to do an eight factor as well, and three of the factors are based on DEA findings.

Mr. Pitts. And why does it sometimes take over a year to make this determination?

Mr. Rannazzisi. Depending on when we receive the recommendation, generally there could be problems. When we get the recommendation, we have to send it back to FDA for a clarification. There might have been something that FDA missed that we want them to look at. Remember, when we take the final scheduling action, and we publish it, there may be a hearing and DEA, not FDA, but DEA has to justify the schedule that that product is being put in. We have to provide the evidence that that drug is properly scheduled. So if the scheduling action is questioned and a hearing is requested, DEA is the one that goes into court and justifies the scheduling. We bring FDA in to provide testimony, but in the end, it is our scheduling action based on A-11.

Mr. Pitts. In your opinion, are there instances where the agency has taken too long to schedule a new molecular entity after FDA approval?

Mr. Rannazzisi. No. In fact, there was a statement I think

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somebody made with a fivefold increase since 1999. I have no idea where that number came from because you have to look at when we received the actual recommendation. It is not when the drug is scheduled. We have to go back because, like as I said, sometimes we get the recommendation well after the approval has been done, 3 to 4 months, so that is when we start. We cannot start the process until we receive the eight factor from HHS.

Mr. Pitts. Section 201-B of the Control Substances Act, it states that DEA is bound by the medical and scientific recommendations of the FDA. Is that correct?

Mr. Rannazzisi. That is correct.

Mr. Pitts. And FDA's recommendations are made after a thorough analysis of the potential for abuse and misuse of the drug products, right?

Mr. Rannazzisi. That is correct.

Mr. Pitts. Now, after a drug product is scheduled and available for marketing, it can be rescheduled. Would you explain how DEA participates in that process and how often has DEA initiated these rescheduling discussions?

Mr. Rannazzisi. Rescheduling action, most recently we have one pending with hydrocodone. We did a scheduling action on carisoprodol, which we had to go and justify in court. Carisoprodol is a muscle relaxant that was not scheduled. We requested a medical and scientific

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evaluation from HHS on two or three occasions. We finally got the justification necessary to reschedule it. It was challenged. We went into court. We justified based on evidence, and we prevailed. It just depends on the specific drug that we are dealing with at the time. Hydrocodone is pending. That is still a pending action.

Mr. Pitts. The chair thanks the gentleman.

My time is expired. I recognize the Ranking Member, Mr. Pallone, for 5 minutes of questions.

Mr. Pallone. Dr. Woodcock, do you want to respond to what Mr. Rannazzisi said about, you know, when the clock stops, in other words -- I mean, when the clock starts, that even after you have approved the drug, it may be like another 4 months or so before its scheduled? He was talking about that.

Dr. Woodcock. Well, there are multiple clocks involved here. We are working off the user fee clock that has been agreed to by Congress and so forth, and sometimes there may be additional information that we need for the eight factor that may come in at different times, and so that might prolong that particular determination. At the moment, that doesn't prevent us from approving the drug, so we go ahead and approve the drug, but we are still working on information that we may have received later in the cycle, which might mean a gap between the time the drug is approved, and that is information on safety and efficacy, and the drug, when we can make a recommendation for

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scheduling.

Mr. Pallone. I am going to go back to Mr. Rannazzisi. I just want to get a little information on so other aspects of this scheduling process. I know Mr. Pitts has addressed this in some way, so I apologize if some of these questions are repetitive, but your responses are significant as we try to move this bill. What is the percentage of times in which DEA scheduled a new drug into a class different from which FDA recommended?

Mr. Rannazzisi. I don't know of a time where we have not scheduled the drug outside of the recommendation.

Mr. Pallone. Okay. So there has never been any instance?

Mr. Rannazzisi. Not that I can remember.

Mr. Pallone. Okay. Can you tell us how long it takes on average for DEA to issue a final scheduling decision starting from the time DEA receives a scheduling recommendation from the FDA?

Mr. Rannazzisi. Again, I can't tell you on average because different drugs require different time periods. It just depends on the information that came back from the HHS on the eight factor analysis. It depends on when we received that information. It depends on if there needs clarification on any one of the eight factors. It is variable. It depends, especially on new molecular entity, because a new molecule entity, we have to do our research, which we try and do as soon as possible. But, again, it involves when we receive

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the recommendation.

Mr. Dingell. Will you yield?

Mr. Pallone. Sure.

Mr. Dingell. Will you explain why you have to do your research and why you can't use FDA's research and why you can't get a memorandum of understanding as to how you are going to cooperate?

Mr. Rannazzisi. Actually, we do have a memorandum of understanding pending. It is being reviewed by both agencies.

Mr. Dingell. I am not hearing you say that today.

Mr. Rannazzisi. Well, we have a memorandum of understanding pending, and we are working out the differences in the MOA, but I am pretty confident that we will have that in place very shortly. But in the meantime, again, our scientists are the ones who will be testifying in the hearing when it is challenged.

Mr. Pallone. I am going to run out of time, so I just want to turn now to the process for registering manufacturers and distributors of controlled substances. What is the statutory deadline for making a decision on an application to become registered as a manufacturer or distributor of a controlled substance, or is there no deadline?

Mr. Rannazzisi. I think it is within a reasonable time period.

Mr. Pallone. Within a what you said?

Mr. Rannazzisi. I think it is a reasonable time period. Once we receive all of the data, we do an investigation of the physical

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location. We grant the registration. As long as they have the proper, appropriate, State licensing.

Mr. Pallone. How long does it usually take on average from application of registration?

Mr. Rannazzisi. Again, it just depends on the entity we are registering.

Mr. Pallone. Does the DEA look at any application to manufacture or distribute a controlled substance for a clinical trial any differently than an application to manufacture or distribute for commercial use? Because I would imagine that the quantities would be considerably smaller for clinical trials?

Mr. Rannazzisi. On a clinical trial, a researcher for a clinic trial, they would send in their application with their research protocols. Once we receive the research protocols, we send the research protocols to FDA. FDA and NIDA review the research protocols. They make a determination that the protocols are consistent with good research. At that point in time, they are approved. They come back to us, and we send diversion investigators on site to review, to ensure that they have the appropriate storage container to lock whatever investigational drug that may be a controlled substance they are using, and we give them the application once they understand what paperwork's involved and security is in place. It is no different than anybody else really, except that the protocols must be approved by HHS.

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Mr. Pallone. My time is expired, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman.

I now recognize the vice chairman of the full committee, Mrs. Blackburn, for 5 minutes for questioning.

Mrs. Blackburn. Thank you so very much, and I appreciate that both of you are here and have just a couple of questions. I want us to be able to move on so we can get to the second panel.

Continuing along kind of with the line that Mr. Pallone was going, I think that when we look at the DEA and look at what is happening with prescription drugs, you know, you can look at -- the laws are very clear when it comes to the illegal drug trade. You know that distribution of heroin or the methamphetamines, you know it is illegal. That type clarity is very helpful in enforcing the law, but when we are talking about the pharmaceutical products, what constitutes legal prescribing and dispensing is not quite as clear.

So let me just ask you if you can list for us what you are doing, articulate what the efforts are that the DEA is engaged in to promulgate some clear standards for the prescribers, for the pharmacies, for the distributors. What is your step by step? You say you have got an MOA. You say that is pending, so give me your tick list.

Mr. Rannazzisi. Well, let's talk about the prescribers first. I believe that the courts have settled what a prescriber must do. He must issue a prescription, a controlled substance prescription for a

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legitimate medical purpose in the usual course of professional practice. That was given to us by U.S. v. Moore 1975, and that hasn't changed. It is very obvious. When we go out and talk to physicians groups, we tell them that is their standard. They know that is the standard. If you looked back when we were doing the Internet pharmacy debacle, when doctors weren't seeing patients -- they were just writing prescriptions without seeing the patient and having a pharmacy over the Internet fill them -- that was not for legitimate medical purpose, not in the usual course of professional practice. There was no established doctor-patient relationship.

Now let's talk about the pharmacists. The pharmacists have a corresponding responsibility to ensure the prescription is valid. We go out and we teach the pharmacists, as does the National Associations of the Boards of Pharmacy and the particular pharmacy boards that that pharmacist sits in, that they have a corresponding responsibility to ensure that that prescription is valid, that it is issued for a legitimate medical purpose in the usual course of professional practice. Pharmacists understand that. There is transparency in the case law. There is transparency in how we do things. We have done prescription drug pharmacy diversion awareness conferences in, I think, 14 States.

Mrs. Blackburn. Okay. Well, a lot of that we know. We were looking for a little bit of that new information, and I guess it is

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kind of a Monday attitude sort of day, so let me move on.

Mr. Rannazzisi. I would like to finish my answer. I guess not.

Mrs. Blackburn. What are you doing to help well-intentioned registrants to determine who they can do business with?

Mr. Rannazzisi. I am sorry? We don't dictate who the registrant does business with.

Mrs. Blackburn. Okay. I thought maybe you were doing a little bit to help --

Mr. Rannazzisi. Well, we are, if I can proceed with the wholesalers and distributors, besides having one-on-one contact with the wholesalers and distributors in the distributor initiative, telling them what to look for and what red flags to look for, our yearly conference with the distributors as a whole to talk to them about what red flags, what we are seeing trend-wise and what they need to look for, besides the onsite investigations that we do, the cyclical investigations, to determination compliance and to assist them in complying, besides the fact that they call in and request assistance --

Mrs. Blackburn. Let me move on, then, if it is laborious.

Mr. Rannazzisi. It is not laborious. You asked me to tick off what I do: 16,651 people in 2010 died of opiate overdose, okay, opiate associated overdose. This is not a game. We are not playing a game.

Mrs. Blackburn. Nobody is saying it is a game, sir. We are just trying to craft some legislation.

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Mr. Rannazzisi. Especially in Tennessee. There is 340 --

Mrs. Blackburn. Your written statement indicates that the DEA has initiated less than 20 administrative cases in the last 6 months. What is behind the significant decline in case initiation, and are you satisfied with the number of cases being initiated?

Mr. Rannazzisi. Well, we are initiating cases, for sure. Our case numbers have not gone down.

Mrs. Blackburn. I think the case numbers have gone down. Okay. If DEA has only initiated 20 administrative cases in the last 6 months, what is DEA doing to help registrants identify the prescribers and pharmacies that they should refuse to do business with?

Mr. Rannazzisi. Ma'am, that is a due process issue. We can't direct a wholesaler or distributor or a pharmacy not to sell to a particular person. They are afforded due process like every other person. So if I told them, "Don't sell to this pharmacy, don't sell to this doctor," then they wouldn't be afforded due process.

Mrs. Blackburn. My time has expired. I yield back.

Mr. Pitts. The chair recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes of questions.

Mr. Waxman. Thank you.

Dr. Woodcock, I think we can all agree that the current process has not been working. Mr. Whitfield and Mr. Dingell have a bill that attempts to fix the problem. Of course, it is rather strange because

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we have got three different bills under discussion, and I am taking a leap from the last one. While I have concerns about elements of their bill, I share their frustration with the current FDA process and their desire to fix it. Will you commit to work with the committee, with the PASS Coalition, and other stakeholders, to come up with a process under which new, safe and effective sunscreens can get to market quickly?

Dr. Woodcock. Yes.

Mr. Waxman. I would like to better understand the current process and how we can help improve it. The central element in H.R. 4250 seems to be giving an FDA advisory committee the ability to make approval decisions, albeit providing FDA with some authority to reject that decision. I have serious concerns about such a model. Can you tell us if there are precedents at FDA for using an advisory committee in this way, what are FDA's views of such an approval, and it does at least appear to have the virtue of speeding up the process?

Dr. Woodcock. Well, I believe possibly in the device realm in the past, there were some areas where the panel recommendations were more binding. However, this is not true for pharmaceuticals.

The process problems with the OTC monograph go well beyond sunscreens and related or pertain to the entire monograph process, which has to be done by regulations. The Time and Extent Applications is what we are talking about here for sunscreens, were put in place

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by us actually in the early 2000s to try to bring more products that seemed to be most appropriate for monographs into the monograph system. However, what happened is that got caught up into the prolonged and torturous history of the sunscreen monograph and all the other monographs that we have to get out under the OTC system.

So, personally, the administration does not have a position on this bill, but I would say that, you know, it is making steps forward, and we need to change some things if we are going to make an efficient process that can respond both to safety problems and get more products into the monograph.

Mr. Waxman. What do you think of the idea of an advisory committee making that decision instead of you?

Dr. Woodcock. Well, I think that will be very difficult because it is a voluminous amount of data, and one of the problems that we have had in general is having time to go through all these data, find out what is missing, figure out what the gaps are, communicate with the sponsors. It is not typical type of thing that an AC would do.

