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RPTS CASWELL

DCMN SECKMAN

MARKUP OF H.R. 5651, TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO REVISE AND EXTEND THE USER-FEE PROGRAMS FOR PRESCRIPTION DRUGS AND FOR MEDICAL DEVICES, TO ESTABLISH USER-FEE PROGRAMS FOR GENERIC DRUGS AND BIOSIMILARS, AND FOR OTHER PURPOSES

THURSDAY, MAY 10, 2012

House of Representatives,
Committee on Energy and Commerce,
Washington, D.C.

The committee met, pursuant to call, at 10:11 a.m., in Room 2123, Rayburn House Office Building, Hon. Fred Upton [chairman of the committee] presiding.

Present: Representatives Upton, Barton, Stearns, Whitfield, Shimkus, Pitts, Bono Mack, Walden, Terry, Myrick, Murphy, Blackburn, Bilbray, Bass, Gingrey, Scalise, Latta, McMorris Rodgers, Harper, Lance, Cassidy, Guthrie, Olson, McKinley, Gardner, Pompeo, Kinzinger, Griffith, Waxman, Dingell, Markey, Towns, Pallone, Rush, Eshoo, Engel,

Green, DeGette, Capps, Doyle, Schakowsky, Gonzalez, Matheson, Butterfield, Barrow, Matsui, Christensen, and Castor.

Staff Present: Clay Alspach, Counsel, Health; Gary Andres, Staff Director; Michael Beckerman, Deputy Staff Director; Mike Bloomquist, General Counsel; Allison Busbee, Legislative Clerk; Howard Cohen, Chief Health Counsel; Nancy Dunlap, Health Fellow; Paul Edattel, Professional Staff Member, Health; Debbie Keller, Press Secretary; Peter Kielty, Associate Counsel; Ryan Long, Chief Counsel, Health; Carly McWilliams, Legislative Clerk; Heidi Stirrup, Health Policy Coordinator; 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. The committee will come to order. At the conclusion of opening statements yesterday, the chair called up H.R. 5651, and the bill was open for amendment at any point.

[The information follows:]

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

The Chairman. Are there any bipartisan amendments to the committee print? Seeing none, are there other amendments?

The chair will recognize -- for what purpose does the gentleman from Texas seek recognition?

Mr. Barton. Mr. Chairman, I have an amendment at the desk.

The Chairman. The clerk will report the title.

The Clerk. Amendment to H.R. 5651, offered by Mr. Barton of Texas.

The Chairman. The amendment will be considered as read.

[The information follows:]

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

The Chairman. And the gentleman from Texas is recognized for 5 minutes in support of his amendment.

Mr. Barton. Well, thank you, Mr. Chairman, and as you and Mr. Waxman, Mr. Pallone, Mr. Pitts know, I am going to withdraw the amendment, so this is primarily an opportunity to give me a forum to speak on an issue that I feel very deeply about.

The bill before us is, obviously, a bipartisan bill. It is a good piece of legislation. I am proud to be an original or at least a cosponsor of the amended committee print that is going to be voted on.

But as I said in the opening remarks yesterday, through various capacities on the Oversight Subcommittee and the Health Subcommittee, I have been involved with the FDA for a quarter of a century, and it is -- it literally is the gold standard for drug reviews and protection of the safety of the public health and the world. They are fine people, and they work very hard, but they are not the most efficient. I don't think anybody would dispute that, and they very rarely perform to what they are required to by law.

So the amendment that has been distributed is pretty straightforward. This legislation reauthorizes, in some cases for the first time, authorizes user fees. I am not an opponent of user fees if properly constructed. And in order to ensure or at least to incentivize performance accomplishment, the amendment says in each of the sections of the FDA that use user fees, after the first year of this bill, if they don't perform to 90 percent of the goal in the bill, the next year they lose 20 percent of their user fees. Now, the intent

is not to cut their user fees 20 percent, the intent is to get them to perform to at least 90 percent of the goal that they have agreed to in negotiations with the stakeholders.

