RPTS MCKENZIE

DCMN HERZFELD

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

WEDNESDAY, MAY 15, 2013

House of Representatives,

Committee on Energy and Commerce,

Washington, D.C.

The committee met, pursuant to call, at 10:15 a.m., in Room 2123, Rayburn House Office Building, Hon. Fred Upton [chairman of the committee] presiding.

Present: Representatives Upton, Hall, Barton, Whitfield, Shimkus, Pitts, Walden, Terry, Rogers, Murphy, Burgess, Gingrey,

Scalise, Latta, McMorris Rodgers, Harper, Lance, Cassidy, Guthrie, Olson, McKinley, Gardner, Pompeo, Kinzinger, Griffith, Bilirakis, Johnson, Long, Waxman, Dingell, Pallone, Rush, Eshoo, Engel, Green, DeGette, Capps, Doyle, Schakowsky, Matheson, Butterfield, Barrow, Christensen, Castor, Sarbanes, McNerney, Braley, Welch, Lujan and Tonko.

Staff Present: Nick Abraham, Legislative Clerk; Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Mike Bloomquist, General Counsel; Matt Bravo, Professional Staff Member; Patrick Currier, Counsel, Energy and Power; Paul Edattel, Professional Staff Member, Health; Steve Ferrara, Health Fellow; Brad Grantz, Policy Coordinator, O&I; Sydne Harwick, Legislative Clerk; Tom Hassenboehler, Chief Counsel, Energy and Power; Brittany Havens, Legislative Clerk; Sean Hayes, Counsel, O&I; Robert Horne, Professional Staff Member, Health; Kirby Howard, Legislative Clerk; Peter Kielty, Deputy General Counsel; Nick Magallanes, Policy Coordinator, CMT; Carly McWilliams, Professional Staff Member, Health; Brandon Mooney, Professional Staff Member; Katie Novaria, Professional Staff Member, Health; Andrew Powaleny, Deputy Press Secretary; Krista Rosenthall, Counsel to Chairman Emeritus; Chris Sarley, Policy Coordinator, Environment and Economy; Charlotte Savercool, Executive Assistant, Legislative Clerk; Heidi Stirrup, Health Policy Coordinator; 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 Lightfoot, Minority Communications Director and Senior Policy Advisor; Karen Nelson, Minority Deputy Committee Staff Director for Health; Rachel Sher, Minority Senior Counsel; and Roger Sherman, Minority Chief Counsel.

The Chairman. We are going to get started. The committee will come to order. I would note that at the conclusion of the opening statements yesterday, the chair called up H.R. 1919, and the bill was open for amendment at any point. So first of all, are there any bipartisan amendments to the bill?

The chair would recognize the gentleman from Ohio.

Mr. Latta. Thank you, Mr. Chairman. I have an amendment at the desk.

The Chairman. The clerk will report the title of the amendment.

The Clerk. Amendment to H.R. 1919 offered by Mr. Latta.

The Chairman. And the amendment will be considered as read. Staff will distribute the amendment. And the gentleman is recognized for 5 minutes in support of the amendment.

[The amendment of Mr. Latta follows:]

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

Mr. Latta. Well thank you very much, Mr. Chairman.

This amendment is being offered by Mr. Matheson and myself. And what it does is it makes a number of clarifying and technical changes to the bill. And I would like to take just a few minutes to describe some of the changes that the amendment makes.

The amendment would ensure that the requirements of the bill related to transactions apply to dispensers when a change of ownership occurs. This change would ensure intracompany transfers of a prescription drug product do not trigger transaction requirements and is consistent with the ownership framework of the bill.

The bipartisan amendment would ensure that prescription drug products dispensed and owned by hospitals, for instance, like the Nationwide Children's Hospital in Columbus, are not unduly burdened by the law when ownership of the drug remains with such hospitals.

The provisions also in the bill relate to e-labeling, and they have been modified to ensure that only information for physicians, pharmacists, and other healthcare professionals fall under the scope of the language rather than the patient-specific information. It would also authorize the Secretary to issue regulations requiring paper information in certain instances to mitigate a safety risk. And finally, it allows this e-labeling provision to be phased in over time.

And along with the other technical changes in the amendment, it improves the bill. And I would urge my colleagues to support it. At this time, Mr. Chairman, I would like to yield to Mr. Matheson, the

cosponsor of the amendment.

Mr. Matheson. I thank my colleague for yielding some of his time, and I appreciate his description of this amendment. It is pretty straightforward, and I am not going to go through and repeat everything that Mr. Latta just said in this amendment.

But I think this issue about the intracompany transfers, this is a thoughtful addition to this bill to try to make sure we are not going too far in terms of applying this in a situation where it shouldn't be applied. So I appreciate the gentleman's clarified amendment. I am glad to have my name on it with him, and I will yield back.

Mr. Latta. I thank the gentleman for yielding back. And, Mr. Chairman, I yield back the balance of my time.

Mr. Waxman. Mr. Chairman?

The Chairman. The chair would recognize the gentleman from California Mr. Waxman.

Mr. Waxman. The amendment was shared with our staff this morning. It appears to be technical in nature. Our staff asked the majority staff that if there is a problem, we would continue to work on it. And I thought that made a lot of sense. So on that basis I would join in support of the amendment.

Mr. Latta. I thank the gentleman.

The Chairman. The gentleman yields back. Are there other Members wishing to speak on the amendment? Seeing none, the vote occurs on the Latta-Matheson amendment. Those in favor will say aye.

Aye.

Those opposed, no.

In the opinion of the chair, the ayes have it. The ayes have it. The amendment is agreed to.

Are there further amendments to the bill?

The gentleman from New Jersey.

Mr. Pallone. Mr. Chairman, I have an amendment at the desk, Pallone 1, I guess.

The Chairman. The clerk will report the title of the amendment.

The Clerk. Amendment to H.R. 1919 offered by Mr. Pallone of New Jersey.

The Chairman. And the amendment will be considered as read.

[The amendment of Mr. Pallone follows:]

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

The Chairman. The gentleman from New Jersey is recognized for 5 minutes in support of his amendment.

Mr. Pallone. Thank you, Mr. Chairman.

My amendment is straightforward. It would ensure that we have a so-called phase 2 in which an electronic, interoperable unit-level system is established by no later than 10 years after enactment. It also requires FDA to implement this system on the basis of specific language in the statute. It does not make the system contingent on FDA's adoption of regulations, which we all know can take years and potentially never happen.

We have repeatedly heard loud and clear from the FDA, Pew, the National Boards of Pharmacy, and many others that if we want a secure drug supply chain, we need an electronic, interoperable unit-level tracking system that can identify illegitimate product in realtime so that it does not end up in patients' hands.

We have also heard repeatedly that creating this kind of system is doable and in the very near future. In fact, a letter I received just last night from a company in Pennsylvania said, and I quote, "From a technical and commercial perspective, I want to assure you that there is no reason to delay unit-level tracking. In fact, any further delay will slow industry momentum and increase the risk of patient safety."

Unfortunately, the bill we are considering today does not actually require the establishment of an electronic, interoperable unit-level system by a date certain. Instead, by 2027, FDA will be

required to issue proposed regulations that would have finalized the establishment of the system. But now the bill also makes the establishment of the interoperable, electronic unit-level system entirely dependent on the issuance of final regulations by FDA. But the bill never even sets a date by which the FDA would be required to finalize the regulations. So the proposed regulations could sit and linger for years before we ever see a final regulation. And on top of this, Mr. Chairman, the bill requires that there be yet another delay of 2 years in implementation after the final regulations are issued, if they ever are. So that is 17 years waiting for something to maybe happen.

These kinds of delays and uncertainty about whether we will ever even see this electronic, interoperable unit-level system are unnecessary. We, I think, can do better than this. We must require the FDA to establish the system based on the requirements in the statute. And this is not a new way to legislate. We do not need to require FDA to implement regulations as a precondition. In fact, in our 2007 drug safety legislation, this is exactly what we did. We gave FDA the authority to impose risk evaluation and mitigation systems, or REMS, post-market-safety studies and to require label changes, all without requiring FDA to first promulgate regulations.

We also know the perils of rulemaking in general. Even if we were to require FDA to issue final regulations by a date certain, there is no guarantee that it will actually happen. And look at what has

unfortunately happened with critical regulations for food safety law that we enacted in 2011.

So, Mr. Chairman, 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 regulations 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 it, we could motivate all parties to work to get a regulation in place instead of some fighting against a regulation.

So I support provisions that require FDA to establish guidances and regulations, hold public meetings, and conduct pilot studies so that there is a transparent process and ample opportunity for stakeholder input, but we simply need to have the certainty that our intentions come to bear fruit. I don't know who is going to be here in 17 years, so in order to justify preempting all State laws, I think a date certain and a self-effectuating system must be in place. So I ask my colleagues to support my amendment to fully operational unit level phase 2. Without its passage I think the bill will fall short.