Mr. Waxman. And do you think if there were such a process, the committee members, I don't know how they would be chosen in particular, how would it affect conflict of interest issues?

Dr. Woodcock. Well, like any other advisory committee, we have to do an extensive screening for conflict of interest, and a committee considering this wide range of issues would have to have a very broad

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representation, all of whom would have to be relatively free of conflict of interest.

Mr. Waxman. The bill sets out mandatory time frames for decisions both by the advisory committee and the FDA and even time frames for applicants to submit new information. I understand the sponsors' interest in moving things along quickly. However, the time frame seems somewhat more ambitious or optimistic than is reasonable.

The advisory committee would have 180 days to make its recommendations after receiving an application. Considering that there are eight outstanding applications, that could be a lot of work to expect the committee to accomplish. It also gives FDA 45 days to agree or disagree with the committee recommendation. Again, that seems rather ambitious, even if the committee were to be making only one recommendation for consideration within that time frame. What are FDA's views on those time frames? What times frames would FDA consider reasonable?

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[3:55 p.m.]

Dr. Woodcock. Well, I understand the impetus behind the desire for short time frames, however, I feel it may be self-defeating. If it is not possible to identify all the problems and get to a considered opinion in that time frame, then it would be likely to turn something down rather than turn it loose on the public.

Mr. Waxman. And what do you think about the shifting of the burden? It appears the advisory committee decision is presumed to be right, unless FDA can prove it is wrong. That seems like an inappropriate shifting of the burden of proof. Seems like a decision could be reversed simply because the FDA reviewer didn't adequately write down the basis for the decision. What is the FDA's view of the appeals process?

Dr. Woodcock. Well, I think this does put a tremendous burden on the FDA. And probably inappropriate -- as written currently, difficult or undoable burden on the advisory committees as well. So I am not sure this process would end up with the desired outcome, which is clarity, public standards, knowing what needs to be done, and the most efficient process for getting it done.

Mr. Waxman. I thank you for your answers and especially your

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willingness to work with us. I think that is going to be very important.

Mr. Pitts. Chair thanks the gentleman, now recognize the vice chairman of the subcommittee, Dr. Burgess, 5 minutes for questions.

Dr. Burgess. Thank you, Mr. Chairman.

Dr. Woodcock, always good to have you back before the committee.

And in fact, let me ask you a question, it is a little bit off topic today. Can you provide the committee with the status of the FDA's guidance on biosimilar naming?

Dr. Woodcock. It is still under consideration, it has not been be issued.

Dr. Burgess. But when is that guidance likely to become final?

Dr. Woodcock. I do not know. However, I realize that it is urgent. We certainly hope that that program will get up and running this year.

Dr. Burgess. Sure. Is there anyone advising, outside of the -- anybody in the administration outside of the FDA itself? Is there anyone in the administration who is playing a role in this, giving you suggestions or recommendations with respect to the guidance?

Dr. Woodcock. Well, the administration has not come to a conclusion on this topic.

Dr. Burgess. Who in the administration?

Dr. Woodcock. I would have to get back to you on that question.

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Dr. Burgess. I really would like for you to do that. And please expect some follow-up on that, because it looks to me as if the administration may be the impediment. You all are taking the fall for it. But it is far too long, and we actually need that.

Mr. Rannazzisi, you mentioned the memorandum of agreement. And you and Dr. Woodcock, I think, both acknowledge there is a memorandum of agreement that is pending; is that correct?

Mr. Rannazzisi. Yes, sir.

Dr. Burgess. You know, I don't know that I was aware of the memorandum of agreement. Is that something, can you make the text of the memorandum available to the subcommittee?

Mr. Rannazzisi. I don't believe we can. Well, you would have to request that from the Department of Justice because it is being actually between the Department of Justice and HHS.

Dr. Burgess. Mr. Chairman, I would, then, suggest that the subcommittee do request that from the Department of Justice.

What is your time line? What is your expectation of when this will be accomplished?

Mr. Rannazzisi. There are several components to this MOA, and I think there are just some things regarding proprietary information that needs to be passed, and I think that is what they were working on. The time limit, we hope to have it soon because it will make the process more efficient in scheduling once we get it in place.

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Dr. Burgess. Let me ask you the same question I asked

Dr. Woodcock. Is there anyone in the administration that is affecting the timeline of this thing adversely?

Mr. Rannazzisi. I don't believe so, no. It is --

Dr. Burgess. But you won't share it with us so we couldn't possibly know that, could we? Since you won't share it with us, I am going to let my imagination run wild. It seems as if we have got someone in the administration that is holding this up, and you won't allow us to see the memorandum.

I would suggest, Mr. Chairman, that that memorandum of agreement be made available to the committee, and allow us to participate before you just visit this upon everyone who is involved in this process.

Mr. Rannazzisi. Well, the problem is, sir, the memorandum of agreement is not finalized. If I gave you a memorandum of agreement right now, it is not a final agreement.

Dr. Burgess. Share the draft with us.

Mr. Rannazzisi. I am going to share something that is not finalized. Really?

Dr. Burgess. Sure. We could help you. We could inform you. We could direct you. Sometimes the legislative and the administrative branches have worked together historically; Mr. Waxman, Mr. Dingell may be able to give you such a time that that happened, but this administration has not worked well with the legislative branch. Here

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would be an excellent opportunity to start.

Let me just ask you a question. Because it keeps coming up. We are going to hear from people on the supply side in the second panel.

But, what are you doing to draw the line between prosecuting those who overprescribe and not differentiating between those individuals who are legitimately trying to help? And bearing in mind the people they are trying to help is a pretty vulnerable population?

Mr. Rannazzisi. Well, it depends. Again, every case is fact specific. The U.S. Attorney makes a judgment call on how we proceed on the cases based on the evidence that is presented to him or her.

The fact is, is the cases that we bring forward are generally pretty egregious. There is no doctor-patient relationship attached, these pain clinics that are operating in Texas, in Tennessee, and pretty much throughout the country now, there is no medical care for rogue pain clinics. They are operating as a facade to distribute controlled substances. In Florida --

Dr. Burgess. And yet they continue to operate. So, you know, look, we do have to get a balance here taking care of people --

Mr. Rannazzisi. Absolutely.

Dr. Burgess. -- who really need the help that they are looking to receive. But sometimes it seems that all the DEA cares about is the number of enforcement actions and not real solutions to stop the abuse.

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Mr. Rannazzisi. That is not correct.

Dr. Burgess. Provide to us data on how that -- what you have done to stop the abuse without interfering with the legitimate practice, medicine, pharmacy, and distribution.

Mr. Rannazzisi. If you would go on our website and look at the cases that are posted on our website, both on the cases against practitioners and also cases, the administrative cases against registrants, you will see that --

Dr. Burgess. Well, it would have been great had you been prepared to provide that for us.

Mr. Chairman, let me ask that on this memorandum of agreement that we have been talking about, maybe at least the department could provide us with the goals of what they are trying to achieve with this. Because, after all, we do have legislation pending before this committee that could be impacted as to what those goals are and how they would affect the practice of medicine pharmacy.

I'll yield back my time.

Mr. Rannazzisi. May I finish my answer? I was not --

Mr. Pitts. You may finish.

Mr. Rannazzisi. The administration has a four-pillar strategy, we follow the four-pillar strategy. Education, treatment, enforcement. The three basic tenets that we provide. Now, education, we provide education throughout the supply chain. We make sure that

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the supply chain, the registrants understand what their obligations are under the act. We provide them with red flags. We provide all of the case law, all of the administrative actions are posted on our website. We can direct them to particular circumstances and cases that they are inquiring about. We go out and look at them face to face and explain to them. The distributors, we talk to before enforcement action is taken on them and give them an opportunity.

See, the fact is, is we are not just enforcement, we are a regulatory organization. We go out to their -- on-site and look at their facilities and determine if there is any exploitation within their site that could be cause of diversion, and I don't see where you think we are just an enforcement agency, because we do so much more than enforcement. Talk to the pharmacists that have been to our classes.

Dr. Burgess. Mr. Chairman, I will reclaim my time. But the vice chair brought it up.

The clarity and the consistency of these regulations at the level of the distribution is things that we hear about all the time. But let's go on with the hearing and I will yield back.

Mr. Pitts. Chair thanks the gentlemen.

Now recognize the ranking member emeritus of the full committee, Mr. Dingell, 5 minutes for questions.

Mr. Dingell. Thank you for your courtesy.

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I am reminded today of when I was a very small boy and used to go to my granddad's farm out in Iowa. He had a bunch of chickens, and so to keep the chickens happy and keep them laying, when he would take the hens -- rather, take the eggs out from under the hens, he would always put a porcelain doorknob in, and those damn chickens would sit on that porcelain doorknob until hell froze over.

I am reminded very much, Dr. Woodcock, of those happy days in Iowa and the chickens that were sitting there very happily on the bloody doorknob.

Now, we got 2 million Americans developed skin cancer each year. 61,000 developed melanoma last year, and 9,000 people died. How many of these do you have laying around down there at Food and Drug where you have an application on these? Just if you haven't got it, submit it for the record.

And how long has each one of them been laying around there? And when will you have action taken on each of them? And how long is it going to take to reach action on each of them? And why have you not been able to reach action on any of them as of this particular time?

Because I note, Doctor, that all of them have been approved and are being used in Europe and other places which have food and drug laws that are roughly equal to ours in terms of their safety.

Dr. Woodcock. The sunscreens are marketed as cosmetics in Europe.

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Mr. Dingell. Well, you are still sitting on them like a hen on a plastic doorknob, and I just find myself thoroughly dissatisfied. So if you will please submit that for the record, I believe it will be most helpful.

[The information follows:]

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Mr. Dingell. Now, skin cancer is an epidemic in the United States. It is a pressing public health issue, is it not?

Dr. Woodcock. Yes.

Mr. Dingell. All right. One of the best ways that we could ensure that the American people have access to the most effective sunscreen ingredients is to see to it that we allow those which are -- been proven to be safe by long use in Europe; isn't that so?

So you are just sitting there looking at these things. Food and Drug is doing nothing about it. Very comfortable. You come up here and tell us how concerned we are that we are not doing anything.

So now, Doctor, do you believe that the American people should have the access to the latest safe and effective sunscreens to prevent skin cancer and melanoma?

Dr. Woodcock. Yes, I do.

Mr. Dingell. Rest of Food and Drug agree with that?

Dr. Woodcock. Yes.

Mr. Dingell. Now Doctor, is it correct that there are eight applications for new sunscreen ingredients that have not received final determination under the time and extent application process at FDA? Yes or no?

Dr. Woodcock. Yes.

Mr. Dingell. Do you believe that time and extent application process has ever worked as intended, yes or no?

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Dr. Woodcock. No.

Mr. Dingell. Yes?

Dr. Woodcock. No, I don't believe it has worked.

Mr. Dingell. But you still got eight sitting around and Food and Drug sitting on them like a hen on an egg; right?

Now, do you believe that we need to reform this?

Dr. Woodcock. Yes.

Mr. Dingell. And this is precisely why I have been joined with by dear friend Mr. Whitfield to introduce the Sunscreens Innovation Act. The goal of this legislation is to ensure a predictable time frame for the review of new sunscreen ingredients while making sure FDA has the final say on all scientific and safety determinations.

Now, Dr. Woodcock, I know there is a request for technical assistance on the Sunscreen Innovation Act that is still outstanding. Will you commit to working with me on this legislation with a goal of resolve the remaining differences by the end of this month?

Dr. Woodcock. I will commit to working with you and with the Congress.

Mr. Dingell. Well, and I would like to have the requested information that I have sought: How many applications you got sitting around down there? How long have they been there? What is holding up each and every one of them? And the other questions that I asked relative to the delay on them, if you please.

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Dr. Woodcock. Certainly. There are eight applications for sunscreens to TEA. We have responded to two of those. We hope to respond to the remainder soon.

Mr. Dingell. But in Europe they are all approved; right?

Dr. Woodcock. In Europe, they are marked as sunscreens, I am not familiar, but I don't believe there is an application process, such as we are discussing here.

Mr. Dingell. They are selling them, aren't they?

Dr. Woodcock. Correct.

Mr. Dingell. And people are using them, aren't they?

Dr. Woodcock. Absolutely.

Mr. Dingell. Do you have any evidence of them being unsafe or causing any danger or -- there are two things that a pharmaceutical has got to be in this country, one, it has got to be safe, and the other, it has got to be effective. Do you have any evidence that any of these doesn't meet those two tests?

Dr. Woodcock. Well, that is part of the point of the TEA process, to have people submit to us what the evidence is about the safety in marketing.

Mr. Dingell. You know the affectionate respect I have for you. But you also know that you are make a bad case today. You just can't defend the fact that these things have been sitting around for 8 to 12 years.

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I yield back the balance of my time. Thank you.

Mr. Pitts. Chair thanks the gentleman.