It is a 1-year review, and then the next year, if they don't perform, they would get cut 20 percent, and then the next year. So it is not on a quarterly basis; it is on an annual basis. That gives them a year, and then the review, and then if they had a cut, the cut would go into effect the third year. So there is enough time involved that I think that they could change the performance if they want to.

So it is straightforward, hopefully, if it were to be accepted at some point in time, it would, I think, go a long way toward making the FDA more efficient. And again, I would stipulate that they are the gold standard for drug review in the world, but some of these drugs take forever, and they simply don't perform, although each 4 or 5 years, when we reauthorize them, they claim they will next year, so this would be a way to make next year actually happen.

I will yield to anybody who wishes to speak, or if nobody wishes to speak, I will withdraw the amendment.

The Chairman. Will the gentleman yield briefly?

Mr. Barton. Sure.

The Chairman. I just welcome your continued participation with this bill. I certainly appreciate you withdrawing the amendment, and I just want to assure the gentleman and all members that this committee will continue its oversight to make sure that FDA does its job, and it is part of the responsibility of this committee.

We feel that this legislation ought to help them do it in a more timely matter, and we will stay on the case. I want to give the gentleman that assurance and all members that.

And I yield back.

Mr. Barton. All right. Mr. Chairman, then I would withdraw the amendment.

The Chairman. The amendment is withdrawn.

Are there any other amendments to the bill?

Mr. Matheson. Mr. Chairman.

The Chairman. The gentleman from Utah.

Mr. Matheson. I would rise to strike the requisite number of words to engage in a colloquy Mr. Waxman.

The Chairman. Yes. The gentleman is recognized for 5 minutes.

Mr. Matheson. First, I would like to thank you and Mr. Waxman for your work on crafting a bipartisan user fee reauthorization bill. It is a good bill. It is going to enhance consumer safety and increase predictability in the FDA's drug and device approval process. I will be proud to vote for this bill.

However, there is still an outstanding issue that I believe we have a tremendous opportunity to resolve this year. I have worked to enact a national pedigree standard to better protect our pharmaceutical supply chain from counterfeiters since before this committee worked on the last FDA user fee reauthorization bill 5 years ago.

A national standard is needed to ensure we are better able to keep adulterated or counterfeit products out of the supply chain and to

provide a single standard, as opposed to a patchwork system of conflicting States laws, which would create regulatory and logistical hurdles for industry stakeholders.

In this Congress, my colleague, Mr. Bilbray, and I have been working with a coalition of stakeholders representing all aspects of the supply chain, from manufacturers to distributors to pharmacists. This coalition, the Pharmaceutical Distribution Security Alliance, has worked together to craft a national pedigree standard that has the backing of all aspects of the supply chain.

I was pleased to see elements of the legislation that Mr. Bilbray and I introduced included in this proposal. Their work and agreement is significant, because a national pedigree standard was not included in the national 2007 FDA user fee bill, largely due to stakeholder disagreement. Now we have a proposal with industry consensus and has bipartisan support in this committee.

Now there are still elements of the proposal that need to be worked out with the FDA, and I stand ready to continue work with the FDA on those issues. Unfortunately, we could not come to a resolution in time for today's markup. However, those discussions are ongoing and yielding very promising and positive results.

I would like to take this time too ask you, Mr. Waxman, for your assurance that you, too, will continue working with me and my colleague, Mr. Bilbray, the FDA, and the alliance on crafting a final legislative agreement to be included in the user fee authorization package that will enhance supply chain security but not be overly burdensome for

industry and ultimately provide a more secure product for consumers.

I yield to my colleague, Mr. Waxman.

Mr. Waxman. I thank you for yielding, and I thank you for your work on this issue.

Ensuring the safety and integrity of our supply chain from beginning to end is a critical issue for this committee, and I commend the committee for including provisions that will bring important oversight to the increasingly global upstream drug supply chain.

I also commend industry stakeholders on their efforts in coming together to present a drug pedigree proposal that is supported by industry at all levels. As we heard in one of our hearings on this issue, California already has a law that mandates a robust pedigree system that traces individual drug-selling units from the point of original distribution to the point of sale, a feature that the FDA has identified as crucial to ensuring safety.