I yield back, Mr. Chairman.

The Chairman. The gentleman yields back. Are there other Members wishing to speak on the amendment?

The chair would recognize the gentlelady from Tennessee.

Mrs. Blackburn. Thank you, Mr. Chairman.

I have to say, I do not support Mr. Pallone's amendment. What this amendment would do very simply is to prioritize the concerns of the bureaucrats over at the FDA over those of our Nation's job creators, including many of our small pharmacies.

Now, what this would do, what this amendment would end up doing is to make phase 2 self-effectuating. While the idea may sound good to the bureaucrats, it would have some detrimental consequences for our job creators. And what it would do with this self-effectuating process would allow the FDA to impose unit-level traceability without having to go through the process of taking input from the American people.

You will notice Mr. Pallone said he supports having the input, and the public notices, and the hearings, but -- and therein is the problem with this. We already have a problem with not enough transparency that is given to the American people. We have problems with the FDA getting their work done. We have problems with putting rules and regulations in place, and then we have to come back and review them because they did not do their job right the first time. So to impose unit-level traceability without having to go through the process of taking that input would be a very difficult situation.

H.R. 1919 is written to make sure that even our Nation's smallest pharmacies and all the supply chain participants, everybody is going to have a seat at the table during this rulemaking process, something

that is an imperative. And having the FDA follow the Administrative Procedures Act while developing their plans for phase 2 is essential to ensuring transparency, and making sure that everyone has an equal opportunity to voice their concerns, and to have those concerns as a part of the record. It is essential to making sure that this bill will work. So I encourage my colleagues to vote "no" on this amendment.

Mr. Pallone. Would the gentlewoman yield just 30 seconds?

Mrs. Blackburn. Sure. I will yield. I had yielded my time back, but certainly --

Mr. Pallone. I just want to repeat what I said before, which is that under this amendment we do require the FDA to establish guidance, to publish guidances, hold public meetings, conduct pilot studies. So there is a transparent process with the amendment that I have. I just wanted to make that clear.

Mrs. Blackburn. I reclaim my time. And I just remind the gentleman that you do have that, but as so many times happened, there is a "but." Your amendment would sound good to the bureaucrats over at the FDA, and it would be very difficult -- make things more difficult for our Nation's job creators. They already have too much regulatory overreach that they are dealing with every day.

And with that, I yield back my time.

Mr. Waxman. Mr. Chairman?

The Chairman. The gentleman from California.

Mr. Waxman. Mr. Chairman and my colleagues, this is not about

bureaucrats over at the FDA versus our job creators. This is about being able to trace a drug that may be counterfeit, or to trace a drug that may be ineffective and harmful because we don't know where it came from. That is what we all want. Otherwise we wouldn't bother with this legislation.

Everybody claims they want that result. But the truth of the matter is, without the Pallone amendment and under this bill, there is no "there" there. For example, they say no sooner than January 1, 2027 -- 14 years from now -- would FDA issue proposed regulations. Even if they are ready to go earlier, they can't do it. That would prioritize those bureaucrats at the FDA.

But that is not the only thing this bill does. After FDA acts 14 years from now, there is no requirement that anything happen because, first of all, there has got to be 2 more years after that before final regulations are issued. So FDA would propose regulations 14 years from now, and then 2 more years before they have final regulations. And there is no guarantee even then we would have anything that would be in effect.

So what is this really all about? Everybody says they want this interoperable tracking, tracing system to protect the consumer -- not bureaucrats, but to protect the consumer. Unless we get to a point where something actually happens, no one is protected. I don't want to have to be here 14, 16, 18, 20 years from now to say, "I told you so." And let me assure you, I am not going to be here 20 years from

now to tell you, "I told you so." That may brighten the day for a lot of you.

But the reality is if we are going to bother with a bill to protect the public, to protect the consumers, let's get something done, because realize what this legislation does. It says, if the States were on this issue, in order to protect their citizens, we are going to preempt them. Right now, as soon as this bill becomes law, they are preempted, California, Florida, others. The States are preempted. Their laws are wiped out while they, along with everybody else, wait for 14 years before FDA may -- not they will, but may -- propose regulations, and then 2 years after that before they are final.

And what will happen? Well, those who don't want regulations will have a good opportunity to keep on pushing further and further and further. But the people who are working on the system to be able to develop the tracking mechanisms are going to have an incentive because they won't have a development for the market of this technology. They are going to be set back.

Now, there is a lot of work going on right now. Talk about job creators. Tell somebody who is working as an entrepreneur to develop something that is needed -- a tracking and tracing system -- that you will have the market for your thing, your entrepreneurship, your invention because this is what the public wants. Well, there is no market if it is 14, plus 2. If this is out in the future, it may never happen. They will go and do something else.

So I would urge support for the Pallone amendment. It gives us some certainty that something is going to happen.

And this bill is -- as I said, there is no "there" there. It says the States cannot act. If they have already acted, their laws are null and void until we wait for an uncertain time in the future, not in our lifetimes as Members of Congress, for the most part, and then we will see if something happens. But it is a recipe for no action at all.

That is why I think the Pallone amendment makes sense. And it is very close to what a bipartisan group in the Senate has in their bill, a bipartisan group, Democrats and Republicans. If you don't move to something actually happening, I can assure you, the people running over to the Senate and saying, why are you actually having a bill where something will happen? Why don't you go along with that bill where nothing will happen, and then we can have an agreement? Well, so much of an agreement for everybody to be happy, except the consumers will not be protected from counterfeit, harmless -- harmful, useless drugs that get into the system and may be given to them in a prescription.

So I urge support for the Pallone amendment and opposition to the bill if the Pallone amendment is not adopted.

The Chairman. The gentleman's time has expired. The chair would recognize the gentleman from Texas Dr. Burgess.

Dr. Burgess. Mr. Chairman, I would like to strike the last word or the requisite number of words.

You know, it is something I have thought a lot about on this. But

the big problem is making phase 2 self-effectuating. This space is not frozen in time. While the big companies may have no difficulty accepting this time frame, smaller companies may. But let us be honest, this pace of medical technology is changing so rapidly, the words we write today, the words we speak today may have little meaning or little reflect what the real world looks like 2 years, 4 years, 6 years hence.

It doesn't seem to me that the Pallone amendment would, in fact, clarify things for the agency making the regulations; but it introduces a host of uncertainty to those -- particularly those smaller pharmacies that are going to have to live under those regulations that are promulgated by the agency.

So I think the intent -- and I do agree with Ranking Member Waxman that it does seem that there is general alignment on the product that is to be produced by the committee, but at the same time, if we make it so restrictive and overbearing, we are going to have difficulty, our smaller pharmacies are going to have difficulty in dealing with the rules that are set forth in the legislation. So H.R. 1919 is carefully written to make sure that even the Nation's smallest pharmacies and all of their supply-chain participants will have a seat at the table during the rulemaking process. And after all, that is what we should be about, openness and transparency. That is what the Obama administration ran on on their first term. They wanted to be the most open and transparent administration in history, and here we

have a chance to help them fulfill that lofty ideal to which we hope they still aspire.

We are simply asking for the FDA to follow the law, follow the Administrative Procedures Act in developing plans for phase 2, and we believe that is essential to ensuring transparency and, in fact, making certain that everyone has equal opportunity to voice their concerns.

It is also essential to making certain that at the end of the day, what do we all want? We want this bill to work. And the base language of the underlying bill is geared toward that. The Pallone amendment actually will make that more difficult to accommodate.

Mr. Shimkus. Would the gentleman yield?

Dr. Burgess. I would be happy to yield.

Mr. Shimkus. I would just follow up on your comments, because, first of all, we are going to have a chance to debate an amendment on preemption, and I look forward to that debate because I think the interstate commerce clause is pretty clear, and that is one I am ready to engage in.

The second point is this is about really regular order and process, and we want everybody to be at the table. And to support the Pallone amendment, you are actually defaulting outside of the process to make sure everyone has a say in the regulation administration.

So I appreciate what my colleague from Texas has said, and I think it is pretty simple, and I urge my colleagues to vote "no" on the Pallone amendment.

I yield back to Dr. Burgess.

Dr. Burgess. I will yield back the balance of my time.

The Chairman. The gentleman yields back.

Do other Members wish to speak?

The gentlelady from Illinois Ms. Schakowsky.

Ms. Schakowsky. Thank you, Mr. Chairman.