Now recognize the gentleman from Kentucky, Mr. Whitfield, 5 minutes for questions.

Mr. Whitfield. Thank you very much.

Dr. Woodcock, you had indicated earlier that FDA had not taken a position on this legislation; is that correct?

Dr. Woodcock. That is correct.

Mr. Whitfield. And I think you said in your testimony and in response to Mr. Dingell's questions and others, you do agree that the TEA process is not working very well as it relates to sunscreens; correct?

Dr. Woodcock. Generally, I believe the monograph process is no longer functioning the way it was intended, and the TEA process is simply a route to get into the monograph process.

Mr. Whitfield. Do you consider the TEA process working?

Dr. Woodcock. I think if it were coupled with a more functional monograph process, it could work, yes.

Mr. Whitfield. Well, how difficult is it to get a more functional monograph process?

Dr. Woodcock. Well, as I said, we had a public meeting 2 weeks ago, and we had few really substantive suggestions there, except we should work harder.

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Mr. Whitfield. Yeah. Well, we all agree on that. But that is why, you know, at least we have a product here, a piece of legislation. Because there is genuine concern and everyone agrees that there is genuine concern.

Dr. Woodcock. I share the concern.

Mr. Whitfield. And when you have these eight applications, earliest of which was submitted in 2002, and you have only responded to two of them in 12 years, you know, something is not working.

Dr. Woodcock. That is a problem.

Mr. Whitfield. So Mr. Waxman, now, he pointed out that he was concerned about this advisory committee, and yet you have indicated in your testimony that in nonprescription drugs or in medical devices, you do have an advisory committee that makes recommendation, and, of course, we are talking about over-the-counter here, we are not even talking about prescription drugs, this is over the counter; and the medical devices, I mean, the artificial knee joints are placed in bodies and that is recommended by advisory committee.

So are you genuinely on that poised to the advisory committee part of this legislation and the process that we have set out in this bill?

Dr. Woodcock. I am not sure that the process you have set out will be functional. I mean, the problem with the current process is not functioning correctly, and I am worried that -- I think that there are some good steps here, and we can build on this. And perhaps get

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something that will really work for everyone.

But, you know, if you press people too hard on matters of safety where you are exposing much of the population of the United States to something, you know, you need to give them the appropriate time and tools.

Mr. Whitfield. Well, I think you know, I hope that you --

Mr. Dingell. Will the gentleman yield?

Mr. Whitfield. I would be happy to yield.

Mr. Dingell. Is 12 years too much pressing? Is 8 years too much pressing? I don't find it so.

And I thank the gentleman for yielding.

Mr. Whitfield. Well, I mean I agree, I mean I think we all agree this is ridiculous. 12 years.

Dr. Woodcock. We all agree. I am not defending the fact that it has taken that long. There are a variety of factors, but that is not appropriate and this process is not working.

Mr. Whitfield. And these ingredients are being used elsewhere. But, the commitment that I am asking for from you and others at FDA is to work with us in a sincere way to improve this process for the health and welfare of the American people. Because we know that skin cancer is the most prevalent cancer out there.

So you will make that commitment to me and we can work --

Dr. Woodcock. Yes, we would be delighted to work with you,

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although we would like to reform the whole process of the monographs. Because the sunscreens are just a microcosm, as I said, of a process of has encountered tremendous problems.

Mr. Whitfield. Well we are focused on sunscreens because of the prevalence of skin cancer.

And in concluding, I know my time hasn't quite expired yet, but I would like to submit for the record, Mr. Chairman, a letter of support from the American Academy of Dermatology Association.

Mr. Pitts. Without objection.

[The information follows:]

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Mr. Whitfield. And with that, I would yield back the balance of my time.

Mr. Pitts. Chair thanks the gentleman.

And I now recognize the gentleman from Texas, Mr. Green, 5 minutes for questions.

Mr. Green. Thank you, Mr. Chairman.

Thank you and both our Ranking Member Pallone for having this hearing, and our witnesses for taking the time.

First, Dr. Woodcock, I learned just recently that the FDA advisory committee voted last week to recommend that the FDA approve two new antibiotics. These drugs were approved based on the GAIN Act that we passed, this committee passed last Congress, and I know they were in the development stage and before GAIN was enacted and their approval was welcome news. And of course we didn't get everything we wanted to out of the Senate, so we have a real bipartisan bill called Adapt that we are working with FDA on now. But I appreciate that.

Mr. Rannazzisi, the FDA is vital to meeting the growing challenges our country faces, including reducing prescription drug abuse, one of our fastest growing public health threats. I commend the FDA for meeting the public safety threats head-on and appreciate it. Because I have seen those same clinics in my area, and frankly, we have a pretty aggressive U.S. Attorney sometimes that gets involved in them. So I am glad of that.

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However, the FDA, as it tackles its mandate in a number of fronts, it is critical that patients who desperately need these medicines have access without undue delay, particularly those with limited potential for abuse or addiction. In 2011, I sent a letter to FDA after learning it takes an average of 5 to 6 months for the DEA -- I sent a letter to DEA -- 5 or 6 months for DEA to schedule a medicine, notwithstanding the drug's classification or potential for diversion. Since then, we have learned that the delays have not shortened and may actually have increased.

I am concerned over the substantial and growing length of time between when the FDA approves a new molecular entity and provides a scheduling recommendation and when the DEA schedules the drug. According to testimony from Dr. Fountain of the Epilepsy Foundation and University of Virginia School of Medicine, the average time between FDA approval and the DEA's final scheduling increased from an average of 49.3 days in the 1990s to an average now of 237.6 days. These delays can result in lack of patient's access to potentially life-saving therapies. Also, a lack of transparency of the DEA scheduling process provides disincentives to companies developing these therapies.

Mr. Rannazzisi, specifically what is the sequence of the internal actions at DEA from a receipt of recommendation by the FDA to the DEA's Federal Register publication?

Mr. Rannazzisi. When we receive the recommendation, our

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pharmacists, our pharmacologists begin the process of drafting the eight factor. They look at all the information that has been presented by FDA, and then all the information that they have procured over the last however long when they know the drug is coming. That is a lot of scientific data. They look at all the abuse data, if there is any abuse data.

Remember, there is transparency in the system. It is called the Administrative Procedures Act. The APA is our guidance on how we get drugs into the scheduling process.

We provide a period of public comment after we do the notice. We have to look at every one of those comments. At that point in time, the public may request a hearing from an administrative law judge.

So the process is very transparent. It just takes time because it is a science. The scientific method takes time, and our scientists, just like the FDA scientists, have to ensure that we have the justification to prevail in court.

Mr. Green. Well, but it is still is the average increase from the late 1990s to today was from 49 days to 237 days.

Mr. Rannazzisi. I don't know where that is coming from.

Mr. Green. Okay, we will get it to you. We will get the numbers there. Because if that is the issue, then somewhere along the way, whether you are not giving some kind of courtesy to what the FDA scientists did and, I expect -- you know, I want FDA to do it. But

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I also know that they expect --

What is your opinion of the shortest time that might plausibly achieve to application this process from start to finish? Is there an average time that the DEA aims for?

Mr. Rannazzisi. I don't believe there is. Because it depends on -- if it is a new molecular entity, that is going to take longer than an established drug that is in a different, you know, a combination of formulations. A drug that we know, a drug that we have done very significant research on.

Mr. Green. Well, I know Congress and the FDA is taking steps to improve the transparency consistency of the regulatory process for new drugs, to provide patients access for these new therapies in a timely manner. The lack of predictability, though, and timing of the DEA scheduling decisions, at least on certainty and drug development, and the process and some delays.

Delays in patient access to new therapies should be addressed in a manner doesn't threaten public health or weaken it DEA's ability to ensure public safety. But somewhere along the way, we need to make the system work faster than we are seeing.

And I know I am out of time, Mr. Chairman. Thank you.

Mr. Pitts. Chair thanks the gentleman.

Now recognize the gentlelady from South Carolina, Mrs. Ellmers, 5 minutes for questions.

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Mrs. Ellmers. Thank you, Mr. Chairman.

Ms. Woodcock, and thank you for our panel for being here today.

You know, I do have questions about the sunscreen. I think that we have gone over that pretty well here in committee, and, you know, as a nurse prior to coming to Congress, obviously, this is an issue that we are all very concerned about with skin cancer. And I guess what I would like to hear from you, is, please, can you just tell our committee that you are committed to improving upon this issue? I mean, obviously the time has been too long.

Dr. Woodcock. It has been too long. As I said a number of months ago when I appeared before this committee, I think I am almost as frustrated as the manufacturers and some of you all about this issue. So I do commit to improving it. We have already taken steps to speed up this process and move it along.

Mrs. Ellmers. Okay. Moving along to some of the issues having to do with ensuring patient access and effective drug enforcement act of 2013.

You know, there again, a very important issue. This is one that I think many of us, you know, we understand the drug abuse issue, we understand the deaths that have occurred as a result, and, you know, we need to be proactive on this issue.

You know, one of the solutions has been put forward that holds promise is the development of abuse-resistant prescription drug

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products. Such formulations make it harder for individuals to break down prescription drugs for abuse purposes. You know, obviously, that would be the actual drug itself.

And I would just like to thank you for the work that you have been doing, and I do want a clarification. My understanding is that there is some progress being made right now, that the agency is doing contracting with some of the academic and research institutions, utilizing research grant funding through the Generic Drug User Fee Act, to study this evaluation of abuse-deterrent formulations; is this correct?

Dr. Woodcock. I can't comment on the funding. But the research is correct, yes.

And we are trying to develop a framework so that as -- we don't want to approve abuse deterrent formulations that then disincentivize people from developing better ones. We have approved one, and it has some abuse deterrent properties. However, we need to get much better than that. So what we need to do is kind of establish both the -- you know, the carrot and the stick incentives, and we are doing research in our own laboratories as well as elsewhere.

Mrs. Ellmers. Will the FDA in its guidance provide flexibility and encourage manufacturers to pursue alternative methods and approaches to develop meaningful abuse deterrent technologies rather than a single development path such that the innovation and advancement

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in science are effective harness -- I mean, are there incentives that are being put forward?

Dr. Woodcock. Absolutely. That is part of the strategy, is to have multiple different abuse deterrent mechanisms so that if one might be overcome -- Mr. Rannazzisi and I were talking earlier that criminals are always sort of one step ahead of you.

Mrs. Ellmers. Sure.

Dr. Woodcock. So we need to keep encouraging that innovation.

Mrs. Ellmers. Thank you, Ms. Woodcock.

And, Mr. Rannazzisi, you know, there again, I think we have -- there is a lot of discussion of clarity and process on how things are moving forward. You know, we are hearing repeatedly that registrants are very concerned about the lack of clarity. However, you have outlined that this is something that the DEA is working on. And you say that you, and I am going to quote you, that you give the opportunity for the registrants to come forward, that there is plenty of opportunity for them.

Is there a process for appeal of a decision by the DEA? And can you describe that, if a registrant is found to have had their -- been revoked their DEA ability to produce suspended or revoked?

Mr. Rannazzisi. I believe they could take it to district court.

Mrs. Ellmers. You believe or you --

Mr. Rannazzisi. They could take it to the district court.

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Mrs. Ellmers. Okay, when we are talking about the hearing process, I know my colleague across the aisle, Mr. Green was referring to some of the hearing procedures, and there seems to be a lot of discrepancy on timing of how long a hearing would take. Can you tell us what the average time is? I know my colleague had said that he had heard of a time frame, and there again, I don't know exactly the number. But you basically said you weren't sure where that number came from; can you tell us?

Mr. Rannazzisi. I don't believe that was for a hearing; I believe that was for -- I think that was for scheduling. The timeframe it takes for scheduling action.

Mrs. Ellmers. To schedule?

Mr. Rannazzisi. Yes.

Mrs. Ellmers. Okay.

Mr. Rannazzisi. For a hearing, again, it depends on if it is an immediate suspension order with an order to show cause or just a plain, ordinary --

Mrs. Ellmers. So to that point, how long would you say that it does take a hearing to be scheduled? And then I know my time is --

Mr. Rannazzisi. When we do an immediate suspension order with an order to show cause, the date of the hearing is on the order to show cause, and I believe if it is within 30 days.

Mrs. Ellmers. Okay. Within 30 days. Thank you so much.

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My time has expired.

Mr. Pitts. Chair thanks the gentlelady.

Now recognize the gentleman from Florida, Mr. Bilirakis for 5 minutes for questions.

Mr. Bilirakis. Thank you, Mr. Chairman. I appreciate it very much.

And again thank you for your testimony. Thank the panel.

Mr. Rannazzisi, numerous seniors in my district are complaining. They call my office on a regular basis because they can't get their pain medications, and the pharmacists have stated that DEA is placing arbitrary and vague quotas on wholesalers and pharmacies.

