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MARKUP OF:

H.R. 271, RESOLVING ENVIRONMENTAL AND GRID RELIABILITY CONFLICTS ACT OF 2013;

H.R. 1407, ANIMAL DRUG USER FEE AMENDMENTS OF 2013, AS AMENDED BY THE SUBCOMMITTEE ON HEALTH; AND

H.R. 1919, SAFEGUARDING AMERICA'S PHARMACEUTICALS ACT OF 2013

TUESDAY, MAY 14, 2013

House of Representatives,

Committee on Energy and Commerce,

Washington, D.C.

The committee met, pursuant to call, at 4:05 p.m., in Room 2123, Rayburn The Capitol, Hon. Joseph R. Pitts presiding.

Present: Representatives Barton, Whitfield, Pitts, Burgess, Scalise, Latta, Olson, Gardner, Bilirakis, Waxman, Dingell, Pallone, Schakowsky, Matheson, and Christensen.

Staff Present: Clay Alspach, Chief Counsel, Health; Charlotte Baker, Press Secretary; Mike Bloomquist, General Counsel; Sean Bonyun, Communications Director; Matt Bravo, Professional Staff Member; Allison Busbee, Policy Coordinator, Energy & Power; Patrick Currier, Counsel, Energy & Power; Sydne Harwick, Legislative Clerk; Tom Hassenboehler, Chief Counsel, Energy & Power; Brittany Havens, Legislative Clerk; Robert Horne, Professional Staff Member, Health; Peter Kielty, Deputy General Counsel; Carly McWilliams, Professional Staff Member, Health; Brandon Mooney, Professional Staff Member; Andrew Powaleny, Deputy Press Secretary; Krista Rosenthall, Counsel to Chairman Emeritus; Heidi Stirrup, Health Policy Coordinator; Lyn Walker, Coordinator, Admin/Human Resources; Jeff Baran, Minority Senior Counsel; Phil Barnett, Minority Staff Director; Jen Berenholz, Minority Chief Clerk; Alli Corr, Minority Policy Analyst; Eric Flamm, Minority FDA Detailee; Karen Nelson, Minority Deputy Committee Staff Director for Health; Rachel Sher, Minority Senior Counsel; and Roger Sherman, Minority Chief Counsel.

Mr. Pitts. The committee will come to order. The chair recognizes himself for an opening statement.

Tomorrow we will consider three important pieces of legislation. H.R. 271, the Resolving Environmental and Grid Reliability Conflicts Act of 2013.

[H.R. 271 follows:]

******** INSERT 1-1 ********

Mr. Pitts. H.R. 1407, the Animal Drug User Fee Amendments Act of 2013, as amended.

[H.R. 1407 follows:]

******** INSERT 1-2 ********

Mr. Pitts. And H.R. 1919, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the pharmaceutical distribution supply chain and for other purposes.

[H.R. 1919 follows:]

******** INSERT 1-3 ********

Mr. Pitts. For the sake of time I will focus my remarks on the two health bills. H.R. 1407, as amended, reauthorizes both the Animal Drug User Fee Act, ADUFA, and the Animal Generic Drug User Fee Act, AGDUFA. ADUFA, first authorized in 2003, and AGDUFA, first authorized in 2008, are successful user fee programs at FDA that help expedite the drug approval process, and reduce application backlogs, and improve communications with drug sponsors. Absent congressional action, both of these programs will expire on September 30, 2013.

Industry and FDA have negotiated new agreements for both ADUFA and AGDUFA, which were delivered to the committee in February and would extend these programs through fiscal year 2018. Under the negotiated proposal for ADUFA III, industry would pay approximately $23.6 million in fiscal year 2014 and similar amounts, adjusted for inflation, for fiscal years 2015 to 2018. Under the proposed AGDUFA II agreement, industry would pay more than $38 million for fiscal years 2015 through 2018.

I would like to thank Representative Shimkus and Gardner for their hard work and leadership on these user fee reauthorizations, and I would urge all of my colleagues to support H.R. 1407.

Regarding the pharmaceutical supply chain, or track-and-trace legislation, on April 25th the Health Subcommittee held a hearing on the initial Latta-Matheson discussion draft, which provides a uniform framework for securing the downstream pharmaceutical supply chain, which includes manufacturers, wholesale distributors, pharmacies,

repackagers, and third-party logistics providers.

Securing the supply chain through this bill will help ensure that counterfeit or stolen drugs do not enter the supply chain and harm patients. It will also ensure that overlapping red tape does impose dramatic cost on patients in the form of higher prescription drug cost or potential drug shortages.

Several changes have been made to the discussion draft since the hearing. Most notably, the updated discussion draft contains two important changes to address concerns from some of my colleagues. First, it ensures that a prescription drug products transaction history will be required starting on January 1st, 2015. It also includes a framework to move towards unit level tracking in a manner that ensures a collaborative process between FDA and stakeholders, respects the unique nature of small businesses and dispensers, and most importantly, is practical and achievable.