In response to my colleague from Illinois, there has also been a big process going on in the Senate. And experts in industry support the development of a nationwide track-and-trace system at the unit level by a certain date, which is incorporated in the Senate bill, which is supported -- this is not about the FDA; I agree with our Ranking Member Waxman that this is about the consumer. But industry groups, including PhRMA, the Health Care Distribution Management Association, National Community Pharmacists Association, the Biotechnology Industry Organization, the Generic Pharmaceutical Association, the Health Industry Distributors Association, the National Association of Chain Drugstores, have all come out in support of the bipartisan Senate bill that requires the creation of a system of unit-level tracking within 10 years and have expressed confidence that this can happen within 10 years.

And so it seems to me -- 10 years, think. It has been mentioned several times how fast technology is moving ahead. Ten years is a lifetime in the ability to be able to develop a track-and-trace system at the unit level. We are not demanding a certain kind of technology

when it comes to that unit level. We are just saying it is at that level that will provide the maximum protection for consumers, and, frankly, the maximum protection also for the pharmaceutical companies or whoever is distributing that to make sure that they have safe drugs that are being distributed.

So I don't get it when we have got the kind of universal support from the industry for a stronger piece of legislation why the House -- and admittedly, many of them are supporting the House bill as well, but why would we go for a bill that provides less protection for consumers when we have the stakeholders at the table?

You know, FDA bureaucracy, that is an easy thing to just -- you know, it rolls off the tongue. But we are talking about all of the experts and the industry stakeholders who support a more protective piece of legislation. So I am urging strong support --

Mr. Waxman. Would the gentlelady yield to me?

Ms. Schakowsky. Who is asking?

Mr. Waxman. Waxman.

Ms. Schakowsky. Oh, of course. Yes.

Mr. Waxman. I just want to underscore the point you have made. The coalition of all the industry groups that are supporting the legislation are supporting a bill that has the Pallone language in it. They are also supporting this bill that is before us because they want to get things moving, but they have endorsed the bill with the Pallone provisions in it.

So I don't think that we ought to worry about the fact that some industry people don't want this bill amended. They are supporting the bill with this particular kind of amendment, specific amendment, in it. Thank you.

Mr. Shimkus. Would the gentlelady yield for just a second?

Ms. Schakowsky. I saw a hand from my colleague Donna Christensen.

Dr. Christensen. I will be very brief. I want to support the amendment as well. Everyone here knows that I have been trying to include a provision that would allow my pharmacists in the Virgin Islands to send their drugs back to the distributor in the States that they bought them from. And this kind of tracking, the unit-level tracking, I think would facilitate our being able to do that. So for that reason also I support the Pallone amendment, and I yield back the time.

Ms. Schakowsky. If my colleague from --

Mr. Shimkus. I mean, you said it. The ranking member said it. But the industry groups that you all mentioned also support this bill without the Pallone amendment. And I yield back.

Ms. Schakowsky. And I yield back.

The Chairman. Other Members wishing to speak?

The gentlelady from California is recognized.

Mrs. Capps. I move to strike the last word, Mr. Chairman. I speak to support the Pallone amendment because it would ensure that

all the work we are doing here today would actually lead to the unit-level trackable system we all agree is necessary.

Unfortunately the current version of H.R. 1919 has no deadline for the final regulation for unit-level traceability. And right now the proposed legislation simply identifies the problem we all know is there, problems we have been trying to address for years in this committee, but it doesn't create a guarantee that meaningful protections will ever be in place for patients or companies.

For over 7 years, my State has been working to develop a system that actually secures the drug supply and increases confidence in the prescription drug distribution. Industry has been preparing, and over 30 organizations, including 3 that testified at our hearing, have indicated that they are operating in good faith to implement the requirements by the deadline in California. After three delays, we are finally just more than a year away from the beginning of stronger consumer protections and supply chain safety.

While I understand and agree with the need and desire for one Federal system that ensures all Americans will benefit while being less onerous on industry, the bill before us actually puts the hard work of so many to waste. I understand implementing this kind of system, particularly at the Federal level, will take some time. No one here is suggesting that the entire Nation can be up and running under a strong system by next year. But given industry's cooperation and commitment, I am disappointed this bill has no final date for any unit-level

interoperability.

Under the current draft, at minimum, it will be 14 years until anything substantial happens; no guarantees that the system will ever go into effect in a full way. It has been already mentioned that if Federal legislation or regulation is enacted, the California law is preempted. And the intention of the preemption clause in California was to allow a stronger uniform track-and-trace system headed by the FDA to lead the way, not to allow a weaker system of inaction to take over.

So if we are going to preempt proactive State laws, we must provide a Federal blueprint that moves us forward in a reasonable time frame, and we need to do it right. And that is why I support the Pallone amendment.

At our legislative hearing a few weeks ago, FDA said that everyone benefits from having a definite date for requiring the use of an electronic system. And this is what the bipartisan Senate bill contains: a firm but fair schedule to create a uniform national system. Accepting this amendment, including this provision for phase 2, in H.R. 1919 moves us forward to achieve a meaningful system.

FDA will be required to conduct a transparent process with ample opportunity for stakeholder input; but in the end if they do not issue a final regulation, as we have seen happen before, there will still be a national unit-level interoperable system that will provide security and confidence with each transaction in the prescription drug

supply chain. That is why I really urge my colleagues on both sides of this committee to support this amendment, which would ensure that all our hard work and the hard work of industry will actually keep our drug supply safe.

And I will be happy to yield to a colleague. Mr. McNerney, I will yield to you.

Mr. McNerney. Thank you, Mrs. Capps. I just want to know why anyone would want to hold technology back. There are innovators out there that are ready to go on this. It has already been done in California. It has been done in Florida. They were ready to implement this.

This bill without the amendment, without the Pallone amendment would hold back progress that has already been made. It will put us back, and it will keep innovation from happening.

Now, the big thrust should be to let innovators do their work. And this will create employment, and it will make the customer safe. So I don't see any reason why the Pallone amendment shouldn't be supported.

And with that I yield back.

Mr. Engel. Would the gentlewoman yield to me?

Mrs. Capps. Yes. I yield whatever time I have left.

Mr. Engel. Thank you.

I want to associate myself with Mr. Pallone's remarks. I am very concerned, as my colleagues are, that this legislation lacks a definite

date with which this country will have an interoperable, electronic unit-level tracking system. We managed to send a man on the Moon in 1969, which is a little more than 8 years after President Kennedy set this goal, and I can't imagine with today's technological advancements it would take another 16-plus years to be able to fully track prescription drugs from manufacturer to patient; that is, if we ever get to that point.

The current bill makes no guarantees this will ever happen, and I am pleased to see that the Senate bill has a firm date of 2023 for unit-level tracking, which would be enough time for technology to develop in the supply chain to properly prepare these requirements.

For those reasons, I support the Pallone amendment.

I yield back.

Mrs. Capps. I yield back.

The Chairman. Time is yielded back. Is there further discussion?

Seeing none, the vote will occur. And I know a roll call will be asked, so I will ask the clerk to call the roll on the Pallone amendment.

The Clerk. Mr. Hall?

Mr. Hall. No.

The Clerk. Mr. Hall votes no.

Mr. Barton?

[No response.]

The Clerk. Mr. Whitfield?

[No response.]

The Clerk. Mr. Shimkus?

Mr. Shimkus. No.

The Clerk. Mr. Shimkus votes no.

Mr. Pitts?

Mr. Pitts. No.

The Clerk. Mr. Pitts votes no.

Mr. Walden?

Mr. Walden. No.

The Clerk. Mr. Walden votes no.

Mr. Terry?

Mr. Terry. No.

The Clerk. Mr. Terry votes no.

Mr. Rogers?

Mr. Rogers. No.

The Clerk. Mr. Rogers votes no.

Mr. Murphy?

Mr. Murphy. No.

The Clerk. Mr. Murphy votes no.

Mr. Burgess?

Dr. Burgess. No.

The Clerk. Mr. Burgess votes no.

Mrs. Blackburn?

[No response.]

The Clerk. Mr. Gingrey?

[No response.]

The Clerk. Mr. Scalise?

Mr. Scalise. No.

The Clerk. Mr. Scalise votes no.

Mr. Latta?

Mr. Latta. No.

The Clerk. Mr. Latta votes no.

Mrs. McMorris Rodgers?

Mrs. McMorris Rodgers. No.

The Clerk. Mrs. McMorris Rodgers votes no.

Mr. Harper?

Mr. Harper. No.

The Clerk. Mr. Harper votes no.

Mr. Lance?

Mr. Lance. No.

The Clerk. Mr. Lance votes no.

Mr. Cassidy?

[No response.]

The Clerk. Mr. Guthrie?

Mr. Guthrie. No.

The Clerk. Mr. Guthrie votes no.

Mr. Olson?

Mr. Olson. No.

The Clerk. Mr. Olson votes no.

Mr. McKinley?

Mr. McKinley. No.

The Clerk. Mr. McKinley votes no.

Mr. Gardner?

Mr. Gardner. No.

The Clerk. Mr. Gardner votes no.

Mr. Pompeo?