I also hear that DEA is telling pharmacists not to fill prescriptions that raise red flags, but has given no guidance about these -- I want to give you -- red flags. I want to give you an opportunity to respond.

But considering DEA's mission to ensure an adequate, uninterrupted supply of controlled medications for patients' needs, what is DEA doing to address the impacts on patients that these confusing policies are causing?

And I know we have touched on this earlier. But if you could elaborate, I would appreciate it.

Mr. Rannazzisi. To start, actually, last year we were down in Florida, and we trained, I think, 1,400 pharmacists on what their role

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is as far as corresponding responsibility and how they very review prescriptions. And we talked about the red flags, and we are trying to do that in every State. The fact is, is that we do not want patients to go without their medication, true pain patients that need their medication. We don't want that. But there is no quota --

Mr. Bilirakis. Tell me what you are doing about it? Because, I mean, we get calls on a regular basis.

Mr. Rannazzisi. There are no quotas set by DEA concerning how much downstream drug goes from the wholesalers to the pharmacies. The wholesalers are required to report suspicious orders. They should know their customers, they should do due diligence. But they have certain things that they must do to reconcile an order before it is sent downstream. The pharmacies that are ordering those drugs, again, have a corresponding responsibility to ensure that the prescriptions they are filling are legitimate, are valid, are for legitimate medical purpose.

That is exactly what happened in Sanford. In Sanford, Florida, those two pharmacies that were stripped of their registration, they were not doing any corresponding responsibility, and there are wholesalers that were sending drugs to them, were not doing their due diligence.

And they were filling hundreds of thousands of tablets per year. And most of those prescriptions were not for legitimate medical

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purpose. They were also filling prescriptions for doctors that didn't have a valid DEA registration.

See, the problem is, is corresponding responsibility has a quite a few different components to it. And this has been in place for 40-plus years.

Mr. Bilirakis. Let me go on to the next one. Thank you for that answer.

Does DEA meet the chronic pain patients groups and others to ensure -- do they meet with chronic pain patients groups and others to ensure that agencies understand the need and concerns of patients? And yes or no, and please elaborate.

Mr. Rannazzisi. If we were asked to meet with a pain patient group, yes, we would.

Mr. Bilirakis. How often are you asked?

Mr. Rannazzisi. We meet with treatment groups, for instance, American Association of Opiate -- AATOD. AATOD. We meet with them. We meet with physicians' groups. We meet with pharmacy groups. Specific patient groups when they request.

Mr. Bilirakis. What is discussed during those meetings? Give me an example.

Mr. Rannazzisi. We meet with -- for instance, AATOD, we give them a trend analysis of what is going on in drug diversions, what drugs are being used. Then we ask them, what are you seeing?

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It is the same thing with community groups. We go into the communities all the time. In fact, I am doing a community function with doctors, pharmacists, and community leaders in Weymouth, Massachusetts, next month.

Mr. Bilirakis. Thank you very much for the answer.

Dr. Woodcock, Zohydro is a new extended-release opioid approved for the market by FDA but without any requirement for abuse deterrents. I find this disturbing because FDA has taken a number of steps to make sure opioid drugs would have these deterrents. FDA has even blocked generics from entering the market because they lacked abuse deterrent properties.

Some brand name drug makers have changed their drug to include abuse deterrents, saying their previous versions were unsafe. 28 State attorneys general sent a letter to FDA asking to reconsider the position on Zohydro. Your own advisory council did not favor approving this drug, from what I understand.

The drug company's own literature says an adult could overdose on two capsules, a child could die from swallowing just one. An addict can easily crush it and receive a dangerous and potentially lethal high.

Why would you approve a drug with 5 times as much hydrocodone as Vicodin with no abuse deterrent properties?

Dr. Woodcock. Well, first of all, there is only one drug that we have approved, and it is on the market, it is a high potency opioid

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that has abuse deterrent properties. All other opioids on the market do not have abuse deterrent properties --

Mr. Bilirakis. But why was that drug approved?

Dr. Woodcock. Pardon me?

Mr. Bilirakis. Why was that drug approved?

Dr. Woodcock. Zohydro?

Mr. Bilirakis. Yes.

Dr. Woodcock. All right. Zohydro is a single ingredient, high-potency opioid. You can't take -- you said Vicodin. You can't take a lot of those if you have severe pain because it acetaminophen in it, and it will be toxic to your liver, and acetaminophen is a very big cause of liver failure, okay and liver transplant. Because people are getting too much acetaminophen. So we need high-potency opioids for people who have severe pain.

Mr. Bilirakis. But why would we make sure that it has abuse deterrent prior to approval?

Dr. Woodcock. Abuse deterrence is really in its infancy, unfortunately. We have approved one product with abuse deterrent properties. Those are quite limited, abuse deterrent properties. I don't want to talk about that further. But they are present, okay. But we have a long way to go, and almost all the opioids on the market do not have abuse-deterrent properties.

Mr. Bilirakis. Okay. Thank you very much.

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I yield back the balance of my time.

Mr. Pitts. Chair thanks the gentleman.

Now recognize the gentleman from Virginia Mr. Griffith for 5 minutes for questions.

Mr. Griffith. Let me pick up on some of what my colleague was just talking about. Because a number of people are having difficulty, particularly at their pharmacies, based on some of the new rules or regulations that have come out.

In fact, I was standing in my local pharmacy waiting to get some drugs for my son a couple of months back, and there was a lady there getting some medication for her mother, and a local judge get something medication for his wife, who just had surgery, and the pharmacist, while I was standing there, had to inform both of them that they had used their allotment under the DEA's new regulations of those particular types of drugs, and they would have to come back next week.

Now, wasn't a problem for the judge. He was coming in, you know, a little early so that he didn't have that pressure, and that she would have the medication she needed.

But for the lady who was getting drug for her mom, it was very stressful. She said, my mother needs this medication. I promised them I would look into it.

What do I tell them? I mean what are we doing to make sure that these folks are heard from and that the drugs are available when there

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is a valid prescription for a valid patient who presents that to a pharmacist?

Mr. Rannazzisi. We talk to the pharmacists about this. The pharmacists are being told by their distributors that DEA is setting up a quota. There is no quota, there has never been a quota when it comes to distributors. I defy anybody to show me where there is a quota.

The fact is, is we ask the distributors to know their customers and ensure that the drugs they are sending downstream are you know, if it is a suspicious order, that it is reconciled before it is sent. But there has then been a quota to, going downstream from wholesaler to pharmacy. The pharmacists are reporting this. That is what they are being told, but we are not telling them that.

Mr. Griffith. Well, can you figure out why it is that that has happened? I mean, are you all making the distributors worry about it? So that if this particular pharmacy deals mostly, not exclusively, obviously, but mostly with older patients, because it has been there in one form or another on Main Street in Salem, Virginia, for about a hundred years, and so a lot of their folks are people that have been in the community for a long time. Some of them are fourth generation, et cetera. But some of them are also older, which means you are going to have, probably, more of those prescriptions.

I think maybe that you all need to talk with the distributors again

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make sure that if it you know is a long-term situation, that drugstore may be a little higher than the CVS down the street just because they have been there forever. So their population by definition is going to be an older population.

Mr. Rannazzisi. And I understand that, and DEA does want anybody to go without their medication, if they are legitimate patient. But the problem is is I have no control to tell a distributor to distribute to a pharmacy.

And the fact is is that if they just complied with the act and complied with the regulations, there wouldn't be a problem.

Mr. Griffith. Well, clearly, there is confusion somewhere. And I hope you will work with us to get that resolved.

Let me move to another subject now, involves the DEA, and also may involve pain medication. Most people are unaware of this, and let me state right up front, I do not support recreational use of marijuana. But, believe it or not, Virginia has the oldest medical marijuana law on the books. It was passed in 1979. Either with the hope that the DEA was going to come around and say these are certain legitimate uses, or in the hopes of encouraging the DEA to do that. But it was passed in 1979. It's 182251.1. And right now, it -- as I think is the proper way to deal with medicinal marijuana, it requires a valid prescription from a valid physician, and then it has to be taken to the pharmacist to be filled.

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Virginia set the construct up, and they did it just for cancer and glaucoma. Because in 1979, that is all the evidence would have justified. So they were trying to work within the construct of the Federal law and the DEA. Needless to say, no doctor in his right mind or her right mind is going to prescribe it, because that would get them in all kinds of trouble with the DEA.

But when is the DEA going to take a look at medicinal marijuana? Forget the crazy laws, as I sometimes call them, that California has passed and some other States that make it open. But a law that would allow the legitimate use of marijuana, smoked marijuana as well, not just the pill form, for purposes of relieving people on any number of areas, but particularly on cancer and glaucoma. Because we know that has been -- that science has been out there for decades.

Mr. Rannazzisi. Well, I think I will answer it and then I am sure my colleague would love to and it as well --

We have a -- maybe not.

We have a --

Mr. Griffith. Our impediment is the DEA won't allow it.

Mr. Rannazzisi. Well a petition process where a person could petition the government to schedule, reschedule, or move through the schedules any drug.

Now, in the case of marijuana, there are several factors. But one is it is based on approval as a medicine, and FDA has looked at

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this twice now, I believe, and the science is not there. There is no scientific evidence that shows that smoked marijuana is beneficial as a medicine.

Mr. Griffith. Well, and let me say, because my time is running out. I haven't ever used marijuana recreationally or otherwise. But I will tell you that I have numerous constituents who feel that it has been of assistance to them, and I tell a story when I go out and talk to people.

Decades ago, I went to -- I knew somebody who was having a problem with cancer, and the story was told to me at the time by some of his friends that the doctors put on his chart "Nobody goes in this room from 11:00 to 12:00, and then bring his food at 12:00." Because the doctors recognized that that would give him some relief.

He was trying to stay alive as long as he could so he could see his 2-year-old child a few more days. Every day he could get was important. I am telling that story in a high school group, what I call my high school town halls. This kid raises his hand up, and I thought it was going to be some question about, what about recreational use? And he says to me, "They did that for my daddy too." And I was in a different part of my district, and my district is about 4 hours long; there are no way they could have been anyway close, plus the kid was way too young. It wasn't the same deal. So we have got doctors out there who are recognizing it.

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Further, I would submit there is a Washington Post article that says that it is difficult to get permission to even do the scientific studies because of the DEA.

So I ask you to work on that, because that is a serious issue, and the American people support it for legitimate use, not abuse. Not recreational, but for legitimate use.

I yield back.

Mr. Pitts. Chair thanks the gentleman.

Now recognize the gentleman from New Jersey, Mr. Lance, 5 minutes for questions.

Mr. Lance. Thank you, Mr. Chairman.

Good afternoon to you both.

I don't want to beat a dead horse. I agree with Congresswoman Ellmers on the issue of the sunscreen, and I hope quick action can be taken, and I would personally benefit. I am in a situation where the sun is poison to me. And I presume that -- I like going to the dermatologist about as much as I assume you like hearing us bark at you this afternoon and I want to work with you so that we might bring these European components to market here in a safe and effective way, Dr. Woodcock.

On a completely different issue. I would like to ask you a couple questions about special protocol assessments. It is my understanding that Congress intended that these agreements should be binding on both

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parties except when a substantial scientific issue has come to light, after an agreement has been reached and testing has begun.

Dr. Woodcock, could you explain to the committee what type of scientific evidence would be so substantial as to cause the FDA to rescind a special protocol assessment for a drug that was otherwise safe and which had met all of its end points?

Dr. Woodcock. Certainly. Well, in some cases, for example, we would learn for a class of drugs that there was a new safety problem, and say for the nonsteroidal, antiinflammatory agents, we learned, as you recall Vioxx and others, that they caused cardiovascular events, myocardial infarction or so, and if we had said, you don't have to study that in depth in the premarket assessment, and then subsequently we learned that that whole class of drugs caused that problem, we would be remiss in approving that drug unless that safety problem had been addressed.

Okay. Now, similarly on the efficacy side, the special protocol assessment has at what end points, how you study the drug and what end points you use, and often we use surrogate end points of different kinds or intermediate clinical end points or whatever.

And if we find that in the interim, there is evidence that comes to light that that end point may no longer be valid and actually predict what we are looking for, then we might say we cannot any longer for any applicant rely upon that end point because its validity has been

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brought into question.

However, I would say that out of -- we have entered into almost a thousand agreements since 2007. And we have only rescinded 10 over that whole time.

Mr. Lance. As a matter of public policy, I do think the FDA should be accountable for continued diligence in identifying issues that bear on the continued enforceability of an SPA agreement, and then notifying the sponsor of such issues within a reasonable period of time after the FDA has become aware of a new situation. Is my understanding correct as to how that system works?

Dr. Woodcock. I am not sure it is a system. But I totally agree with you that is what we should do.