I look forward to moving these important pieces of legislation to the floor. And I now recognize my friend from California, Mr. Waxman, for 5 minutes for his opening statement.

[The prepared statement of Mr. Pitts follows:]

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Mr. Waxman. Thank you very much, Mr. Chairman. Thank you, Mr. Chairman, for recognizing me for this opening statement.

Today we consider a bill designed to improve the integrity of our drug supply chain. Unfortunately, this bill falls far short of achieving that goal. Throughout last year members on a bipartisan, bicameral basis engaged in extensive discussions on legislation to protect our supply chain, and I was part of this group, as was Chairman Upton and Representatives Pallone, Dingell, Matheson, and Bilbray. During those months of discussion last year and at our hearing last month we repeatedly heard loud and clear from the Food and Drug Administration, the National Boards of Pharmacy, and many others that if we want a secure drug supply chain we ultimately need an electronic interoperable unit-level tracking system that involves the entire supply chain and that can identify illegitimate products in real time to prevent it from ending up in patients' hands.

We also heard repeatedly that creating this kind of system is doable. One of our witnesses told us it is already being done in China. Unfortunately, the bill we are considering today, or will be considering tomorrow, could actually slow down the progress we have made thus far toward building that kind of system. The bill does not require the establishment of an electronic interoperable unit-level system.

By 2027, 14 years from now, FDA will be required to issue proposed regulations for such a system. But there is no requirement that these

regulations ever be finalized. And if they are ever finalized they cannot go into effect for at least 2 more years. Almost certainly we are looking at 2030 or beyond under this proposed bill, and in fact it may never be done.

I cannot support a bill with these kinds of delays and uncertainty about whether we will ever see even an electronic interoperable unit-level system. I say this not just because the bill would preempt on day one strong state laws that are already in place in states like California and Florida, I say this because it removes the incentives for the parties to come to the table and solve the problem. There is simply no reason to wait to put enforceable standards in place.

Last month Senators Burr, Bennet, Harkin, and Alexander distributed a draft bill that does not make the establishment of this kind of system we all agree we need contingent on FDA rulemaking. That bill requires the establishment of a unit-level electronic interoperable system within 10 years and FDA is clearly required to establish this system based on the requirements in the statute. So getting the kind of certainty we need is not some farfetched idea, it is incorporated in a bipartisan bill that is now moving through the Senate today.

To be clear, I am concerned about the preemption of California's and other States' laws in both the Senate and the House bill. I do not think even the Senate bill goes far enough to provide the same level of protection that California does, and I think it should be

strengthened. At the very least the House bill should be as strong as the Senate bill.

Our fundamental goal in establishing a Federal system should be to prevent Americans from being harmed by counterfeit and substandard medicines. If we cannot assure the public that legislation will establish a system that will protect them by a date certain, then in my view it is just not worth doing. I urge all members to oppose this bill.

We are also considering in committee the Olson bill. This bill would shield utilities complying with the Department of Energy emergency order from any liability for noncompliance with any Federal, State, or local environmental law or regulation resulting from actions taken to comply with the DOE order. An identical bill passed the House last Congress with broad bipartisan support.

Last year I opposed the bill in its original form. However the bill sponsors, Chairman Upton, and the affected industry were willing to engage in serious, substantive negotiations that produced significant improvements. The version of the bill that ultimately passed the House was more narrowly crafted and provided some environmental safeguards. The language of this bill represents a delicate compromise that was carefully negotiated and is one that I plan to support.

Thank you, Mr. Chairman. Yield back my time.

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Mr. Waxman follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. Chair reminds members that, pursuant to committee rules, all members' opening statements will be made part of the record. Are there further opening statements? Chair recognizes the gentleman from Texas, Mr. Barton, for 3 minutes for his opening statement.

Mr. Barton. Thank you, Mr. Chairman. I rise in support of H.R. 271, H.R. 1407, and H.R. 1919. These three bills are all good legislation, and I am told that all three have been worked on in a bipartisan fashion. I could be corrected on that, but I believe that is a true statement.

The H.R. 1919 I think is a bill that is realistic in its intent and will help protect the safety of Americans. The Republican staff has worked with the Democratic staff to address the minority's concern, and this is a strong bipartisan bill that will help patients and not hinder medical providers.

H.R. 271, Resolving Environmental and Grid Reliability Conflicts, is another good piece of legislation. As you know, Mr. Chairman, we have a situation where we have conflicting Federal law. We have one law that prevents the emissions of certain things at power plants and then we have a law that allows in times of distress the ability for the President to issue a decision that power plants can operate above their emission standards. Mr. Olson's bill resolves these conflicts in a way that I think Members on both sides of the aisle can support.