Mr. Pompeo. No.

The Clerk. Mr. Pompeo votes no.

Mr. Kinzinger?

[No response.]

The Clerk. Mr. Griffith?

Mr. Griffith. No.

The Clerk. Mr. Griffith votes no.

Mr. Bilirakis?

Mr. Bilirakis. No.

The Clerk. Mr. Bilirakis votes no.

Mr. Johnson?

Mr. Johnson. No.

The Clerk. Mr. Johnson votes no.

Mr. Long?

Mr. Long. No.

The Clerk. Mr. Long votes no.

Mrs. Ellmers?

[No response.]

The Clerk. Mr. Waxman?

Mr. Waxman. Aye.

The Clerk. Mr. Waxman votes aye.

Mr. Dingell?

Mr. Dingell. Aye.

The Clerk. Mr. Dingell votes aye.

Mr. Markey?

[No response.]

The Clerk. Mr. Pallone?

Mr. Pallone. Aye.

The Clerk. Mr. Pallone votes aye.

Mr. Rush?

[No response.]

The Clerk. Ms. Eshoo?

Ms. Eshoo. Aye.

The Clerk. Mr. Eshoo votes aye.

Mr. Engel?

Mr. Engel. Aye.

The Clerk. Mr. Engel votes aye.

Mr. Green?

Mr. Green. Aye.

The Clerk. Mr. Green votes aye.

Ms. DeGette?

Ms. DeGette. Aye.

The Clerk. Ms. DeGette votes aye.

Mrs. Capps?

Mrs. Capps. Aye.

The Clerk. Mrs. Capps votes aye.

Mr. Doyle?

Mr. Doyle. Aye.

The Clerk. Mr. Doyle votes aye.

Ms. Schakowsky?

Ms. Schakowsky. Aye.

The Clerk. Ms. Schakowsky votes aye.

Mr. Matheson?

Mr. Matheson. No.

The Clerk. Mr. Matheson votes no.

Mr. Butterfield?

Mr. Butterfield. Aye.

The Clerk. Mr. Butterfield votes aye.

Mr. Barrow?

Mr. Barrow. No.

The Clerk. Mr. Barrow votes no.

Ms. Matsui?

[No response.]

The Clerk. Mrs. Christensen?

Dr. Christensen. Aye.

The Clerk. Mrs. Christensen votes aye.

Ms. Castor?

Ms. Castor. Aye.

The Clerk. Ms. Castor votes aye.

Mr. Sarbanes?

Mr. Sarbanes. Aye.

The Clerk. Mr. Sarbanes votes aye.

Mr. McNerney?

Mr. McNerney. Aye.

The Clerk. Mr. McNerney votes aye.

Mr. Braley?

Mr. Braley. Yes.

The Clerk. Mr. Braley votes aye.

Mr. Welch?

Mr. Welch. Aye.

The Clerk. Mr. Welch votes aye.

Mr. Lujan?

Mr. Lujan. Aye.

The Clerk. Mr. Lujan votes aye.

Mr. Tonko?

Mr. Tonko. Aye.

The Clerk. Mr. Tonko votes aye.

Chairman Upton?

The Chairman. Votes no.

The Clerk. Chairman Upton votes no.

The Chairman. Other Members wishing to vote?

Mr. Whitfield?

Mr. Whitfield. No.

The Clerk. Mr. Whitfield votes no.

The Chairman. Mrs. Blackburn?

Mrs. Blackburn. No.

The Clerk. Mrs. Blackburn votes no.

The Chairman. Did Mr. Cassidy vote?

Mr. Cassidy?

Dr. Cassidy. No.

The Clerk. Mr. Cassidy votes no.

The Chairman. Other Members wishing to cast a vote?

Seeing none, the clerk will call the tally.

The Clerk. Mr. Chairman, on that vote there were 19 ayes and 28 nays.

The Chairman. Nineteen yeas, twenty-eight nays. The amendment is not agreed to.

Are there further amendments to the bill?

Mr. Engel. Mr. Chairman?

The Chairman. The gentleman from New York.

Mr. Engel. Thank you, Mr. Chairman. I have an amendment at the

desk.

The Chairman. The clerk will read the title of the amendment.

The Clerk. Amendment to H.R. 1919 offered by Mr. Engel of New York.

The Chairman. And the amendment will be considered as read, staff will distribute the amendment, and the gentleman is recognized for 5 minutes in support of his amendment.

[The amendment of Mr. Engel follows:]

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

Mr. Engel. Thank you very much, Mr. Chairman.

I believe it is very vital that any track-and-trace legislation make every effort to fully secure our pharmaceutical distribution chain. Unfortunately H.R. 1919 as currently written has a significant loophole with which suspect or illegitimate prescription drug products could enter into our supply chain through the returns process. Concerns about this bill's return provisions were raised during our subcommittee markup last week, but unfortunately these concerns have not been addressed in this bill.

Last year during our extensive discussions about drug shortages, an investigation by Oversight and Government Reform Committee ranking member Elijah Cummings, Senator Jay Rockefeller and Senator Tom Harkin looked at 300 drug pedigrees of gray market drugs that were sold at exorbitant prices because they were in short supply. Our colleagues found that in two-thirds of these cases, the drugs entered the so-called gray market through pharmacies.

My amendment would address this loophole. One year after the enactment of this law, my amendment would require that wholesalers check to ensure the returned product matches the applicable transaction history and transaction statement before distributing returned drug products. It will be the responsibility of the wholesalers to see that the returned product from the dispenser matches the product that the wholesaler sold to that dispenser. It is perfectly logical and makes good common sense.

It would also require the transaction history to include a notation that the drug product is a return so that the recipient will know why the transaction history begins with the wholesaler and does not refer back to the drug manufacturer.

I believe that closing this loophole will help reduce the ability of suspect or counterfeit products to enter into our supply chain, further safeguarding our supply chain. Again, this makes good common sense. I cannot see why anybody would oppose this, and I urge all Members to support this amendment.

Mr. Waxman. Would the gentleman yield?

Mr. Engel. Yes. I yield.

Mr. Waxman. I recently asked my mail-order pharmacy to fill a prescription, and they sent me the wrong drug. And I was surprised that I got the wrong drug, so I called them back and I said, I have not opened it. I want to send it back to you because it is the wrong drug. It is not what I wanted. They said, oh, well, we cannot take it back because we can't be sure that you are sending us the same drugs we sent you. I said, well, I haven't opened it even. They said, it doesn't make any difference. So I got stuck with some drugs that I didn't need, and they didn't want to take it back because they didn't trust me.

Now, if a wholesaler sold drugs to a pharmacy, and the pharmacy sent back the drugs to the wholesaler, the wholesaler is going to take those drugs and then sell them again. Well, what this amendment says

is that before the wholesaler takes those drugs back, they have got to have a system to be sure these are the drugs they actually sold in the first place to the pharmacy. That should make sense.

And I could see how they didn't want to take my drugs back, because they are responsible for the security of drugs. They want to be sure that the drugs that they send to somebody is exactly what is manufactured for this purpose. So I understood why they said no to me, but a wholesaler ought to say -- they don't have to say no to a pharmacy, they just ought to have a system. And the gentleman from New York's amendment gives them time to develop a system so they can be sure these are the drugs they sold in the first place, and they are not taking back something other than that.

It is a commonsense amendment. I don't know how anybody could oppose it, and I urge Members to support it.

The Chairman. The gentleman from Ohio is recognized for 5 minutes.

Mr. Latta. Thank you, Mr. Chairman. And I wish to oppose the amendment.

You know, the purpose of this legislation -- you know, overall it is one thing: We want to make sure we have patient safety out there. Again, I would urge my colleagues to oppose the amendment because it upsets the delicate balance that the bill has done relating to returns on prescription drug products, and it also imposes a huge cost and a burden on our Nation's pharmacies and the distributors, which then

would bring higher drug prices, less jobs, and less time with patients.

We have to remember that in the bill, the underlying framework is that for all people involved, from manufacturers down to those dispensers at the pharmacy, that there is going to be transaction histories that are going to be starting on January 21, 2015. And this is a huge step to make sure that we are going to make sure we secure that supply chain, the uniform standard that protects Americans across the country from counterfeit drugs.

The amendment would require that a distributor note on a product's transaction history that the returned product -- would prohibit distributors from selling returned products unless they can associate that bottle with a particular transaction statement. And also we believe that this would extend their transaction histories -- and some would believe that this would extend to transaction histories for salable returns, and that salable returns should have a special mark noting that it is a returned product. This requires very large data sets related to transaction history to moving a prescription drug product, and it would impose an undue burden on the entire supply chain.

The amendment would also raise questions regarding prescription drug products that are safe to use. Under the system laid out in the bill, distributors would have to ensure that products leaving their facilities are a good product. If they don't, these distributors will have their name associated with a product on a transaction history under the requirements of this bill and face penalties under the Food, Drug,

and Cosmetic Act.