Mr. Lance. Thank you. I hope to work with you in a more extended way on this issue, and I appreciate your attention to the matter.

And, Mr. Chairman, I yield back a minute and 20 seconds.

Mr. Pitts. Chair thanks the gentleman.

Now recognize the gentleman from Pennsylvania, Dr. Murphy, 5 minutes for questions.

Mr. Murphy. Thank you, Mr. Chairman. I yield my time to you.

Mr. Pitts. All right. Thank you.

Mr. Rannazzisi, with respect to scheduling, is it your understanding that you cannot speak to, at the very least, the goals of the MOA that DEA and FDA are trying to achieve?

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Mr. Rannazzisi. The MOA will give us the opportunity to share information, both proprietary and information pertaining to our different databases, on just about anything in the process. Not only scheduling, but other things as well, and that is something that has never been in place before. So that memorandum of understanding, will give us the opportunity to move information back and forth under agreement of how it should be maintained.

Mr. Pitts. Dr. Woodcock, is that your understanding?

Dr. Woodcock. Absolutely. And I would like to add that I think it will be extremely beneficial in some -- we work closely with DEA, but we are not able to share certain information, which impedes, say, in the premarket realm, us working as closely as we would like.

Mr. Pitts. Thank you.

Will you both commit to working with the committee to provide this information, as much information as possible, by the end of the week to ensure that we can consider your efforts as we work on our legislation?

Dr. Woodcock.

Dr. Woodcock. Yeah, as much information as possible, certainly.

Mr. Pitts. Mr. Rannazzisi?

Mr. Rannazzisi. I would agree with that.

Mr. Pitts. Well, that concludes the questions.

Mrs. Ellmers. Mr. Chairman, do you mind if I?

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Mr. Pitts. I yield to Ms. Ellmers.

Mrs. Ellmers. Mr. Rannazzisi, I just have one question that just is burning in my mind. And, you know, as we have had these discussions on the process that the DEA is taking, I guess I just don't understand why we are not going after the bad actors, those physicians who are the ones who are writing the prescriptions to those patients. We know they are out there. What is the DEA doing about the physicians who -- because look I am in the medical community. I know it exists. And I know that I have known doctors who have abused this system. Where is the progress there?

Mr. Rannazzisi. Absolutely. Well, when we started initially with the Internet, we went after the physicians, the physicians that were prescribing over the Internet.

But the problem evolved. As soon as Congress passed Ryan Haight, they immediately started opening rogue pain clinics. It closed down the Internet, and rogue pain clinics flourished. First in Florida, then in Georgia, Tennessee, Missouri, Kentucky --

Mrs. Ellmers. Okay, to that point, and I understand. Because -- you are pointing out a -- we kind of went on an explosion. But, you know, we all live in small -- I live in a very small community. I live in a small community where I know this is happening.

Mr. Rannazzisi. Yes.

Mrs. Ellmers. What is the DEA doing in those communities where

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you know they exist?

Mr. Rannazzisi. We have right now 66 task forces, State, local, and Federal task forces, that are working with HHS, OIG, and FBI and other agencies, and we go after these doctors.

But the problem is, there are so many bad clinics right now. We are kind of overwhelmed, just as the States are. If you look at what is happening in Georgia, there is a lot of bad actors out there. And we are doing our best to keep up with them.

As it spreads, as it spreads, for instance, in Texas, we are just -- you are overwhelmed by the numbers. And these are not clinics that provide medical care. These are things that distributing --

Mrs. Ellmers. Pain. And to that point, and then we will finish here so that we can move on. But, you know I do believe there is value in making an example of a physician, a physician's office that repeatedly abuses the system and continues to be that cycle.

Because, unfortunately, what we have learned is that those who are in the community and they are drug seeking and drug shopping, they network very well. They know who the physicians are that will write those prescriptions, and I would just imagine that, you know, maybe even just taking a step backward and just looking at it in a more singular level, especially in some of our rural communities, that that might go a long way.

Mr. Rannazzisi. That is exactly idea administrative -- the

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immediate suspension order is so important. Because I could stop the hemorrhaging by issuing the immediate suspension order, and, quite frankly, the burden is a lot less than charging the bad actor with a crime. Not that he won't be charged. But if I want to stop the hemorrhaging, I use the immediate suspension order to stop him from doing it. Then working with the State backtrack, and hit him with a criminal charge.

So, yes, it happens, but it takes time. All of these cases take time. It is not distributing heroin or LSD. Those are illegal per se. It is distributing a legal substance illegally.

Mrs. Elmers. Well, thank you, sir.

And thank you to the chairman for allowing me to use the remainder of his time.

Mr. Pitts. All right. Chair thanks the members.

Mr. Pallone has a U.C. request.

Mr. Pallone. Thank you, Mr. Chairman, I have just ask unanimous consent to submit into the record a comment letter on H.R. 4069 from the Drug Policy Alliance. I believe you have it.

Mr. Pitts. Without objection, so ordered.

[The information follows:]

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Mr. Pitts. That concludes the questions of the members here at this point. We will send follow-up questions to you. We ask that you please respond as soon as possible.

And the subcommittee will take a 5-minute recess as we set up for the second panel. Subcommittee is in recess.

[Recess.]

Mr. Pitts. We will ask the witnesses to please take their seats. On our second panel today we have five witnesses, Dr. Nathan Fountain, chair, Medical Advisory Board, Epilepsy Foundation; Mr. John Gray, President and CEO Healthcare Distribution Management Association; thirdly, Mr. D. Linden Barber, Partner and Director DEA Compliance Operations, Quarles and Brady; fourthly, Ms. Wendy Selig, President and CEO of the Melanoma Research Alliance; and Mr. Scott Faber, Vice President of Governmental Affairs, the Environmental Working Group.

Thank you all for coming. Your written testimony will be made part of the record. You will each be given 5 minutes to summarize.

And, Dr. Fountain, we will start with you. You are recognized for 5 minutes.

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STATEMENTS OF DR. NATHAN B. FOUNTAIN, CHAIR, MEDICAL ADVISORY BOARD, EPILEPSY FOUNDATION; JOHN M. GRAY, PRESIDENT AND CEO, HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION; D. LINDEN BARBER, PARTNER AND DIRECTOR, DEA COMPLIANCE OPERATIONS, QUALRES & BRADY; WENDY K.D. SELIG, PRESIDENT AND CEO, MELANOMA RESEARCH ALLIANCE; SCOTT FABER, VICE PRESIDENT, GOVERNMENT AFFAIRS, ENVIRONMENTAL WORKING GROUP

STATEMENT OF DR. NATHAN B. FOUNTAIN

Dr. Fountain. Thank you.

Thank you, Chairman Pitts, and Ranking Member Pallone, for allowing the Epilepsy Foundation to provide comments to H.R. 4299 today.

I am a neurologist at the University of Virginia and also director of the comprehensive epilepsy program there. But I am reporting the Epilepsy Foundation today -- representing the Epilepsy Foundation today as the chair of the professional advisory board. The Epilepsy Foundation is the largest patient advocacy group in the United States for epilepsy, indeed, in the world.

And the two facts to start with, at least before our earlier discussion, I thought were sort of not in dispute, was first that DEA has progressively taken longer to schedule drugs after approval by the

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FDA. So the information that was quoted earlier is that in a referenced publication that we can provide if it is not in my written comments, is that between the years 1997 and 1999, the average drug approval by DEA, so the time to scheduling, was 49 days, so about a month and a half. In the period between 2009 and 2013, that increased to 237 days, or about 8 and a half months. So from 1 and a half months to 8 and a half months.

This second point that I think is at least clear to me is that DEA has always agreed with FDA's recommendations for scheduling, at least according to the same published analysis I referred to before. I think we heard that as well.

The epilepsy community is so sensitive to this issue because anti-epileptic drugs, or anti-seizure medications, the medications that people with epilepsy have to take each day, have progressively been more frequently scheduled by the DEA. If you went back to older drugs for epilepsy, they weren't an issue. But newer drugs, because of various reasons, are now scheduled by the DEA.

So the most recently approved seizure medication was approved by the FDA on October 22, 2012 and received scheduling and approval for marketing by DEA on January 2, 2014, an astounding 14 months later, according to FDA news. And I think if I understood their comments, that was even 11 months after it arrived at the DEA from FDA. So I think probably by any measure a very long time.

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Some brief background information about epilepsy illustrates why this delay is so important to Americans. Epilepsy is any condition that predisposes to spontaneous, recurrent seizures. You can imagine happens by many different insults to the brain, such as a stroke or head trauma. But in fact it most often is caused by some microscopic change in the brain or some genetic predisposition to seizures in people who are otherwise fine and perfectly normal.

Seizures are an electrical storm of the brain. The kind of seizure that people are most familiar with is a generalized tonic-clonic or grand mal seizure, when someone stiffens up, falls to the ground, and jerks rhythmically all over for a few minutes. They are then unconscious for a little while, and over the course of about an hour return back to normal.

But the electrical storm of the drain can start in just one spot. Seizures can arise focally in just one area, and the most common focal area they arise is in the temporal lobe. The temporal lobe behind your temple here, controls consciousness and awareness, and during temporal lobe seizures, people don't fall down and jerk all over, but instead stare off, unaware of what is going on around them.

They are awake, but they are confused and don't know what is going on, and that means that they may continue to do behaviors they are doing but they don't do it correctly. So, for example, if they are ironing, they may continue to iron, but unfortunately they may pick up the hot

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side of the iron, and iron with that, burning their hand. If they are cooking with boiling water, they may put their hand, immerse it into the boiling water to pick something up because they are confused about what they are doing. If they are chopping something, they continue to chop and chop their own fingers. So it can be a very dramatic and difficult thing for people with this kind of seizure, which is the most common type.

But the greatest risk from epilepsy is death. Death from sudden unexpected death in epilepsy, or SUDEP, S-U-D-E-P, sudden unexpected death in epilepsy, in which patients die for no apparent reason. They are typically found dead in bed, sometimes associated with a seizure, the same seizure they have had ten, hundreds, thousands of times before. But for whatever reason in this particular seizure, they don't awaken and they die. SUDEP.

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Dr. Fountain. Matthew is an engineering student at a Virginia university -- I am from Virginia -- with intractable epilepsy. He had seizures in his sleep that happened several times a week. Typically they weren't such a substantial problem because as far as he knew, he didn't have them. They just occurred in his sleep, but eventually, they started to occur during the day. When they started to occur during the day, you can imagine all different ways its disrupted his life. Besides the risk of injury, there are more common ways in which you can imagine if you have seizures that you can't drive, difficulty working and so forth.

He was an otherwise very personable, pleasant young man. I have an 18-year old son who is at the University of Virginia, a freshman. Could have about been my son, could have been your son, could have been your daughter. And as his seizures persisted, we tried more and more medications to treat them. Eventually, for those situations we consider surgery. It is a several month long evaluation to localize exactly where the seizure is coming from in the brain; if that is a safe spot to remove, then removing that spot. But unfortunately a couple of months into is evaluation, I got an email message I received too many times in which the subject line is "sad news." And whenever

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that happens, my heart just sinks because I know what is coming next. So, on opening the email, it says, from my nurse, "Matthew's mother called today. He was found dead in bed. He went to bed last night perfectly fine, but he didn't come down for breakfast and went to check. He was dead."

So you can imagine there is no more devastating thing that could happen to you. What could possibly be more devastating? Most of us would rather cut off our arm than lose a child. Right? And, of course, it doesn't just happen to children and young adults. It happens to everyone with epilepsy. So the question is, how common is this? What is the scope of the problem? Is he just one guy in my thousands of patients with epilepsy? No. I am afraid not.

Take a step back for the scope of the whole problem. Epilepsy is common. About 1 in 26 people have epilepsy at some time in their life. Earlier today there were 96 people in this room. That means three or four of them had epilepsy. Some of them had it as a child. They outgrew it. It went away. Some of them haven't gotten it yet because its highest incidence is in the very young and in the elderly, as you can imagine. But that is pretty common. About 3 million Americans have epilepsy today. That is quite a lot of Americans. And about a third of these people have seizures that are not controlled with available medications. That means they persist in having seizures, despite our best efforts, like Matthew.

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I follow about 2,000 people with epilepsy in my clinic per year, and I get this message about twice per year. So I now have accumulated about 50, actually 52 people with epilepsy who have died, mostly in this manner. It is not a small problem. It is a huge problem and as a general sense affecting almost 3 million Americans; in a specific sense, the risk of death for those people with intractable epilepsy, at least a million.

Now, we started Matthew's evaluation when the last drug I mentioned had been approved by the FDA but was awaiting scheduling at the DEA. That is when he died.

Mr. Pitts. Could you please summarize, Doctor --

Dr. Fountain. One last sentence. So I can't tell that you that Matthew would be alive if he had this drug available, but he certainly might be, as would other patients with epilepsy who desperately need these kind of treatments that have been found safe and effective by the FDA. Thank you.