And then of course the 1407, Animal Drug User Fee Amendment Act,

I am told is noncontroversial. So I hope we can mark these bill up tomorrow in a bipartisan fashion. And with that, Mr. Chairman, I yield back.

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Mr. Barton follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. Chair now recognize the ranking member emeritus, the gentleman from Michigan, Mr. Dingell, for 3 minutes.

Mr. Dingell. Thank you, Mr. Chairman. Mr. Chairman, this is a good bill. I intend to support it. As my old dad used to tell me, if we all agreed on everything we would all be married to the same woman. I think that would be a hell of a mess.

Having said that, I can support the Senate bill or I can support the House bill. And I think that this is a long stride forward in our efforts to improve food and drug law. It is something on which we are able to come to agreement and something on which we have been able to make significant progress, and more remains to be done. Our constituents deserve the piece of mind in knowing that the pharmaceuticals they take have not been stolen, misbranded, counterfeited, or otherwise altered. H.R. 1919 is a good step in that direction. And I want to thank my friends Mr. Matheson and Mr. Latta for their hard work on this matter.

As I have said before, we can't let the perfect be the enemy of the good, and I believe we need to move the legislative process forward on this issue. And either the Senate bill or the House bill will make significant progress in an area of real need.

And I want to remind my colleagues that this is not our last bite at the apple. We have a chance to pass the bill and we then have a chance to reconcile it with the bipartisan Senate counterpart. I think we must let the process work, and we will reach agreement if we work

together. The committee has a history of doing just that, and I find in my time here that some time it is -- in fact oftentimes it is best to be part of the process in order to, first of all, influence the outcome, and, second, to achieve a desirable and a good outcome.

At the end of the day we all share the goal of enacting a fair, feasible traceability system where all the supply chain are responsible for ensuring the safety of pharmaceuticals and the government can take the steps necessary to see to it that the pharmaceuticals are safe and that they can be recalled and that they can be properly traced. When we get done here we have more to do. It will go to the floor. It will then go to the Senate if the Senate is ready, and we will then have a negotiation between these two bodies, at which time we can then move forward towards achieving the final perfection that everybody seems to want.

In the meantime I would remind my colleagues that if we don't work together we are not going to get to that last step. So I will be supporting some amendments, but I also am going to be working hard to get this legislation through, I urge my colleagues to join me.

I yield back the balance of my time.

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Mr. Dingell follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. And now recognize the chairman of the Subcommittee on Energy and Power, Mr. Whitfield, for 3 minutes for his opening statement.

Mr. Whitfield. Chairman Pitts, thank you so much. And I am delighted that the two bills that were reported favorably by the Health Subcommittee will be here for markup, H.R. 1407 and H.R. 1919. And Chairman Pitts has already made comments about these bills, and I hope that all of us will support it.

I do want to make some brief comments about the Resolving Environmental and Grid Reliability Conflicts Act of 2013 and thank Congressman Olson and Mr. Doyle, Mr. Terry, Mr. Green and Mr. Kinzinger for bringing that legislation to the committee. It will protect our Nation's electricity producers from being penalized when they are ordered to operate during an emergency if in doing so they violate an environmental law or regulation. This legislation will prevent them from being penalized or sued during that emergency order. It is a good piece of legislation and I would recommend that we all support it. I yield back the balance of my time.

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Mr. Whitfield follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. Now recognize the ranking member of the Health Subcommittee, Mr. Pallone, 3 minutes for an opening statement.

Mr. Pallone. Thank you, Mr. Chairman.

I am able to lend my support today to H.R. 271, the Resolving Environmental and Grid Reliability Conflicts Act of 2013, as well as H.R. 1407, the Animal Drug User Fee Amendments of 2013, or ADUFA.

H.R. 271 is identical to legislation passed out of this committee in the previous Congress. The bill makes certain that power companies are able to comply with Department of Energy emergency power orders without facing penalties for violating conflicting environmental laws. When emergencies threaten the electricity supply and the Department of Energy requires generators to operate, which is a very rare occurrence, these companies should not face fines or legal action.

H.R. 1407, or ADUFA, was reported out of the Health Subcommittee last week by a voice vote, and as a cosponsor of the bill I encourage my colleagues to support this legislation. The Senate last week passed ADUFA by unanimous consent. I am hopeful that the House can follow suit soon.

Congress enacted both agreements to help improve the FDA renew of new and generic animal drugs, and these programs have been extremely effective and have helped expedite the approval process, reduce application backlogs, and improve communications with drug sponsors.

Unfortunately, Mr. Chairman, at this point I still cannot support H.R. 1919, Safeguarding America's Pharmaceuticals Act of 2013.