Changes to the bill made at the subcommittee markup require distributors to begin a transaction history on salable returns, giving the FDA the ability to know where the product is coming from and hold bad actors within the supply chain accountable.

The bill takes large steps towards securing our drug supply chain and will ultimately get us toward that unit-level tracking system. It also strikes a balance at this time to ensure that the system is both feasible and achievable. And rather than impose these unrealistic requirements that are both costly and unfeasible, let us put forth a system that actually works and gets better over time.

I yield back.

The Chairman. The gentleman yields back.

The chair would recognize the gentleman from New Jersey Mr. Pallone.

Mr. Pallone. Thank you, Mr. Chairman.

I wanted to speak in support of the Engel amendment because I think it is important to ensure that returned drugs that reenter the supply chain are just as safe as drugs going through the chain for the first time. If adequate controls are not in place, there is a potential for the entry of illegitimate drug products into the supply chain. For example, pharmacies could sell counterfeit or substandard medicines back to a wholesaler, and then the wholesaler could redistribute that product to a different pharmacy.

Not only should a transaction history accompany a returned drug product that is being distributed, but it should indicate that the product is a return so that the recipient knows why the transaction history began, and that it began with the wholesaler and does not trace back to the manufacturer.

To further protect patients and reduce the likelihood of counterfeit or substandard products entering the supply chain, we should require that wholesalers associate the returned product with the product that the wholesaler sold to that dispenser.

So I think this is a good amendment. I would support it. I believe that the gentlewoman from the Virgin Islands -- I will yield her such time.

Dr. Christensen. Thank you for yielding.

Just again to say that this amendment, as I understand it, could also be a vehicle that could fix the problem that I am trying to address in the Virgin Islands. And I support the amendment.

I yield back.

Mr. Pallone. Thank you.

If anyone else would like my time; otherwise I will yield back, Mr. Chairman.

The Chairman. The gentleman yields back.

Other Members wishing to speak?

Seeing none, the chair will ask the question: Those in favor, say aye on the amendment. Aye.

Mr. Engel. Roll call, Mr. Chairman.

The Chairman. Roll call is asked. The clerk will call the tally.

The Clerk. Mr. Hall?

Mr. Hall. No.

The Clerk. Mr. Hall votes no.

Mr. Barton?

[No response.]

The Clerk. Mr. Whitfield?

Mr. Whitfield. No.

The Clerk. Mr. Whitfield votes no.

Mr. Shimkus?

Mr. Shimkus. No.

The Clerk. Mr. Shimkus votes no.

Mr. Pitts?

Mr. Pitts. No.

The Clerk. Mr. Pitts votes no.

Mr. Walden?

Mr. Walden. No.

The Clerk. Mr. Walden votes no.

Mr. Terry?

[No response.]

The Clerk. Mr. Rogers?

Mr. Rogers. No.

The Clerk. Mr. Rogers votes no.

Mr. Murphy?

Mr. Murphy. No.

The Clerk. Mr. Murphy votes no.

Mr. Burgess?

Dr. Burgess. No.

The Clerk. Mr. Burgess votes no.

Mrs. Blackburn?

[No response.]

The Clerk. Mr. Gingrey?

[No response.]

The Clerk. Mr. Scalise?

Mr. Scalise. No.

The Clerk. Mr. Scalise votes no.

Mr. Latta?

Mr. Latta. No.

The Clerk. Mr. Latta votes no.

Mrs. McMorris Rodgers?

[No response.]

The Clerk. Mr. Harper?

Mr. Harper. No.

The Clerk. Mr. Harper votes no.

Mr. Lance?

Mr. Lance. No.

The Clerk. Mr. Lance votes no.

Mr. Cassidy?

Dr. Cassidy. No.

The Clerk. Mr. Cassidy votes no.

Mr. Guthrie?

Mr. Guthrie. No.

The Clerk. Mr. Guthrie votes no.

Mr. Olson?

[No response.]

The Clerk. Mr. McKinley?

Mr. McKinley. No.

The Clerk. Mr. McKinley votes no.

Mr. Gardner?

Mr. Gardner. No.

The Clerk. Mr. Gardner votes no.

Mr. Pompeo?

Mr. Pompeo. No.

The Clerk. Mr. Pompeo votes no.

Mr. Kinzinger?

[No response.]

The Clerk. Mr. Griffith?

Mr. Griffith. No.

The Clerk. Mr. Griffith votes no.

Mr. Bilirakis?

Mr. Bilirakis. No.

The Clerk. Mr. Bilirakis votes no.

Mr. Johnson?

Mr. Johnson. No.

The Clerk. Mr. Johnson votes no.

Mr. Long?

Mr. Long. No.

The Clerk. Mr. Long votes no.

Mrs. Ellmers?

[No response.]

The Clerk. Mr. Waxman?

Mr. Waxman. Aye.

The Clerk. Mr. Waxman votes aye.

Mr. Dingell?

Mr. Dingell. Votes aye.

The Clerk. Mr. Dingell votes aye.

Mr. Markey?

[No response.]

The Clerk. Mr. Pallone?

Mr. Pallone. Aye.

The Clerk. Mr. Pallone votes aye.

Mr. Rush?

Mr. Rush. Aye.

The Clerk. Mr. Rush votes aye.

Ms. Eshoo?

Ms. Eshoo. Aye.

The Clerk. Ms. Eshoo votes aye.

Mr. Engel?

Mr. Engel. Aye.

The Clerk. Mr. Engel votes aye.

Mr. Green?

Mr. Green. Aye.

The Clerk. Mr. Green votes aye.

Ms. DeGette?

Ms. DeGette. Aye.

The Clerk. Ms. DeGette votes aye.

Mrs. Capps?

Mrs. Capps. Aye.

The Clerk. Mrs. Capps votes aye.

Mr. Doyle?

Mr. Doyle. Yes.

The Clerk. Mr. Doyle votes aye.

Ms. Schakowsky?

Ms. Schakowsky. Aye.

The Clerk. Ms. Schakowsky votes aye.

Mr. Matheson?

Mr. Matheson. No.

The Clerk. Mr. Matheson votes no.

Mr. Butterfield?

Mr. Butterfield. Aye.

The Clerk. Mr. Butterfield votes aye.

Mr. Barrow?

Mr. Barrow. No.

The Clerk. Mr. Barrow votes no.

Ms. Matsui?

[No response.]

The Clerk. Mrs. Christensen?

Dr. Christensen. Aye.

The Clerk. Mrs. Christensen votes aye.

Ms. Castor?

Ms. Castor. Aye.

The Clerk. Ms. Castor votes aye.

Mr. Sarbanes?

Mr. Sarbanes. Aye.

The Clerk. Mr. Sarbanes votes aye.

Mr. McNerney?

Mr. McNerney. Aye.

The Clerk. Mr. McNerney votes aye.

Mr. Braley?

Mr. Braley. Aye.

The Clerk. Mr. Braley votes aye.

Mr. Welch?

Mr. Welch. Aye.

The Clerk. Mr. Welch votes aye.

Mr. Lujan?

Mr. Lujan. Aye.

The Clerk. Mr. Lujan votes aye.

Mr. Tonko?

Mr. Tonko. Aye.

The Clerk. Mr. Tonko votes aye.

Chairman Upton?

The Chairman. Votes no.

The Clerk. Chairman Upton votes no.

The Chairman. Members missing a vote.

Mrs. Blackburn?

Mrs. Blackburn. No.

The Clerk. Mrs. Blackburn votes no.

The Chairman. Mr. Barton?

Mr. Barton. No.

The Clerk. Mr. Barton votes no.

The Chairman. Cathy McMorris Rodgers?

Mrs. McMorris Rodgers. No.

The Clerk. Mrs. McMorris Rodgers votes no.

The Chairman. Mr. Terry?

Mr. Terry. Votes no.

The Clerk. Mr. Terry votes no.

The Chairman. Mr. Olson?

Mr. Olson. No.

The Clerk. Mr. Olson votes no.

The Chairman. Other Members?

Seeing none, the clerk will report the tally.

The Clerk. Mr. Chairman, on that vote there were 20 ayes and 29 nays.

The Chairman. Twenty ayes, twenty-nine nays. The amendment is not agreed to.

Are there further amendments to the bill?

The chair will recognize the gentlelady from Florida.

Ms. Castor. Mr. Chairman, I have an amendment at the desk.

The Chairman. The clerk will report the title of the amendment.

The Clerk. Amendment to H.R. 1919 offered by Ms. Castor of Florida.

The Chairman. The amendment will be considered as read, the staff will distribute the amendment, and the gentlelady is recognized for 5 minutes in support of her amendment.