Mr. Pitts. Thank you.

[The prepared statement of Dr. Fountain follows:]

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Mr. Pitts. Mr. Gray, you are recognized for 5 minutes for your summary.

STATEMENT OF JOHN M. GRAY

Mr. Gray. Good afternoon, and to members of the Energy Subcommittee on Health, Ranking Member Pallone and Chairman Pitts, I am John Gray, President and CEO of the Healthcare Distribution Management Association. I want to thank you for the opportunity to come here to talk about Representatives Blackburn and Marino, the Ensuring Patient Access and Drug Enforcement Act of 2014, H.R. 4069.

HDMA is the national association representing America's primary pharmaceutical distributors, the vital link we say between manufacturers, pharmacies and health care providers. Our industries' prime mission is to operate the safest and most secure supply chain in the world. As part of the mission, the pharmaceutical distribution industry is committed to addressing the serious national epidemic of prescription drug abuse. Drug abuse and diversion as we have heard here today is a complex, challenging problem calling for a collaborative effort on the part of doctors, pharmacists, distributors, manufacturers and importantly State and Federal authorities.

HDMA members are committed to working proactively with the DEA,

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local law enforcement and other regulatory agencies, to investigate potential cases of diversion and implement protocols to monitor and report suspicious orders.

The supply chain is a complex one depending on numerous core components working closely with one another to ensure patients receive the medicines they need and to prevent the diversion to individuals who would abuse the drugs. It is sometimes difficult to find the balance between proactive and anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.

We hope this legislation will address the need for balance and encourage some cooperation and collaboration between prescribers, dispensers, distributors, manufacturers, regulators and the like, while making sure that the legitimate patient population continues to get what they require for medication. All HDMA members take seriously this obligation to fill only legitimate and appropriate orders for controlled substances.

However, in many instances, our members struggle with applying the Controlled Substances Act and its accompanying regulations to the specific situation when balancing the need for preventing the diversion at the pharmacy or the doctor's office and ensuring that the legitimate patient needs are addressed. This is one of the reasons why HDMA supports 4069, the legislation's timely and thoughtful

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approach to addressing the prescription drug epidemic. And we believe it will foster, again, better collaboration, communication and transparency between the industry stakeholders and the regulators, especially the DEA. Our members appreciate the importance of DEA's law enforcement activities, confronting, disrupting, and dismantling illegal drug trafficking. However, establishing a collaborative working relationship between DEA and our members will serve as a more effective way to curb the diversion of legal medicines. We feel this legislation will improve the interaction with DEA as they engage in their regulatory duties to prevent the diversion of these substances. The several key components, the bill clarifies the regulatory environment by defining terms that will facilitate greater compliance with and consistent enforcement of the Controlled Substances Act. Another key provision is the bill establishes a corrective action for plan registrants working with the DEA. This concept first raised by Representative Blackburn during a hearing on drug abuse here 2 years ago, is intended to mirror the way the FDA interacts with and regulates pharmaceutical manufacturers.

The bill will allow DEA-registered companies to submit corrective plans, to address and mitigate any of the agency's concerns, we hope and we believe creating a more robust, transparent, time-sensitive approach to addressing diversion. Preventing this diversion and abuse requires a clear understanding of the regulations consistent with the

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CSA and prompt communication between supply chain members and the regulators. The provision ensures that law enforcement registrants will collaborate to achieve these aims.

Finally, the bill establishes a prescription drug abuse working group to encourage meaningful dialogue and coordination between the supply chain stakeholders, law enforcement, patient advocacy groups, as well as State and Federal regulators. Ultimately, the working group will provide guidance to Congress on the most effective strategies to curb this prescription drug abuse.

HDMA has long been working to improve the collaboration among industry stakeholders. We recently joined the Alliance to Prevent the Abuse of Medicines. The alliance is in the process of developing a platform of policy recommendations to address numerous aspects of the drug abuse diversion problem, and that alliance does support 4069.

We recognize there isn't a one-size-fits-all solution to this problem. There never is. But we believe pharmaceutical distributors, along with our other supply chain partners, are committed to a more coordinated and transparent approach, balancing between addressing enforcement, public health and treatment efforts. We are neither seeking to restrict DEA's authority nor increase the regulatory burden on registrants. What we are seeking is clarity, consistency to ensure that the public health needs are adequately addressed in a balanced, collaborative and effective manner. In the end, we share

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the same goal, ensure patient access, sufficient, safe and secure supply chain of medicines for the necessary therapies while keeping these drugs out of hands of individuals who will abuse them. The anti-diversion efforts need to strike a balance between the need to reduce abuse and diversion while avoiding disruptions to legitimate patients.

Thank you again for this opportunity to participate in the hearing, and I hope this overview was valuable to the committee. Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Gray follows:]

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Mr. Pitts. And now recognizes Mr. Barber 5 minutes for opening statement.

STATEMENT OF D. LINDEN BARBER

Mr. Barber. Good afternoon, Chairman Pitts, Ranking Member Pallone, and members of the subcommittee. Thank you for the opportunity to testify.

My name is Linden Barber, partner at Quarles & Brady. I am a former associate chief counsel at DEA. H.R. 4069 provides much needed clarity in the Controlled Substances Act, and that clarity will foster compliance, communication and collaboration, which is essential to preventing prescription drug abuse and ensuring that patients have access to controlled medications.

History tells us why clarity is important. In 2006, DEA stopped issuing immediate suspensions for 8 months because a Federal court ruled that the way DEA issued suspensions was unconstitutional. During that critical time, Internet pharmacies were fueling prescription drug abuse with millions of pills, and the agency issued zero immediate suspensions. That is Exhibit A for why clarity in the law is so important. The CSA allows DEA to immediately suspend a registration based on imminent danger to the public health, but the act does not currently define "imminent danger." This lack of clarity

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and DEA's inconsistent approach to immediate suspensions has led to judicial intervention. Defining imminent danger will protect DEA's ability to issue immediate suspensions.

In 1974, a year after DEA was created, a pharmacy successfully challenged DEA's immediate suspension order because the alleged danger was one single incident that occurred more than 7 months before the suspension, far from an imminent danger. More recently, the 2006 case I mentioned echoed that same theme, and last year, the D.C. Circuit Court of Appeals raised pointed concerns about the DEA's apparent lack of a standard in applying the imminent danger definition or lack thereof when issuing suspensions. History is sending a message. In the absence of clarity in the law, courts will intervene, and they will curtail DEA's powers.

After the 2006 adverse decision, I became the associate chief counsel at DEA and was charged with fixing the immediate suspension process for the agency. As part of that, the agency took a disciplined approach to applying the imminent danger standard, an approach that is consistent with the definition of imminent danger in H.R. 4069. Using that approach, we issued a record number of immediate suspensions in 2007 and 2008. I am confident that defining imminent danger the way this bill does will not impede DEA's ability to issue immediate suspensions.

The lack of clarity in DEA's inconsistency has unintended but

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devastating consequences for the public. Why would a pharmacist tell DEA about a doctor's bad prescribing habits if DEA was going to use that to suspend the pharmacy's registration, even though the pharmacy was no longer filling those prescriptions. This is not a hypothetical. The agency has issued suspensions for conduct that it knew was no longer occurring. Registrants get this message: Don't tell DEA about a bad prescriber who is the real source of diversion because DEA might take action against you.

Clarity in the law will remove that fear and foster communication that helps DEA identify truly bad actors. Clarity also promotes access to controlled medications for patients. Without clarity, registrants often act to reduce the perceived risk of regulatory action. A pharmacist refuses to fill legitimate prescriptions for narcotics simply because dispensing a high volume of narcotics brings the attention of the agency and the supplier on the pharmacy.

No one wants cancer patients or wounded veterans or those with chronic pain to go without their pain medication, but restricting access is an unintended consequence of a regulatory environment that lacks clarity.

The corrective action plan section of the bill also promotes communication with the agency by assuring registrants that the agency will consider remedial actions they have taken. It is important to note that the remedial action section and corrective action plan does

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not apply to immediate suspensions for the reasons I discussed in my written testimony.

Nearly a decade ago, DEA crippled illicit Internet pharmacy schemes. We issued a record number of administrative actions, collected record-setting civil penalties, but prescription drug abuse continued to rise. All along, DEA was working tirelessly to protect the public, and all along, the vast majority of registrants were looking for ways to cooperate with the agency.

Members of the subcommittee, how can these efforts of the agency and industry be harnessed to effectively address medications for patients and to prevent diversion? The answer is with clarity. Clarity will produce compliance, communication and collaboration, and that collaboration will produce real results in preventing the prescription of diversion drugs and their abuse.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Barber follows:]

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Mr. Pitts. I now recognize Ms. Selig, 5 minutes for an opening statement.

STATEMENT OF WENDY K. D. SELIG

Ms. Selig. Thank you, Mr. Chairman, good afternoon, Ranking Member Pallone and members of the subcommittee. My name is Wendy Selig, and I am the president and CEO of the Melanoma Research Alliance, known as MRA. Thank you again for inviting me to testify on behalf of my colleagues in the Public Access to Sunscreens Coalition, known as the PASS Coalition, in support of H.R. 4250.

The PASS Coalition is a multistakeholder group that advocates for a regulatory pathway for new, safe and effective sunscreen ingredients. The goal of the coalition is to work collaboratively to establish a transparent and predictable process for premarket review of sunscreen components. MRA is a unique non-profit organization whose mission is to end suffering and death due to melanoma by collaborating with all stakeholders to accelerate powerful research, advance cures for all patients, and prevent more melanoma. We are the leading private funder of melanoma research, having awarded more than \$51 million in cutting-edge scientific projects around the world.

Mr. Chairman, as has been discussed here this afternoon, skin cancer is the most common form of cancer diagnosed in the United States,

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with more new cases of skin cancer than breast, prostate, lung, and colon cancer combined every year. Melanoma, which is the deadliest of the skin cancers as a result of its ability to move quickly and to spread to distant organs in the body, is rising dramatically across demographic groups.

Each year, more than 76,000 Americans are diagnosed with melanoma, one every 8 minutes, and more than 9,400 Americans die, one every hour. So, in the time that we have been sitting here, we have lost several melanoma patients.

We have made real strides on the treatment front, as four new drugs have been approved for use by the sickest of these patients. We commend the FDA and especially Drs. Woodcock and Pazdur and their colleagues for their work in this area, including landmark efforts in immune therapy, biomarker-driven targeted therapies, combination therapies, and breakthrough therapy designation to speed review processes. These new drugs are saving lives, and their approval and use are paving the way for continued investment and innovations that will bring about even more dramatic progress.

Still we know that more effective options for patients are urgently needed. Everyone is at risk for developing melanoma. One of the risk factors, as we have been discussing today, for all skin cancer and specifically for melanoma is exposure to UV radiation. In fact, one blistering sunburn that happens during childhood can double

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a person's lifetime chance of developing this deadly skin cancer. We take every opportunity to urge people to protect themselves and their loved ones by reducing exposure to UV from the sun, from tanning beds, and to examine their skin and watch for changes and see a dermatologist regularly, especially if they notice a change.

A central message is that people should use effective sunscreen protection all year round. As you know, FDA is responsible for ensuring the safety and effectiveness of all drugs, including evaluating medical claims related to sunscreens and sunscreen ingredients. The 2002 TEA process envisioned a 90 to 180 day evaluation process. Yet as we have been discussing today, FDA has not completed the review of any new sunscreen component under TEA or its preexisting OTC process since the 1990s. I think everyone agrees the current sunscreen premarket review process needs to be reformed.

It is important that I point out that the sunscreens Americans use today can be effective for those who use them correctly. However, the latest products developed and used around the world can offer important steps forward and should be made available in the U.S. if found to be safe and effective. Finding innovative ways to make these products more effective and user friendly can help ensure more people are using them properly and to maximum effect. Unfortunately, given the history of stalled reviews under the FDA's current process, there is a strong disincentive for investment in this kind of sunscreen

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innovation for the U.S. market.

The Sunscreen Innovation Act would codify a time frame for review and provide FDA with the authority to make a final scientific decision on the application instead of going through the cumbersome and delayed rulemaking process. While keeping the existing process whereby FDA makes an ultimate eligibility determination, the act says an existing advisory committee of experts will review the safety and advocacy data. It ensures that all submissions are reviewed within a predictable time frame. Enactment of this legislation would be a victory for everyone, for the FDA, for manufacturers and, most importantly, the American people. Mr. Chairman, and members of this subcommittee, I commend you for holding this hearing and to Mr. Whitfield and Mr. Dingell for taking the lead on this bill.