During our subcommittee markup my colleagues and I raised a number of concerns with the bill. At the top of that list was ensuring that the process we set up for drug distribution security must result in a clear path to self-effectuating unit-level traceability. The bill requires FDA to issue only a proposed regulation on unit-level traceability in 2027. It also requires a 2-year implementation delay with no timeline for a final rule.

I belive strongly that the public deserves to know that the prescriptions they receive are safe and effective and that the product can be traced back to the manufacturer, wholesaler, and other parties involved if necessary. But the bill before us does not give the public that assurance. In fact, all we know is that in 17 years something might happen -- and, look, many of us won't be here in 17 years. We have no idea who will be president, what party will be in the majority, what the world will look like. And whether we like it or not, sometimes regulations can be delayed by forces out of Congress' control.

I agree that it is frustrating to think that a regulation required by law may never come out, but that is simply the truth. And if my Republican friends think that won't happen, then there would be no problem with putting in place a self-effectuating component as a backstop. If it is unneeded there is no harm. And perhaps by having one it would motivate all parties to work to get a regulation in place instead of some fighting against a regulation.

I want to see a process that allows stakeholders to engage in the

policy. I want to see FDA hold public meetings, complete a thorough proposed and final rulemaking process. But I also want and need to see some assurance that a unit-level system will be in place in the future. Without that, I simply can't support the bill.

So, Mr. Chairman, I am also disappointed that the committee has not worked with us on the other concerns we raised at the subcommittee. We brought out three other issues to the Republicans in hopes that we could address changes in the legislation. These include a request to change the preemption of State laws from day 1 of enactment to a day closer to 1215 when the Federal requirements on passage of transaction information are in effect. Currently there are State and Federal requirements in place that mandate the passage of pedigrees for drug transactions. Dr. Woodcock told us at the hearing that these requirements are an important tool for law enforcement when they are going after counterfeiters and grey market privateers trying to profit from drug shortages. So to wipe out the requirement that pedigrees be passed even if it is only for a year and a half is a significant issue that can't be ignored.

We also ask that the bill be changed to allow States to put in place further requirements on distributors and third-party logistic providers as they see fit for their individual states. And finally we ask that the policy on returns be strengthened, which we believe would close loopholes in the bill that allow for counterfeit and substandard drugs to find a place to enter the system. And I am sorry

to say, Mr. Chairman, that your staff was not willing to address these concerns.

So I am saddened that my Republican colleagues weren't able to work more closely with me in developing this legislation. I hope that doesn't become the norm. And, Mr. Chairman, while the bill before us today is a step in the right direction it is not the proposal that will truly bring security to the pharmaceutical distribution supply chain. And so I urge my colleagues to oppose H.R. 1919.

Thank you, Mr. Chairman.

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Mr. Pallone follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. Now recognize the vice chairman of the Health Subcommittee, Dr. Burgess, for 3 minutes for an opening statement.

Dr. Burgess. I thank the chairman for the recognition. We are going to mark up three important bills. I appreciate the chairman letting me be involved in the development of these.

I do want to say a few words about some of the important steps we are taking regarding the track-and-trace bill, H.R. 1919. The United States has one of the best drug supply chains in the world, but it faces attack each and every day by counterfeiters, thieves, and rogue distributors. American consumers could assume that prescription drugs are sold and tracked rigorously from manufacturer to retailer. I mean, after all companies contract shipments of books, clothing, shipments of Britney Spears CDs down to the minute that they arrive at a retailer. Surely our prescription drug chain is recorded and regulated.

Well, American consumers could make that assumption, but in fact they would be wrong. Current law leaves a great deal of leeway for counterfeit medications to enter the market. And the punishment, the punishment for counterfeiting prescription medications is astonishing light. From fake flu vaccines to fake cancer drugs, counterfeit medications have been manufactured and allowed to enter the supply chain and administered. The United States may be more secure, but we are still at risk. In an era of increasingly sophisticated domestic and international threats to the integrity of the Nation's prescription

drug supply, the current State-by-State regulatory structure simply cannot provide the strong and consistent standards that we need to protect the public and give faith to the healthcare workforce that the drugs they are dispensing or administering are the ones that came from the manufacturer.

It is particularly important to me as a physician to know THAT when I administer a drug it is what I think it is and it is what the patient thinks that they are purchasing. We have, unfortunately, heard stories about when counterfeit medications do enter the system, the harm that they cause.

I think the bill before us is guided by the strong principle of patient safety and supply chain integrity. The bill, however, is flexible and does not seek to be overly burdensome to States, suppliers, and small businesses. Maintaining the integrity of the United States prescription drug supply is a compelling national priority. I certainly look forward to us working together to get this bill passed tomorrow, look forward to it coming to the floor. I would support it. I thank you and I yield back.