[The amendment of Ms. Castor follows:]

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

Ms. Castor. Thank you, Mr. Chairman.

Members, my amendment would ensure that existing State and Federal laws relating to drug tracking, the so-called pedigree, are not preempted until the provisions of this new Federal law are fully implemented. And here is the difference: The bill says that we are going to preempt State laws upon enactment when the President signs the bill into law, not when the provisions of the new law are fully implemented. So what that does is that creates a gap that criminals are sure to exploit.

I hope that we are all here today with the common goal to ensure that the pharmaceutical supply chain is safe for families across America. The problem with the current vision is that it would prematurely preempt a very effective law that we have had in place in Florida since 2003 and other State laws that are out there until the -- well, and we don't have a guarantee when the implementation will come.

Now, during the Health Subcommittee consideration of this bill, I raised this concern that relates here looking at the summaries of the uniform national policy section of the bill we are discussing today.

Now, in Florida, the Florida law requires a pedigree that identifies each previous sale of a drug back to the manufacturer accompany most drug transactions. And there was a strong reason that Florida passed such a law in 2003, and that was because Florida was a hotbed of criminal activity when it came to wholesale pharmaceuticals

and counterfeiting. There was story after story of criminals moving away from traditional crimes, like distributing illegal drugs, robbery, et cetera, and instead got engaged in the wholesale pharmaceutical business. Counterfeit and adulterated prescriptions were making their way into the market, and criminals were making millions and millions of dollars selling counterfeit drugs like the anemia drug Procrit, AIDS drugs, and cholesterol medication.

Here are a few examples of headlines from 2003 in Florida: "Former Convicts Try a Safer Venture: Pharmaceuticals." Here is another one: "Prescription Drug Corruption Rampant Among Florida Wholesalers." Here is another one, more recent: "Three Indicted for Diversion of Prescription Drugs." And I was glad to hear that their convictions were upheld by an appeals court.

So, Members, this is a very simple fix for the bill, and I am just basing this upon the success we have had in the State of Florida since 2003 that has largely stopped counterfeiting and this criminal activity. Unfortunately this bill would force States like Florida into limbo. The flaw that is still in the bill that we are considering today is that it would preempt existing laws like Florida's on the day of enactment rather than a time in the future when the law is implemented that is much more appropriate.

At our hearing a few weeks ago, FDA's Dr. Janet Woodcock urged all of us not to eliminate the existing pedigree requirements until they are fully replaced with a new and improved system. So I

respectfully request that the committee do not take our laws away from us, like in the State of Florida. Allow local law enforcement to maintain these tools so that they can protect us from counterfeit medications. If this bill is signed into law, it would dismantle the successful system we have had in place for over 10 years and replace it with nothing for who knows how long, maybe 2015.

And I asked Chairman Pitts and Chairman Upton to work with our side of the aisle to correct this error. Regrettably, the preemption language is still in the bill.

But I urge you all, don't take these tools away from local law enforcement. Don't create this gap in the law that could subject our families to counterfeit drugs that could harm their health. I urge all the Members to support the Castor amendment.

The Chairman. Yield back?

Ms. Castor. I yield back.

The Chairman. The chair recognizes the gentleman from Illinois Mr. Shimkus.

Mr. Shimkus. Thank you. Mr. Chairman, I rise to speak against the amendment.

Mr. Chairman, we can all go back to years in the past -- and I find this debate really beneficial -- but it wasn't too long ago when we had this fight on reimportation, which had drugs coming from anywhere that was going to be foreign countries and the like. So now we are trying to get to a point of who is a credible manufacturer, who is a

credible wholesaler, how does it get to the retail location, and how does it get to the individual consumer, which is what everyone wants to do.

The preemption debate, again, is a great constitutional argument about the interstate commerce clause and who sets standards, and in this case it is really important, because without it, we will have a duplication. We will have the whole chain trying to spend money, organize to meet this new law while they are still trying to comply with maybe a very separate type of system, and it will delay the process. And it will be costly, it will be inefficient, and it won't get us to where we want to as a Nation to have this process onboard.

It is necessary for our manufacturers and wholesalers and pharmacies to be prepared for January 1. And I would just state that some States have moved forward and have done credible work; some States may not be in the same position. This bill cries for a national standard, a national timeline to get everybody on board, and by allowing two different standards and systems, we actually will do more harm than good. So I would ask rejection of the Castor amendment, and I yield back my time.

The Chairman. The gentleman yields back.

The chair will recognize Mr. Waxman for 5 minutes.

Mr. Waxman. Mr. Chairman, we are talking about a period of over a year for everyone to keep doing what they have been doing for years in many cases and -- I don't understand this talking point.

Look, this amendment, the Castor amendment, says before we preempt the States, the States, as I hear from my colleagues all the time, are the people closest to the problems. They are the ones who know best. They should be given the right to act. The Federal Government doesn't know everything. We don't have some wisdom here that we should take things away from the States.

So what do we have? A bill that takes away and preempts the States where they have passed laws and told them they can't have those laws because it might conflict with a Federal standard that doesn't exist. So if a State wants to protect their own citizens, we are telling them, oh, no, you can't do that. You can't do that. Well, what do you mean you can't do that? There are police powers in the States to protect the health and well-being of their own people.

So if we are going to preempt -- and many times it makes sense to preempt so we don't have businesses having to figure out how to meet 15 different standards -- we ought to make sure that we have a national standard. But to preempt the States when there is no national standard in place -- and in my view, it may never happen -- is just simply saying Washington knows best, better not do anything anywhere.

So the amendment before us says, you don't preempt until there is a Federal standard. And I think that makes sense, and I would urge my colleagues on both sides of the aisle who believe the States do exist and have purposes to act and all wisdom doesn't come out of Washington, until we tell them our wisdom, we ought to let them act on their own.

Mr. Shimkus. Would the gentleman yield?

Mr. Waxman. I would be happy to.

Mr. Shimkus. Just because I was prepared for the states' rights debate because we have it in other issues, as you know, coming down the pike. There is a difference here. This is interstate commerce. So this is actually goods and services and manufacturers going across State lines versus other issues we will address in a couple of weeks that are wholly contained within the State.

So you can mock the duplication of different sides, but I think there is a fair constitutional grounding on why we can preempt on a Federal law interstate commerce versus on maybe rules and regulations solely contained within State lines. And I thank you.

Mr. Waxman. Reclaiming my time, I am not saying that it is unconstitutional to preempt. I would be for preemption so we can have one national standard. But to preempt before there is a national standard the efforts of the States to act as they see fit doesn't make sense to me. It doesn't seem fair. If you want nothing done at the State or the Federal level, this is a really good bill, because nothing ever has to get done.

And so I think the amendment before us makes sense. Let the States act and then preempt them when you have done something at the Federal level, not when you set in place a bill that will say 14 years from now maybe they can do some regs, and then, of course, years after that they can finalize it, but they never have to finalize it, and it

never have to go into effect. That is not a Federal standard, that is a Federal cop-out. So I support the amendment before us.

I yield back my time.

The Chairman. The gentleman yields back. Are there other Members wishing to speak on the amendment?

The gentleman from New Jersey Mr. Pallone.

RPTS JOHNSON

DCMN HERZFELD

[11:10 a.m.]

Mr. Pallone. I just want to indicate support for the Castor amendment as well, because I am concerned that under the legislation before us that existing State pedigrees would be immediately wiped out without any new pedigree requirement in place. Not only would the bill preempt State pedigrees from day one, it would also invalidate current Federal requirements in section 503(e) of the Federal Food, Drug and Cosmetic Act. And as we have heard, in the absence of strong Federal standards, some States have enacted their own laws to address the issue of security of the supply chain, and a number of States have adopted final rules.

I think we should work to ensure that no existing laws requiring passage of pedigree information are preempted until the Federal requirements under the track and trace legislation are fully implemented. And under the bill we are considering today, the requirements would be fully implemented no later than July 1, 2015.

At our legislative hearing in the subcommittee a couple weeks ago, even the FDA witness, Dr. Janet Woodcock, indicated that we should not eliminate existing pedigree requirements until they are replaced with the new system. In fact, she told us that these requirements are an important tool for law enforcement when they are going after

counterfeiters and gray 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. So it is only logical that existing State and Federal pedigree requirements stay in effect until the new requirements are fully in effect.

And I also disagree with my colleagues when they argue this change would require industry stakeholders to set up two systems, because we simply want to extend what is happening in the supply chain now until something else is in its place.

So I urge my colleagues to support the Castor amendment. It makes sense.

I yield back unless somebody wants my time.

Mrs. Blackburn. [Presiding.] The gentleman yields back.

Do you claim the balance? Mr. Pallone, do you -- you want your own time.

Is anyone seeking further time?

Mr. Green. Thank you, Madam Chairman. And I would like to strike the last word.