May is melanoma awareness month, just a few weeks from now. As the weather improves and people are once again making plans for outdoor activities, MRA and the PASS Coalition look forward to working collaboratively with you and the FDA to enact the Sunscreen Innovation Act this year, and we hope perhaps we can see progress on that in Melanoma Awareness Month.

Mr. Pitts. The chair thanks the gentlelady.

[The prepared statement of Ms. Selig follows:]

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Mr. Pitts. And I now recognize Mr. Faber 5 minutes for an opening statement.

STATEMENT OF SCOTT FABER

Mr. Faber. Thank you, Mr. Chairman, members of the committee. EWG strongly supports the goals of the Sunscreen Innovation Act, and we look forward to working with the committee to expedite the review of sunscreen ingredients.

I don't think I need to spend any time describing why skin cancer is a public health crisis or how FDA has not had the incentives to quickly review and approve sunscreen ingredients that have been used in Europe, Australia and other countries. So let me just take a few minutes to describe some of the truly modest improvements that we would propose to this act that we think would ultimately make it a more workable piece of legislation.

So, first, and Mr. Dingell referred to this, we believe that to be eligible for expedited review, that a sunscreen ingredient should have been used for 5 years in a country with a competent regulatory system or, as Mr. Dingell put it, roughly equal to ours. As currently drafted the Sunscreen Innovation Act would allow expedited review for an ingredient that has been used in any one country for 5 years. It doesn't distinguish between any one country and other countries that

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may have similar review systems to the U.S. review systems.

Second, ingredients that are subject to expedited review should have been used as sunscreen ingredients, not as cosmetic ingredients or ingredients in dietary supplements, and one provision of the bill does suggest that those ingredients, ingredients that have been used for this purposes, could be eligible for this expedited review of sunscreen ingredients in the U.S.

Third, and perhaps most importantly, I think it is very important that the panel that does review these ingredients that have been used in the EU and Australia and elsewhere has the technical competency to review potential health risks posed by sunscreen ingredients as Dr. Woodcock said, that might result from repeated long-term exposures. And while the Nonprescription Drugs Advisory Committee has many experts, they may not have the expertise to quickly and thoroughly review all of the potential health effects that might result from the sorts of ingredients that we are requiring for review.

Fourth, and we have heard a little bit about this already. We think that Congress should set deadlines but workable deadlines for FDA and this advisory committee. For example, the current draft, under the current draft, the expert panel would be required to review all of the eight pending Time and Extent Applications that FDA within 180 days, which seems like a herculean task. So while we think deadlines are important, in light of the long history of delay, deadlines are

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essential, we think those deadlines need to be workable and, again, that the advisory panel that reviews these ingredients has the technical competency to really do a thorough evaluation.

Similarly, we think the FDA should have more than 45 days to respond to a recommendation by the advisory panel envisioned by the Sunscreen Innovation Act.

Fifth, we think that ultimately, although there is an important role here to be played by a panel of experts, that ultimately, FDA should make the final determination of ingredient safety and that supervisors who are reviewing CDER staff decisions should have the power to ask for more information, either from FDA staff or from the panel, not simply to decide whether or not the ingredient should enter commerce or not.

Sixth, we believe that applicants seeking expedited review should provide both published and unpublished data regarding the safety and efficacy of sunscreen ingredients, and that data should be shared with the public. Obviously, the current bill does envision a role for the public, and we appreciate that. I think we just need to be clear about precisely what we are asking companies to provide, if they are going to receive expedited review and how much of that is available to the public.

And then, lastly, we think it is critically important that FDA be required to finalize a proposal to restrict the use of SPF claims

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greater than 50. Other countries have taken steps, including Australia and Japan and others, to restrict SPF claims greater than 50. But we do think that FDA should be given more time than is envisioned in the current bill to assess the inhalation risks and other risks posed by aerosol sprays. FDA has started to look at this question. It has only begun in the last few years. It is a critically important health question. We think they should be given the time to do a thorough and a fair assessment.

Let me just simply close by saying that we applaud Congressman Whitfield and Mr. Dingell for your leadership. We share the goals of the Sunscreen Innovation Act. We look forward to working with you to give FDA the help it needs to quickly review and approve these promising ingredients. Thank you.

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Mr. Faber follows:]

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Mr. Pitts. That concludes the opening statements.

We will now go to questioning. I will recognize myself 5 minutes for that purpose.

Dr. Fountain, can you please describe the impact DEA delays have on patients suffering from epilepsy?

Dr. Fountain. Well, in addition to the impact we talked about before, of the risk of death during the whole time seizures are active, there is a much wider and more difficult perspective. So about 3 million Americans have epilepsy and about 1 million of them, so almost a million of them, have intractable epilepsy, meaning they continue to have seizures despite our best efforts. So for all of those people, having a delay in treatment can be life-threatening, as we talked about. And that affects a relatively few people in a very important way. There is also a huge effect on everyone else. Because for the remainder of people, they need new drugs available soon because they are waiting for a new drug to control their seizures.

Epilepsy is difficult in many ways, but one of the ways is that although we now have almost 20 drugs available for the treatment of epilepsy, we still have this group of people that continue to have seizures despite our best efforts. But as each new drug is approved, we are able to control more and more people with epilepsy. And if you are in that group that is controlled, then waiting for that drug is a longer time that exposes you to the problems of epilepsy.

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Mr. Pitts. Thank you.

Mr. Barber, do you believe DEA adequately factor legitimate patient access into its registration and scheduling time frames as well as its enforcement decisions?

Mr. Barber. Mr. Chairman, I will first address the issue of scheduling, particularly with regard to new molecular entities. The studies that are done by HHS are binding on DEA when it comes to the medical and scientific factors, and so the delay time in studying a new molecular entity is curious because there is no law enforcement data for a molecule that has not previously existed. So looking for issues of real diversion and law enforcement activity around a new molecular entity seem like they should be very brief because the entity has not previously existed.

I believe that DEA does care about patient access. I am not sure that they necessarily take into account the unintended consequences of the significant delays that come with new molecular entities when scheduling.

With respect to enforcement activity, certainly, Mr. Chairman, I do believe and as a long time DEA employee -- I have been gone for 2 and a half years -- I believe the agency cares about patient access. But, again, it is the unintended consequences. Mr. Rannazzisi testified previously and knowing him, he is a pharmacist, he does care about patient access. I am just not convinced that the way the agency

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handles enforcement activities contemplates all of the unintended consequences in the supply chain.

Mr. Pitts. Mr. Gray, do you have anything to add on this front?

Mr. Gray. I believe his assessment is correct. I think they have a legitimate goal.

I think, as you said, Mr. Rannazzisi is a pharmacist himself. But it is the law of unintended consequences when you apply what I would call enforcement tactics for illegal drugs to the legal market. And what happens is what has happened in the case of our members is without specific guidance and detail as far as how they are to interpret suspicious orders, then our members are forced into situations where they make decisions to terminate relationships with pharmacies, thereby immediately limiting that pharmacy's ability to get certain Schedule II drugs.

Mr. Pitts. Would either of you comment on how a more collaborative relationship between supply chain, stakeholders, and the DEA, would help in our effort to address prescription drug abuse and diversion?

Mr. Barber. Certainly, Mr. Chairman.

I will point to a historical example that really brings this to light. There was a significant problem with methadone overdose deaths related to the 40-milligram methadone diskette. And without any regulation, without any new law, DEA called manufacturers and

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distributors in and asked them to voluntarily not sell the 40-milligram methadone diskette, except for narcotic treatment programs, not to sell it for dispensing for pain. And the manufacturers and distributors responded and voluntarily did that, and it reduced the overdose deaths related to 40-milligram diskettes, so collaboration absolutely actually addresses the real problem of prescription drug abuse.

Mr. Pitts. Ms. Selig, Mr. Faber, Dr. Woodcock committed to working with the committee to improve the timelines and predictability of the Time and Extent Application, TEA, process is a it relates to new sunscreen ingredients. Do you think the TEA process provides an efficient mechanism by which these types of products can get to consumers in the U.S., and what else can be done?

Ms. Selig. Thank you, Mr. Chairman. I appreciate Dr. Woodcock's statement, and we look forward to continuing to work with FDA. That said, I think that we have heard repeatedly from FDA, and our own assessment is we need your help here in Congress, and that is why we support this legislation, that the current regulatory process that the TEA system and the OTC system for sunscreens is based on has really been broken. And in order to not only clear out the backlog that exists with those eight applications that are pending, but to encourage innovation and to bring the most cutting-edge innovation to American consumers, we need your help with this legislation.

Mr. Pitts. Mr. Faber, do you want to add anything?

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Mr. Faber. I will just had that this process has been in place since 2002, and FDA has been unable to review and improve even one sunscreen ingredient, and that six of the eight ingredients that have sought applications, have filed applications, have languished at FDA for more than 8 years. So I think, clearly, as we have all heard today, that this process is not working for consumers or for manufacturers.

I do think, with all due respect to Dr. Woodcock, that we should not have to wait for a reformation of the sense of the monograph process for FDA and with the help of an advisory panel to review and approve some of these very promising ingredients.

Mr. Pitts. The chair thanks the gentleman. My time is expired. The chair now recognizes Mr. Green 5 minutes for questions.

Mr. Green. Thank you, Mr. Chairman.

Dr. Fountain, can you describe what your organization's communication with DEA is like, and how do you think it could be improved?

Dr. Fountain. Our communication has been limited to more or less the issue at hand because of the seemingly desperate situation that I mentioned before about how long it has taken to have the most recently approved, FDA approved drug scheduled by the DEA. In that case, the communication was sent to DEA and received a response 7 and a half months later, and we don't have -- I would have to inquire of the whole organization, but I am not aware of any ongoing dialogue.

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Mr. Green. And as you know from my questions of the DEA, I have problems with that. I think the DEA needs to be more transparent in dealings with patients, doctors and companies regarding scheduling and registration decisions. I think it needs to have a predictable time frame for making these decisions, and I think the decisions need to be made more quickly, and I hope we can pass our bill to fix it.

Mr. Faber and Ms. Selig, H.R. 4250 could be seen as ceding to FDA decisionmaking authority to an advisory committee, although it does provide the FDA with some authority to reject that decision. As far as I know, this would be unprecedented use of the advisory committee. I would like to get both of your reactions to the description in the bill.

Mr. Faber. As I said earlier, I do think that there needs to be some very modest improvements made to the Sunscreen Innovation Act that would give FDA more time to review the recommendation of a technically competent advisory panel and that the FDA should have the final say regarding the safety and efficacy of a sunscreen ingredient. I think one of the important changes is that there is an appeals process envisioned in this bill where the supervisory staff, CDER staff, could ultimately overrule a staff decision. That supervisor should have the power to ask staff for more information, to ask the panel for more information, and not simply be in the position of having to approve the panel's recommendation.

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Mr. Green. Would the PASS Coalition be willing to work with the committee and the FDA to improve the legislation to get a bill that would work for all of us?

Ms. Selig. Absolutely. The coalition has been attempting to work with everybody involved throughout this process and has had multiple conversations and meetings with all stakeholders and will absolutely continue to do that.

I think that the bill as drafted would be a great step forward, and we envision, obviously, and from the perspective of melanoma patients and from the public in terms of our recommendation to the American people about using safe and effective sunscreen and using it properly, we definitely want to make sure that these products are reviewed in an appropriate regulatory environment by the FDA to be both safe and effective.

That said, the current process doesn't work. One reason that we have been told that it has been so difficult is because of the regulatory rulemaking process. So I think the proposal that is in the legislation is aimed at trying to get out from under that so that we can move these things forward in an appropriately timely manner and get back to innovating in this country, as opposed to watching the rest of the world have access to more innovation than we are having here. So we absolutely will work with everybody to try to make this bill better, but we definitely want to see the legislation move toward.

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Mr. Green. Mr. Gray, prescription drug abuse on the rise and represents significant growing public health threat. Congress and relevant Federal agencies in public and private have responsibilities to address this epidemic and ensure the health and safety of the American people. What in your opinion is the appropriate role of prescription drug distributors in the fight to eliminate and prevent this prescription drug abuse?

Mr. Gray. Well, my members, we have 34 companies that deliver over 98 percent of the prescription drugs in this country, so we are a logical choice to look at where the drugs are coming through and going to. We have the ability to, as we do every day, to monitor the ordering of Schedule II drugs to every pharmacy and clinic in the country. We keep that data. We give it weekly to the DEA. And, in fact, that has been one of the conundrums we face is each distributor submits their data to the DEA. The DEA collects the entire picture but does not share even a redacted version of that entire picture. So one distributor may know what they give to a certain pharmacy, but they don't know what the other wholesalers what they are providing that pharmacy. So it is not a complete picture. The information is there. Our members have the technical capability to create that information. And our goal here is to be able to work collaboratively with DEA as a partner in this problem to say, does your information show what our information is, that this pharmacy is over its limits? Great. Cut that pharmacy off.