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Dr. Burgess follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. Now recognize the gentleman from Utah, Mr. Matheson, 3 minutes for an opening statement.

Mr. Matheson. Thank you, Mr. Chairman. Thank you for holding this markup.

When it comes to the track-and-trace issue, this has been a long time coming. Over the years I have had the pleasure to work with several members on this committee, starting with Mr. Buyer and then Mr. Bilbray, and now I am happy to be working with my friend and colleague Mr. Latta on this issue.

I think this bill is important because it can provide some immediate steps to strengthen the integrity of the drug supply chain, and it is going to provide industry stakeholders a path toward what will be unit-level traceability at some point, too. Without such action, I think everyone in the supply chain is going to be forced to comply with an ever-changing and complicated patchwork of different State laws. And I don't think anybody thinks that is a good idea, but if we don't do this bill that is the path we could be going down.

Twenty-nine States have done some form of looking at this issue, not that they have all passed their own track-and-trace. But 29 different sets of rules, that isn't going to work for our Nation's drug supply chain. So I do think it is important that we recognize the value of setting a national standard so that everyone in the supply chain can play by the same set of rules and implement these rules.

It is also important that we do this because we have got to make

sure we make maintain the integrity of the supply chain due to the opportunity that counterfeiters see in our drug supply chain. When you have a roughly $325 billion market each year in the United States of America, that is a lot of money on the table, it is an attractive target. And while we have had great success over the years to maintain the integrity of the drug supply chain in this country, it is important for us as technology evolves for us to also make sure that we have rules and procedures in place to enhance the integrity of that supply chain because I just think it is too much of an inviting target.

Now, this legislation does a lot to develop regulations on unit-level traceability. The process set forth is one of collaboration between stakeholders and the FDA. The bill establishes the FDA is going to conduct pilot projects, it is going to hold regular meetings with the industry to better inform the agency as to the feasibility of unit-level traceability and the processes needed to achieve that goal.

That is important to note. This is complicated. Complicated to do this well and to do it right. How many times have we seen action at State level or at Federal level to say here we want this by a date certain, but the technology isn't there to make it happen by that date certain. We have seen already situations with the e-pedigree law in California, for example, where it has had to be delayed on numerous occasions, because it is important that you get it right.

I want to make sure everyone in the supply chain has an opportunity

to communicate and collaborate with the FDA on this matter. This legislation allows that to happen. I urge my colleagues on both sides to support this legislation. We all value the integrity of our drug supply chain, we all value trying to make sure we have taken appropriate steps to ensure the integrity, and I look forward to continuing with this markup tomorrow.

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

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Mr. Matheson follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. Now recognize the gentleman from Ohio, Mr. Latta, 3 minutes for an opening statement.

Mr. Latta. Well, thank you, Chairman, and thank you very much for holding today's markup on these three important pieces of legislation, especially H.R. 1919, the Safeguarding America's Pharmaceuticals Act of 2013. This legislation is a culmination of many years of hard work by legislators and stakeholders, and I am honored to have introduced this legislation along with Congressman Matheson.

Securing our Nation's pharmaceutical supply chain is an extremely important issue, and I am pleased that the committee has made the issue a top priority of this Congress. The pharmaceutical supply chain touches every part of the healthcare system, and it is imperative that we get the structure and segments of it connected in a save, secure, and effective manner that provides the best protection for patients.

H.R. 1919 will make improvements to the current supply chain while providing a clear path for industry stakeholders toward enhanced supply chain protections. Pharmaceutical distribution occurs nationwide and it is estimated that within the United States there are more than 4 billion prescriptions filled each year. By replacing the current patchwork of multiple State laws with a uniform national standard we improve safety, eliminate duplicative regulations, and create certainty for all members of the pharmaceutical supply chain. When an individual takes a prescribed medication they should have full confidence that the medication is as prescribed and will not impose

harm.

It is of utmost importance that we implement commonsense solutions to safeguard our distribution supply chain against counterfeit and stolen drugs, as well as improve security integrity throughout the supply chain. This legislation is an important step to ensure greater patient safety for all Americans. To protect patient safety this bill would replace multiple State laws and create a uniform national standard for securing the pharmaceutical distribution supply chain, therefore preventing, again, duplicative State and Federal requirements.

It would increase the security of the supply chain by establishing tracing requirements for manufacturers, wholesale distributors, pharmacies, and repackagers based on changes in ownership. The bill also establishes a collaborative, transparent process between the FDA and stakeholders to study ways to even further secure the pharmaceutical supply chain. Finally the bill puts in place a requirement for the FDA to issue proposed regulations on unit-level traceability.

The timeline put forth in this bill for all steps is reasonable and will allow enough time for stakeholders to comply with the new national standards and ensure that, through feedback from these same stakeholders, that phase two is done efficiently and correctly. There has been much work done on this issue over many years, and I am appreciative of all the input that I have received on this bill from

stakeholders and interested parties.