I support this amendment by my colleague Congresswoman Castor, but also the number of other amendments that we have. I am concerned about the underlying bill text because it doesn't go far enough soon enough.

I understand this draft has garnered bipartisan support, and I am pleased that the majority has engaged with Members of our side; however, it seems that they did not agree to one single change since we saw this text in the subcommittee. I served on the subcommittee, I brought some issues up that some of these amendments will alleviate, but we haven't seen any change in the text. We thought we would do it between the subcommittee and the full committee, but now we are not seeing that happen.

An offer to negotiate is not one just to take it or leave it, and I am disappointed that some of our Democratic changes were not made. Now that we are at markup, these amendments will go down along a party-line vote.

There is a bipartisan draft in the Senate. The Democratic changes are consistent with that draft, and it is a reasonable path forward. I don't believe it is necessary to find the perfect solution in any legislative process, but certainly coming close to a draft that a bipartisan group of Senators can agree to would be preferable. This issue is far too important. It is about protecting consumers and making sure that medicines we are giving our kids, our parents, and ourselves are what we think they are. We shouldn't have to wait almost 20 years for the proper level of certainty, which this bill actually does.

I am opposed to the underlying bill, but I support this amendment and other amendments because I think it makes needed improvements in

it. And I yield back my time.

Mrs. Blackburn. The gentleman yields back.

Is there further discussion on the bill?

Mr. Matheson, you are recognized.

Mr. Matheson. Move to strike the last word.

I think this issue of State preemption is one that we ought to think real carefully about. When we are talking about implementing a nationwide track-and-trace system, this isn't something you do in a week. This requires a significant effort among a whole bunch of people along the supply chain.

The notion that a couple of my colleagues had said that, oh, that means they would have to keep track of two systems if we don't preempt is not true. It is more than two systems. It is whichever State may have a different system. And that is really the fundamental argument for preemption anyway is it is in a nationwide effort to have one set of standards as opposed to a patchwork of different regulations on a State-by-State basis.

That is ultimately why we all acknowledge in the long run that we want to at least acknowledge or see that preemption. But I am suggesting even in the short run we ought to be real careful about a situation where we are asking everyone in the supply chain to invest significant time, and effort, and resources in terms of money as well to create this new system that at the same time we want to say, but you got to keep track of all these other systems as well. And it very

well may delay the development of the nationwide system.

Mention has been made of the bipartisan Senate draft. The bipartisan Senate draft has the exact same preemption language as this bill. It calls for preemption on day of enactment. When there was an extensive bipartisan, bicameral discussion that took place last year, which resulted in a discussion draft in October, same thing. It called for preemption on day of enactment.

So I think this is always a tough issue when you talk about timing and implementation, and if you are leaving gaps in enforcement. I don't dismiss those issues out of hand, but I would suggest in the context of something of this magnitude, where people have been working on this at a State level for a long time and still haven't come up in various States with a system that is necessarily very effective because we are dealing with emerging technologies and a pretty complicated set of issues that we want to make sure we get right, I think that preemption is the appropriate course to take, and I would suggest my colleagues oppose this amendment.

I yield back my time.

Mr. Latta. Would the gentleman yield?

Mr. Matheson. Sure.

Mr. Latta. Thanks very much. I appreciate the gentleman for yielding.

You know, I think it is important to point out, as you said in your statement, it is just not a couple of States that are doing this

right now. On this chart right here with the copy, you know, you see the United States on here, we have 18 States that have already filed their final rules, they have 2 that have enacted legislation, and 8 that have enacted legislation. So, you know, we are talking quite a few States, around 28. And you are absolutely right when you say that, you know, you are going to have duplicity out there, and it is going to be very complicated to begin with.

So I think it is very important to note that, that, you know, we already have 28 States out there. And it is important that we defeat the amendment.

I yield back to the gentleman.

Mrs. Blackburn. Does the gentleman yield back?

Mr. Matheson. Yes.

Mrs. Blackburn. Is there further discussion?

There being no further discussion, the vote occurs on the amendment. All those in favor, signify by saying aye.

All those opposed, no.

In the opinion of the chair, the nays have it, and the amendment is not agreed to.

Are there further amendments?

The gentlelady.

Mrs. Capps. I have an amendment at the desk.

Mrs. Blackburn. The clerk will report the amendment.

The Clerk. Amendment to H.R. 1919 offered by Mrs. Capps of

California.

Mrs. Blackburn. Without objection, the reading of the amendment is dispensed with.

[The information follows:]

******** INSERT 2-X ********

Mrs. Blackburn. The gentlelady is recognized for 5 minutes on her amendment.

Mrs. Capps. Thank you, Madam Chair.

I want to make clear that I am in support of the effort we are making to develop a national track-and-trace standard, but there are still many holes in this current draft that make it difficult to support. And one that I mentioned both at our hearing and in the subcommittee markup is a concern about the way wholesalers will be licensed if the current version of the bill becomes law.

I do fully support the efforts to have FDA develop a national standard for the State licensure of wholesale distributors, and I agree that it is critical to ensure that all States have minimum wholesale licensure requirements, but, as written, the provisions would also prevent States from addressing new issues as they arrive in their particular State, and it would bar them from adapting requirements to meet the specific needs of their State.

As I noted in committee markup -- subcommittee markup, California has taken great strides to protect its supply chain and, in response to significant weaknesses in the system, has developed wholesale licensure requirements that protect it for both companies and for patients. And this includes annual self-assessments for wholesalers to ensure compliance with licensure requirements.

With 500 wholesale distributors, California needed an extremely efficient system for addressing their compliance with licensure

requirements, and this provision both aids the wholesalers in ensuring their own compliance, but it also aids State inspectors in monitoring that compliance. There are States with few wholesale distributors, and they may not need such a mechanism, but California would lose this flexibility if the bill before us is adopted, as would other proactive States.

Similarly in California, wholesale distributors must report sales of certain controlled substances, drugs, when such sales to any one pharmacy are above a certain threshold. This aids California in identifying potentially high-risk pharmacies that may warrant further attention. This provision was added not by the Federal Government, but by the State in response to identified public safety needs, but if this bill becomes law, this California protection could be lost for this State.

We all agree we do need a baseline standard for licensure, but we should also agree that States should have the right to protect their constituents to a higher level if they feel that they need to and have reason for doing so. We must allow for the flexibility of these States to ensure a safe drug supply and also continue their working systems.

I would also note that this is the same approach the bipartisan Senate bill has taken, and I believe that it should be the same approach that we take here in the House. My amendment would make this consistent by making the FDA Federal licensure requirements in the bill a floor, but not a ceiling for State licensure of wholesale distributors. It

is a small but important step to protecting our communities safe, but it also protects the rights of States to do the particular issues -- address the particular issues that their States are concerned with.

So I urge my colleagues to support this amendment, and I yield back at this time -- or I yield to another colleague. I will yield to Mr. Pallone.

Mr. Pallone. Thank you.

I just wanted to indicate my support for the Capps amendment because I don't think the Federal wholesale distributor licensure requirements should act as a floor and not as a floor and a ceiling. And the bill before us today requires FDA to set national standards for the State licensure of wholesale distributors, and that is critical. But the bill also prevents States from setting additional licensure requirements for wholesalers in their State.

It is concerning because State-specific issues may arise that, under this version of the bill, States would not be able to address. By preventing States from establishing requirements above the Federal standard, we would be tying States' hands and preventing them from adopting new requirements or adopting requirements to meet the unique needs of their State.

I think we should pass legislation that sets minimum Federal standards, but also allow States to enact stronger licensure requirements so that they can respond to State-specific needs as they

see fit, and that is what the Capps amendment does. So I think we should support it.

I yield back the to the gentlewoman.

Mrs. Capps. Yield back.

Mrs. Blackburn. The gentlelady yields back.

Dr. Burgess from Texas, you are recognized for 5 minutes.

Dr. Burgess. Thank you, Madam Chairman.

And I am going to oppose this amendment. Mr. Matheson just gave a very articulate description of the difficulties involved in this industry when you create the patchwork system. And the patchwork system is going to have loopholes, it is going to have a greater expense, and, in fact, will make the system more vulnerable because, let us be honest, the amount of products shipped in this country is significant.

It really seems like it has become more and more apparent, certainly to the committee, that the supply chain needs to be strengthened, and that strengthening needs to occur at the Federal level instead of this current form of makeshift State regulations. And it is actually the inconsistencies within those State regulations relating to the drug supply chain that allows the bad guys to be able to capitalize and prey on consumers in States with less rigorous regulations.

The inconsistent State regulations force wholesalers to comply with 50 different types of regulation. The cost of compliance of those different regulations increases the total price of doing business.

And who ultimately pays that price? It is the patient. It is the consumer.