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And unfortunately, that is not the relationship we have today.

Mr. Green. Thank you, Mr. Chairman. I am out of time.

Mr. Pitts. Chair thanks the gentleman.

I now recommend the vice chair of the full committee, Mrs. Blackburn, for 5 minutes of questioning.

Mrs. Blackburn. Thank you so much, and I want to stay with Mr. Gray and follow on with Mr. Green's questioning, because as Mr. Rannazzisi said several times, DEA doesn't have quotas for the distributors, so it is up to the distributors to basically model how they are going to interact with the pharmacies on this product. So looking at the answer you just gave, is there anything else you would add into how these distributors are modeling their activity on the distribution of these drugs? And then I would like for you to talk for just a second about why this is problematic for our smaller pharmacies.

Mr. Gray. Well, let's go back on that story line we were just talking about. When our members submit their suspicious orders on a weekly basis, DEA collects that data. They collect data from all wholesalers. Imagine it as a piece of pie. They see the pharmacy as a piece of pie. They will see the 360 degrees of that piece of pie. They see everything going in the door of that pharmacy with respect to Schedule II drugs. The particular distributor, who DEA may be questioning -- and you can correct me if I am wrong on this,

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Linden -- but the DEA sees the whole picture. That particular distributor sees only their slice of the pie. They do not see what other distributors are doing.

Mrs. Blackburn. So let me ask you. Would it be helpful then if the DEA were to periodically give a report back to those distributors as to where they are seeing patterns that are troublesome?

And Mr. Barber, you may want to weigh in on this since you basically were involved in taking action.

Mr. Gray. It would certainly help because I know, in many cases, talking to my members, is that they will approach the regional office of DEA and say, We have got a pharmacy here, pharmacy X; pharmacy X to us has suddenly seen an increase in ordering. This is out of their normal historical trend. Mr. DEA agent or Ms. DEA agent, should we cut that pharmacy off?

And the answer most typically back is, Well, that is a business decision the wholesaler needs to make on their own, and then we will essentially fundamentally let you know if you were wrong after the fact.

So you are right. He was right. There are no quotas, but again, that creates the conundrum and the problem because not having quotas gives DEA the flexibility to take enforcement action I think without any kind of clarity to the wholesalers as to whether or not they are making the right decision in terminating that pharmacy.

Linden, I don't know if you have a different opinion.

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Mr. Barber. Mrs. Blackburn, I have looked at some of the DEA information that they have provided the industry. One of the things that we hear over and over again from the agency is there is an average number of pills that a pharmacy uses, but a pharmacy that fills 50 prescriptions a day uses a lot less drugs than a pharmacy that fills 500 prescriptions a day, and being above average is meaningless because if you have a normal distribution curve, half of your customers are going to be above average, and so it would be very helpful to industry if there was trending and modeling done not just by the industry, but by the agency who has all of the information.

Mrs. Blackburn. Okay. Mr. Barber, in your testimony, you focused a little bit on the importance of clarity of the law, and are there some specific areas that you think we should highlight in working with the DEA on how they should be more clear with the registrant?

Mr. Barber. Certainly, and I think your bill takes a great first step in creating the environment that is necessary by clarifying what "imminent danger" means and what "consistent with the public health and safety" means. At an industry conference recently, a DEA official told the industry that it means whatever DEA says it does. That is not really helpful when you are trying to comply with the law. There are other areas where I believe that oversight can be helpful, particularly in the regulatory environment. The agency will talk about things like due diligence by distributors on customers and yet

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you won't find the term "due diligence" anywhere in DEA's regulation. And so areas like that require clarification and notice and comment rule making because it is those types of initiatives that actually will prevent prescription drug abuse.

Mrs. Blackburn. Thank you.

I yield back.

Mr. Pitts. Chair thanks the gentlelady.

Now recognizes the ranking member emeritus Mr. Dingell for 5 minutes for questions.

Mr. Dingell. Mr. Chairman, thank you for your courtesy. These questions are for Ms. Wendy Selig of the Melanoma Research Alliance. They will only require yes or no answers.

Ms. Selig, do you believe that skin cancer is a public health crisis in this country today? Yes or no.

Ms. Selig. Yes.

Mr. Dingell. Ms. Selig, is it correct that one American dies of melanoma every hour? Yes or no.

Ms. Selig. Yes.

Mr. Dingell. Ms. Selig, is exposure to UV radiation a major risk factor for skin cancer? Yes or no.

Ms. Selig. Yes.

Mr. Dingell. Now, Mr. Faber. This is for Mr. Scott Faber. Mr. Faber, your organization has extensive experience in this area. Do

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you agree that sunscreens which provide balanced UVA and UVB protections help lower the risk of getting skin cancer? Yes or no.

Mr. Faber. Yes, sir.

Mr. Dingell. Mr. Faber, to confirm, do people in Europe, Canada, and elsewhere, have access to more new innovative sunscreen products than do consumers in the United States? Yes or no.

Mr. Faber. Yes.

Mr. Dingell. Very quickly, why is that?

Mr. Faber. Because our FDA has failed to provide a process that allows expedited review of promising sunscreen ingredients.

Mr. Dingell. I have been observing that they are sitting on those regulations like a hen on a porcelain doorknob.

Mr. Faber. Yes, sir.

Mr. Dingell. Now, Mr. Faber, is it correct that FDA has not acted on applications for several chemicals that offer strong UVA protection but are already in use in the European Union and in Australia? Yes or no.

Mr. Faber. Yes, sir.

Mr. Dingell. Mr. Faber, do you believe that the American people deserve access to these promising sunscreen technologies as long as they are proven to be safe and effective? Yes or no.

Mr. Faber. Absolutely. Yes, sir.

Mr. Dingell. Mr. Faber, do you agree that the legislation is

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needed to improve FDA's review of sunscreen ingredients? Yes or no.

Mr. Faber. Yes, sir.

Mr. Dingell. Mr. Faber, you have been before this committee on a number of occasions, and I have always appreciated your wisdom and assistance.

Thank you to our panel.

It is clear to me that skin cancer is today a major public health crisis in this country, and legislation is needed to improve FDA's review of new sunscreen ingredients, which they are sitting most tranquilly by.

The Sunscreen Innovation Act is one way to do so. I look forward to working with all of my colleagues to improve this legislation in whatever bipartisan manner may be necessary so it can be signed into law this year.

I would point out that each hour, there is going to be an American somewhere dying of melanoma and skin cancer, and it does seem that maybe the Congress can assist the Food and Drug to come to a proper conclusion of addressing the concerns that we have about keeping Americans safe and affording them the same privileges and protections that are given in Europe, where there have apparently been no backlash, no problems about the question of safety with regard to these pharmaceuticals.

Ladies and gentlemen of the panel, thank you.

Mr. Pitts. The chair thanks the gentleman.

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Now recognize the gentleman from Kentucky, Mr. Whitfield, 5 minutes for questions.

Mr. Whitfield. Thank you, and I certainly agree with all the comments made by Mr. Dingell and particularly that relating to the porcelain knob. I like that.

Let me just say this, Mr. Faber, thank you for your testimony and for coming up with some concrete suggestions on ways to improve the legislation, and Ms. Selig, I really do want to thank you and the Melanoma Research Alliance as well as the task group for sort of leading the charge on this issue. I was wondering, had you been aware of the suggestions that Mr. Faber made today before he made them today?

Ms. Selig. I think recently, yes, and we really appreciate the constructive effort to help everybody come up with a product that Congress can move forward with quickly.

Mr. Whitfield. I wish that the PASS group would get together with Mr. Faber's organization and see if we can come up with some improvements, and then maybe both sides of the aisle working together, we can move this legislation. And I know that Dr. Woodcock and others at the FDA have indicated they want to do something, so maybe we can help them make the decision on what should be done. So if you all would do that and get back with us, we would appreciate it.

Mr. Faber. Absolutely.

Mr. Whitfield. I yield back now.

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Mr. Pitts. The chair thanks the gentleman.

I now recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for questioning.

Mr. Griffith. Thank you, Mr. Chairman.

Mr. Gray, I am up here trying to problem solve and figure these things out because you may have heard my example earlier when I was standing in my local pharmacy, and they were under the impression, DEA witness testified that that was incorrect, that there is no quota, and you have said that as well, but the distributors have to watch it and be careful, and they don't really know when it is they are going to get in trouble with the DEA.

Mr. Gray. Correct.

Mr. Griffith. So here is what I have come up with that may be affecting -- and I represent a fairly rural district that has a lot of small pharmacies. We have fewer mom-and-pop pharmacies than we used to, but still serve a fairly rural, somewhat suburban, but fairly rural community, and that is that apparently it may be true that at some of the smaller pharmacies, they only use one distributor. Has that been your experience, that maybe some of the small pharmacies use one distributor for their drugs?

Mr. Gray. You know, I think that will depend upon the where and the when. I mean, I would say, and this is just anecdotal, that is probably true the more rural that it is. More than likely it is one

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wholesaler involved.

But that being said, there is a growing secondary and tertiary industry. When pharmacy cannot get product, they go into those markets to get that product. So it very well may be that they are actually dealing with other wholesalers that may or may not be reporting data to the DEA. It is very possible.

Mr. Griffith. The concern that I have is that maybe they are being flagged, and the distributor is saying, Okay, we can't send you any more because you are getting more than the distributor, you know, next valley over or down the road, depending on the size of the pharmacy. And if you are only using one, that is going to flag. As you said, the DEA gets the whole picture, but each distributor only sees what they are doing.

Mr. Gray. Correct.

Mr. Griffith. And so they can see a pharmacist perhaps that is using one wholesaler or distributor getting more drugs than some of his contemporaries nearby, but they may be using two distributors, but the first distributor is never going to know that they are getting two sources or three sources versus just the one.

Mr. Gray. Well, the layer of complexity to that is then it depends upon the demographics of that pharmacy and the patient population because the pharmacy in your district may have historically a number of pain patients. They may be near pain clinics. They may

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be hospitals or cancer clinics. And so it does vary. This is a difficult target because it does vary by pharmacy, by the location, by the demographics of the pharmacy, by the business model, where it is relative to other health care delivery systems in the area. So it is not as black and white as you might think, and that is where any amount of clarity we can get from the DEA as a wholesaler will be of extraordinary help.

Mr. Griffith. And so that is why you feel that they ought to share some of that information so that you all can get the big picture, too. Not that we want to help the bad guys.

Mr. Gray. That is right.

Mr. Griffith. And so you think that perhaps the information sharing that is envisioned by 4069 would be a good thing?

Mr. Gray. I think it would be an excellent thing.

Mr. Griffith. And you think that this might help my pharmacy back home?

Mr. Gay. I think it would help your pharmacy back home because whatever that wholesaler, whoever it was, made that decision, made it because they know the historical purchasing and delivering with that pharmacy, and they probably saw an uptick depending upon the time of the year or whatever. And the way it is played now, is if there is an uptick, then that is defined in the wholesaler's mind, that is suspicious. And the immediate reaction is if it is suspicious, you

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must terminate, and then talk with the appropriate people. So the decision always is to terminate first when in doubt.

Mr. Griffith. Now, in this case, they didn't apparently terminate long term. Is that what the normal is, or just say no more for this month, or this cycle?

Mr. Gray. Well, good point. It should be for a finite set of time. In fact, we submitted a series of questions on two occasions to the DEA in the last 24 months. Do not have answers to those questions. One of them actually addressed that issue. For example, we asked a group of our members, said is 90 days, is 120 days, what is the appropriate amount of time before a wholesaler should reinstitute sales to that? What is the appropriate move on the trend line of the purchase order of that pharmacy to make that decision? Unfortunately, to this date, we have no answers. We have got no guidance from the agency.

Mr. Griffith. It is a difficult answer, and so I certainly don't want to be critical of the DEA trying to control medications that shouldn't be out there on the street and making sure that they are not going to folks who shouldn't have them. At the same time, we want to make sure that the Judge's wife, and that this lady whose mother desperately needed that medication are able to get it. So it is a balancing act. I appreciate that, and of course, being a legislator by nature and at heart, having served here not so long, but served a

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long time in Virginia, I recognize that it is the role of the legislative body to help enact that and move things forward, so I hope that we can get some form of 4069 passed.

And, Mr. Chairman, I yield back.

Mr. Pitts. The chair thanks the gentleman and also thanks the witnesses for your testimony, for answering our questions. There will be follow-up questions. We will provide those to you in writing. We ask that you please respond as promptly as possible. I will remind members they have 10 business days to submit questions for the record, and that means members should submit their questions by the close of business on Monday April 21. Very important health and public safety issues raised today. Thank you very much.

Without objection, the subcommittee is adjourned.

[Whereupon, at 5:51 p.m., the subcommittee was adjourned.]