I want to specifically thank the Health Subcommittee staff, my staff, and other House staff for all their hard work on this legislation. I look forward to continuing to work with Chairman Upton, Subcommittee Chairman Pitts to move this legislation to the House floor, and I urge full support of H.R. 1919.

Thank you, Mr. Chairman. I yield back.

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Mr. Latta follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. Now recognize the gentlelady from the Virgin Islands, Dr. Christensen, for 3 minutes for an opening statement.

Dr. Christensen. Thank you, Mr. Chairman. I thank you and the ranking member for the opportunity to make an opening statement on these three important bills. We know that the reauthorization of both the Animal Drug User Fee Act and the Animal Generic Drug User Fee Act are critically important, not only to the FDA, but also to the animal drug approval process and the application pipeline. And so these two bills in today's markup represent important progress, and I support H.R. 1407, as well as H.R. 271.

This body is marking up H.R. 1919, the bill intended to bolster the security of the pharmaceutical drug distribution supply chain, and I support it because the issue of counterfeit, as has been said, and substandard or altered medications entering our supply chain is critically important for the FDA and the American public and for this body to address. But it also provides me with an opportunity to address a longstanding challenge facing only pharmacists in the U.S. Virgin Islands. And I also support the inclusion of the interoperable units electronic system.

My pharmacies need this remedy to keep their doors open and to continue serving my constituents. I hope that the parliamentarian has found this. In our jurisdiction the issue of a treaty should not be relevant here. We are not asking to amend the treaty, just to recognize that the V.I. is part of the U.S. and that my pharmacies are American,

are U.S. pharmacies.

And if there is going to be an interoperable units electronic system to ensure unit-level traceability, as I also believe there should be in this bill, that would allow us to ensure that what my pharmacies say is being sent is exactly that. And all we are asking is that they would be allowed to send medication back to the same U.S. distributor that they bought them from.

However we resolve this important issue for my district it needs to be done, and, again, I thank the chairs and ranking members of the subcommittee and of the full committee and many of my colleagues for their willingness to work with me on this issue. I yield back the balance of my time.

Mr. Pitts. Chair thanks the gentlelady.

[The prepared statement of Dr. Christensen follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. Now recognize the gentleman from Texas, Mr. Olson, for 3 minutes an opening statement.

Mr. Olson. Thank you, Mr. Chairman, for holding this markup. I support all these bills that we are marking up today. I especially thank you for bringing H.R. 271, the Resolving Environmental and Grid Reliability Conflicts Act of 2013, before the full committee for markup. This bill, which passed the House by voice vote last year, clarifies that compliance with an emergency order issued by the Department of Energy is not a legal violation of any Federal, State, or local environmental rules.

As we have seen in my home State of Texas, heat waves can come on quickly, and when the air conditioning is cranked up on successive 100-degree days the power grid can become overcome. When the power goes out it is the young, the elderly, and the poor who face life-threatening situations. Section 202(c) of the Federal Power Act allows DOE to order a plant to run when grid reliability is at stake, even if it puts an operator in conflict with an environmental law. Currently that plant's operator can be open to third-party lawsuits and fines despite the fact that they were ordered to run. It happened in California in 2001, it happened right here across the Potomac in 2005.

With many coal plants slated to close in the next few years, reliability concerns in pockets of our country are rising. That is why I have 10 letters of support for this bill which I ask to enter

into the record.

I want to remind my colleagues that these are short-term emergency orders, of limited duration, they are not issued lightly. This bill is about preventing grid failure, not avoiding environmental compliance. While there are concerns that H.R. 271 doesn't offer enough protection to plant operators who might face lawsuits from environmental groups, H.R. 271 is a vast improvement over current law. Major utilities in both public and investor-owned power trade associations strongly believe that a Federal court would be hard pressed to overrule an emergency order issued by the DOE. H.R. 271 ensures that DOE will consult with clean air regulators, but the final decision in emergencies always remains firmly in the hands of the those charged with keeping the power flowing.

This is a rare bipartisan bill that protects the environment and grid reliability. I look forward to working with my colleagues on both sides of the aisle to move it through the House, through the Senate, and to President Obama's desk for signature into law.

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

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Mr. Olson follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. And the document the gentleman asked to be entered into the record will be entered into the record with unanimous consent. Without objection, so ordered.

[The letters of support follow:]

******** COMMITTEE INSERT ********

Mr. Pitts. Chair recognizes the gentlelady from Illinois, Ms. Schakowsky, for 3 minutes for an opening statement.

Ms. Schakowsky. Thank you, Mr. Chairman.

I support H.R. 271, the Resolving Environmental and Grid Reliability Conflicts Act of 2013, and I am glad that we were able to work together in a bipartisan basis on this important piece of legislation. I hope our bipartisan work on this bill will lead to bipartisan work on global warming as well.