We need uniform standards that can be applied to all States and, in doing so, lower the cost of doing business and lower the cost to the consumer. By applying a rigorous Federal wholesale distributor law which sets both a standard floor and a ceiling, this ensures that only licensed good actors are distributing products, and all States are playing on a level playing field. This national standard guarantees that wholesalers who ship products all over the country are compliant with one standard instead of varying requirements in every State.

This bill does strike an important balance between preserving the States' rights and upholding the Food and Drug Administration's authority in monitoring the drug supply chain. States will still have the ability to issue licenses. They will keep the revenue. They will maintain their active role in protecting their citizens. Rejecting this amendment is the best thing for the distributors, best thing for the patients, for the States, and for the country, and I urge members of the committee to reject the amendment.

And I will yield back the balance of my time.

The Chairman. [Presiding.] The gentleman yields back.

Are there other Members wishing -- the gentleman from California is recognized for 5 minutes.

Mr. Waxman. Let me, Mr. Chairman and my colleagues, give an

example, a real-life situation. You know, it is sort of antiseptic. We got these wholesale this and that, and we got these terms, and we are going to have a Federal standard, FDA is going to issue a standard. But oftentimes we have a Federal standard, but we let States go beyond that Federal standard.

For example, there are some drugs for which there is a shortage right now. So what happens is there is a primary wholesaler, and a secondary wholesaler, and a pharmacy. Well, the secondary wholesaler was -- a real-life situation -- colluding with the pharmacy to get drugs for which there is a shortage. And when they were colluding to get these drugs for which there is a shortage, the reason they did it is because they can then turn around, because of the shortage, and resell them to clinics and hospitals at a huge markup. Well, those are the people, these wholesalers, that would be colluding to do this, to gouge the system, are the ones we are going to protect from the States being able to say, no, we don't want you to do that.

In California, we have prohibited this kind of collusion by a wholesaler, secondary wholesaler, and a pharmacy. But what some of the wholesalers decided they would do instead is rather than take drugs back from the pharmacy in that State, they would go to other States and ask the pharmacists in these other States to sell back the drugs to them, for which they paid them a good handsome price, so that they could then resell them at an even higher price above that.

To say that we are protecting everybody is not quite accurate,

because somebody is going to be paying a lot of money for a drug, because there is a shortage, through this kind of chicanery. And we don't have any assurance that the drug's safety is going to be protected because we can't monitor what drugs are really being recycled in the system.

So we hope FDA will come up with a good, strong standard, but there is no assurance that they will. And when they do, a State would be able, under this amendment, to adopt that standard as a floor and be able to do something more stringent.

I don't think we have to worry about States establishing wildly different systems. What we expect and hope that FDA will issue strong standards, and States will be eager to adopt it, but if we have standards alone, that is not going to create a largely uniform system. We ought to let the States go beyond that, consider it a floor, not a ceiling.

So I join in support of the amendment, and yield to Mr. McNerney.

Mr. McNerney. Thank you, Mr. Waxman.

There is a difference in philosophy here. We want to do the same things, both sides of the aisle. We want to protect consumers, and we want to prevent a patchwork of standards. Now, what is going to be the best way to go about that? Do we want to adopt some Federal standards briefly, quickly, or do we want to wait and delay Federal standards?

And in my opinion, the longer we delay Federal standards from being adopted, the more likely it is that there is going to be a large patchwork of standards, the more likely it is going to be difficult

to adopt for each company. If we do move forward aggressively and get some Federal standards in place, the technology is going to catch up to it, and we will see this thing implemented in probably less than 10 years.

So I support the amendment, and I yield back to Mr. Waxman.

Mr. Waxman. I yield back the time.

The Chairman. The gentleman yields back.

Are there other Members wishing to speak on the amendment?

Seeing none, the vote occurs on the amendment. Those in favor will say aye.

Those opposed, say no.

In the opinion of the chair, the noes have it. The noes have it. The amendment is not agreed to.

Are there other amendments to the bill?

Seeing none, the vote occurs on H.R. 1919, as amended, to the House. All those in favor will say aye.

Those opposed, say no.

In the opinion of the chair, the ayes have it. The ayes have it, and the bill is passed, as amended.

The Chairman. The chair now calls up H.R. 1407 and asks the clerk to report.

The Clerk. H.R. 1407, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs.

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

[The information follows:]

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

The Chairman. Are there any bipartisan amendments to the bill?

Seeing none, are there any amendments to the bill?

Mr. Waxman. Mr. Chairman?

The Chairman. The gentleman from California.

Mr. Waxman. I seek recognition to strike the last word.

The Chairman. The gentleman is recognized for 5 minutes.

Mr. Waxman. Mr. Chairman, I think it is necessary for us, eventually, to get to the point where we are going to ban the use of antibiotics for animals for nontherapeutic purposes. If we are treating an animal to cure an animal of a disease, it is appropriate to use antibiotics. But when we give antibiotics to animals just to keep them well, to try to protect them from a disease, we are degrading the ability of antibiotics to protect people. And we would like at some point to move to ban the use of antibiotics on animals, but we are told over and over again we don't have enough data on the subject. And so I have introduced a bill that would require us that we collect the data. The people who sell these antibiotics know how they are being used, and they can keep track of it, and we can learn whether this concern is a justifiable concern, as I believe it is.

But due to the request by the majority to support this bill without this amendment being offered because it is a bill that we all support and want to see passed, I am not offering that amendment. But I do want to bring up the subject so Members will think about it, because I don't want us to just ignore this issue.

We have bugs that don't respond to the antibiotics we now have available to us, and this is a growing concern. So I would hope that at some point we will visit this issue. I know we have had some hearings on the subject of antibiotics and how to encourage the development of new antibiotics, but we ought to stop the degradation of antibiotics and their effectiveness by overuse of them in the -- given to animals not for the health of the animal, but just for the purposes of maybe keeping them well.

We wouldn't do that to our kids. We don't believe we ought to give all our kids antibiotics just to be giving them a healthy dose of something to fight a disease. You don't prescribe an antibiotic to be used unless there is a medical reason for it, because we all suffer when bugs are developed that resist those antibiotics.

I want to point out that we are not offering this amendment. I want Members to think about it, and at some convenient time I would like the committee to visit this issue and move legislation at least to gather the data. And I will be talking to the chairman. Hopefully, we can consider this approach in the future.

Otherwise, I yield back the balance of my time. I will support this bill, and I hope other Members do as well.

The Chairman. The gentleman yields back.

The chair will recognize the gentleman from Illinois to strike the last word.

Mr. Shimkus. Strike the last word.

And, Mr. Chairman, I appreciate the comments by Ranking Member Waxman. I am glad to have worked in a bipartisan manner to move this legislation to the full committee today.

As we have said in this process, reauthorization will maintain FDA's ability to focus resources it needs for animal drug products to move through the approval process in a timely manner, at the same time ensuring our country remains the leader in having innovative, safe drugs available in our livestock and pet communities. When all is said and done, this legislation will have a positive effect on constituents in all our districts, as American consumers benefit from the availability of safe and more affordable food.

I want to thank my colleagues on both sides of the aisle and their staffs, Chairman Upton, Chairman Pitts, Ranking Member Waxman, Ranking Member Pallone, and Cory Gardner, for recognizing the importance of this reauthorization and working together in a bipartisan fashion to move ADUFA swiftly. I look forward to working with them on a clean reauthorization on the House floor and reconciling any differences we may have with the legislation from our Senate colleagues.

And I yield back the balance of my time.

The Chairman. The gentleman yields back.

The chair would like to put unanimous consent. I neglected to put this letter in on the last bill because it moved so quickly, on H.R. 1407. But it is a letter from the Health Care Supply Chain Association. I would just like to have it in the record in support

of the bill. Without objection, so ordered.

[The information follows:]

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

The Chairman. Are there other amendments, further amendments, to this bill, 1407? If not, the chair will call the question on the bill. All those in favor will say aye.

Those opposed, say no.

The ayes have it, and the bill is passed, favorably reported.

The Chairman. The chair now calls up H.R. 271 and asks the clerk to report.

The Clerk. H.R. 271, to clarify that compliance with an emergency order under section 202(c) of the Federal Power Act may not be considered a violation of any Federal, State, or local environmental law or regulation, and for other purposes.

The Chairman. Without objection, the first reading of the bill is dispensed with. The bill will be open for amendment at any point.

[The information follows:]

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

The Chairman. Are there any bipartisan amendments to the bill?

Are there any amendments to the bill?

Seeing none, the question now occurs on favorably reporting H.R. 271 to the House. All those in favor will say aye.

Those opposed, say no.

Ayes appear to have it. The ayes have it. The bill is favorably reported.

And without objection, the staff is authorized to make technical and conforming changes to the bills reported by the committee today. So ordered. And without objection, the committee stands adjourned.

[Whereupon, at 11:35 a.m., the committee was adjourned.]