I also support H.R. 1407, the Animal Drug User Fee Amendments Act of 2013. This legislation would allow the FDA to continue the successful animal drug user fee program without interruption. After passage of this legislation I hope we can work together to pass legislation that limits the unnecessary antibiotic use in animals in order to prevent the development of antibiotic-resistant bacteria that threaten human life and human health.

However, I can't support H.R. 1919, the Safeguarding America's Pharmaceuticals Act of 2013. As it is currently written this legislation falls short of its stated goal of safeguarding our drug supply. I strongly agree with the universally held goal of creating a nationwide system that ensures the safety and security of prescription drugs through our supply chain. Ensuring that we prevent counterfeit and substandard drugs from entering our supply chain has to be a priority. Patients should not bear the burden of worrying whether their treatment could fail due to receiving counterfeit or

substandard products that have entered our drug supply.

Experts in the industry agree that the solution to truly securing our supply chain is the creation of a nationwide electronic system of track and trace at the unit or package level. While H.R. 1919 puts industry on the path toward such a system, it does not require the establishment of a nationwide electronic tracking system at the unit level by a date certain.

What is a mystery to me is why we wouldn't support a bill that does just those things. There is universal support from the industry, PhRMA, the distributors, the manufacturers, the pharmacists for the Senate bill that includes those provisions. They have expressed an ability, they believe, to met the 10-year date that is set in the Senate bill for being able to actually comply with the provisions of the law. So I am a bit unclear why we aren't willing to do it because I feel that the failure limits our ability to protect consumers, leaves our supply chain vulnerable to the entry of illegitimate drugs, and leaves patients at risk of receiving counterfeit or substandard drugs, and we shouldn't allow this.

And I thank the chairman and yield back.

Mr. Pitts. Chair thanks the gentlelady.

[The prepared statement of Ms. Schakowsky follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. Now recognize the gentleman from Colorado, Mr. Gardner, 3 minutes for an opening statement.

Mr. Gardner. Thank you, Mr. Chairman, thank you for convening this markup on three important pieces of legislation.

The first bill before the committee, H.R. 271, the Resolving Environmental and Grid Reliability Conflicts Act, will strengthen our electric grid reliability by allowing electricity-generation units to run during an emergency without violating environmental regulations.

The second, H.R. 1919, the Safeguarding America's Pharmaceuticals Act, will put in place much needed measures to ensure safe and accountable access to medications. This bill increases supply chain security and holds bad actors responsible for tampering with prescription medications.

Finally, we will consider H.R. 1407, the Animal Drug User Fee Amendments of 2013. This bipartisan bill passed out of the Health Subcommittee last week and was amended to include the Animal Generic Drug User Fee Amendments of 2013 or AGDUFA. I had the honor to introduce AGDUFA with the support from many colleagues on both sides of the aisle in this committee and our efforts to reauthorize this important program at FDA.

I would like to thank Congressman Shimkus for his leadership on the Animal Drug User Fee Amendments Act. During the legislative hearings on these bills I mentioned that my congressional district is home to over 2.8 million head of cattle, 450,000 hogs and pigs, and

close to 160,000 sheep and goats. And, yes, there are more cows in my home county than there are people. Colorado is also home to one of the Nation's premier schools of veterinary medicine at Colorado State University. This legislation allows farmers, ranchers, and animal caregivers to have access to medications that they need for treatment of herds and pets.

In regard to AGDUFA, during questioning before the Health Subcommittee, Dr. Bernadette Dunham, the Director of the Center for Veterinary Medicine at the FDA, cited the importance of having generic animal drugs on the market. She stated, just like on the human side, generic drugs provide an opportunity to have a safe and effective drug that would be able to give you cost saving. She further said that the more that we can have generic drugs come through and have their approval, it is going to be helping everybody.

The animal generic drug user fee program at FDA has achieved noteworthy success since first being authorized in 2008. It is an honor to have the opportunity to lead the reauthorization of AGDUFA through this committee. I look forward to its swift passage for consideration on the House floor, and, again, thank the chairman for his leadership.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Gardner follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. Now recognize the gentleman from Louisiana, Mr. Scalise, 3 minutes for an opening statement.

Mr. Scalise. I want to thank the chairman for holding this markup today. I would like to begin with H.R. 1919, my colleague Mr. Latta's legislation that aims to improve the integrity of our pharmaceutical supply chain.

With the increasing utilization of pharmaceuticals and their key role in improving the health of Americans, it has become even more important to protect the pharmaceutical supply chain and protect patients from counterfeit medicines. And while it is very important for us to focus on the need to safeguard America's pharmaceutical supply chain, it is unfortunate that we have to deal with the radical regulations coming out of California which threaten to raise the cost of everyone's medicines across the country because of the cost of complying with one of the State's radical regulations that has driven millions of jobs out of the State. Yet again, in its infinite wisdom, California, the State with one of the highest unemployment rates, highest tax rates, and coincidentally mountains of radical regulations, has decided to put in place a supply chain system that if left unchecked will affect and impose new costs on families and patients all across the country, including my home State of Louisiana.

I appreciate Mr. Latta's commitment to this issue and the work he has done on this legislation.

Another piece of legislation we are marking up, Mr. Olson's grid

reliability bill, passed the full House by voice vote last year and I commend the chairman for bringing up this commonsense bill. The security of our Nation depends on a reliable power grid, and Mr. Olson's legislation provides tools to ensure that third-party lawsuits don't jeopardize the reliability of our grid system in an emergency.

People that produce power for our country are, unfortunately, posed with the dilemma in the event of emergency, and there is a recognition that if a company is placed in this situation you want them to be able to act in the best interest of consumers and not have a fear that doing so will open them up to a host of environmental lawsuits. H.R. 271 would fairly protect generation operators from liability for bypassing Federal, State, or local environmental laws or regulations that conflict with the concurrent Federal directive to operate consistent with the public interest to maintain health safety.

Finally, I want to commend my colleague Mr. Shimkus for his work on H.R. 1407. We look forward to bringing all these bills up to the full committee. And, Mr. Chairman, thank you, and I yield back.

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Mr. Scalise follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. Now recognize the gentleman from Florida, Mr. Bilirakis, 3 minutes for an opening statement.

Mr. Bilirakis. Thank you, Mr. Chairman. I appreciate it very much. Thank you again for bringing up these important bills.

The Resolving Environmental and Grid Reliability Conflicts Act will ensure Florida utilities have the necessary protections to operate when mandated by the Federal Government because of a natural disaster. The Department of Energy has the authority under the Federal Power Act to order an electric-generating facility continue to operate in order to prevent a reliability emergency. If that facility were not operating because of environmental regulations, then the utility would be in the position of having to choose which mandate to comply with.

H.R. 271 creates a process so that utilities are able to follow these emergency orders without being forced into serious legal jeopardy. This bipartisan piece of legislation will help utilities keep the power running when natural disasters such as hurricanes strike, protecting lives and aiding the recovery process. With the start of hurricane season only a few short weeks away, I urge my colleagues to support this important piece of legislation.

The Animal Drug User Fee Act is an important bill that will help to ensure new innovative animal drugs and cheaper generic animal drugs get to market in a timely manner. Animal drugs help contribute to the health and well-being of animals and the overall public health. It allows our farmers to continue to raise healthy animals, protecting

the integrity of our food supply. These user fees are used by the FDA to deal with the drug application process with adequate resources. This prevents large-scale backlogs from developing and allows the FDA to approve future animal drugs without adding to the burden on taxpayers in this era of trillion-dollar deficits.

Finally, the Safeguarding America's Pharmaceuticals Act establishes a national track-and-trace standard. Florida has had its own track-and-trace legislation, which was first passed in 2003 when I was in the State legislature. The Florida law is a good law that tracks pharmaceuticals in the supply chain from the wholesaler to the pharmacy. H.R. 1919 uses Florida's law as a model and goes even further by tracking pharmaceuticals from the manufacturer to the pharmacy, closing a loophole that the Florida law could not address. It will also take us to unit-level tracking of medicine.

While this bill is not perfect and my staff has talked with the committee about my concerns regarding a possible gap in coverage, it is a major step toward securing our pharmaceutical supply chain and ensuring a safe and stable supply of medicine. I hope that between now and the floor we can work on improving this bill. Again, Mr. Chairman, I support passage of all these three bills, and I thank the chairman for his hard work. Thank you, and I yield back.

Mr. Pitts. Chair thanks the gentleman.

[The prepared statement of Mr. Bilirakis follows:]

******** COMMITTEE INSERT ********

Mr. Pitts. That concludes the opening statements. The Chair calls up H.R. 1919 and asks the clerk to report.

The Clerk. H.R. 1919, to amend the Federal Food, Drug, and Cosmetic Act with respect to the pharmaceutical distribution supply chain and for other purposes.

Mr. Pitts. Without objection, the first reading of the bill is dispensed with and the bill will be open for amendment at any point. So ordered.

For the information of members, we are now on H.R. 1919. The committee will reconvene at 10 o'clock a.m. tomorrow morning. And I remind members that the chair will give priority recognition to amendments offered on a bipartisan basis. Look forward to seeing all of you tomorrow. Without objection, the committee stands in recess.

[Whereupon, at 4:55 p.m., the committee was recessed, to reconvene at 10:00 a.m., Wednesday, May 15, 2013.]