I am aware that many experts say that it is not currently possible to reliably track each such unit through the drug delivery chain and that it will be impossible to implement the California law. Nonetheless, we know that California and many companies are working diligently to implement and comply with the law.

We also know from past experience that such demanding laws can spur innovation and development of technology necessary for compliance, so we should not be satisfied only with what can be done yesterday or today. We need to think about what we will be able to do tomorrow and far into the future.

I agree with you, Mr. Matheson, that we should continue working on legislation to create a robust, downstream drug pedigree system to ensure the safety of pharmaceuticals from counterfeit and adulteration as they travel to consumers. I hope that we will be able to reach agreement with industry, California and the FDA on the national standard that will prove strong enough now and in the future to warrant preempting strong State laws that currently exist.

Mr. Matheson. Well, I thank the gentleman for his assurances and look forward to continue working with him on this issue.

And I would now like to yield to my colleague, Mr. Bilbray.

Mr. Bilbray. Thank you, very much, I appreciate that.

Mr. Chairman, congratulations on this bill. I think just the discussion in the last few moments shows that, to everybody's astonishment around the world, that bipartisanship is breaking out everywhere in this committee. I am sure it will be on the headlines and on the teasers on every station in America tonight.

I would just say that I appreciate the leadership that my colleague has taken on addressing this issue, and I think that we have got to recognize that we have got a real opportunity to work on this component and add to this bipartisan bill somewhere down the line. As we all know, there has been a difference made where there is cooperation working not just between members of this committee but in the industry itself.

We have language that can create a national pedigree system to replace the patchwork of State laws that are currently being considered

or being placed forward. This legislation is a step in creating a secure supply chain system which will protect the American public and make sure that lifesaving drugs are and services are available to those who desperately need it.

Look, I have worked on technology forcing regulations for decades. This is a very inexact science. There are ways we can push technology to respond, but we have got to be sensitive to reality, and I think that is what we are trying to do is address this.

Mr. Chairman, I understand that at this time, the legislation could not be included in this draft that we have today, but I hope that we will continue to work together in order to finalize the legislative solutions that can be included in the final package, this kind of agreement and the kind of consensus to go to the President for his final signature.

So at this time I yield to the gentleman from the great State of West Virginia, Mr. McKinley.

Mr. McKinley. Thank you, Congressman.

I support your effort to establish a nationwide tracking and trace program on prescription drugs. I would request, however, that as we move forward with this discussion on pedigree, we also include a study on elabeling of prescription drugs. Elabeling could eliminate the requirement for paper information attached to the packaging of prescription drugs and move to electronic documentation; elabeling has the potential to create more efficiency for the pharmaceutical supply chain to make sure that pharmacists have the most up-to-date

information on drugs and save the industry millions of dollars that could be spent on research. I am asking for a study on this issue, and not legislation, because the concerns of the effect this could have on small community pharmacies and rural areas and possible liability.

Discussions have been held among manufacturers, distributors, dispensers and the FDA on this issue for years, but no recommendation has yet been forthcoming. As we move forward on the pedigree effort, I ask the committee to please consider adding this to your legislation.

Thank you and I yield back.

The Chairman. Would the gentleman yield?

I just want to commend both of you for your very hard work. This is a priority for me, a uniform national policy for track and trace is something that I certainly support, and I know many of our colleagues, if not all of us, support a plan that would be absolutely necessary to protect our pharmaceutical supply chain and reduce unnecessary costs, from the patchwork of State laws. Without such a system, weak links can be exploited by bad actors.

So I want to thank all of you, and as the legislation moves forward, I commit to continue to work with both of you to make sure that we have an efficient and cost-effective track and trace pedigree system.

The gentleman's time has expired.

Mr. Waxman.

Mr. Waxman. Mr. Chairman, I would just like to ask unanimous consent that a letter from the California State Board of Pharmacy, dated

May 9, 2012, be entered into the record on this subject.

The Chairman. Without objection.

[The information follows:]

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

The Chairman. It is my understanding we have two brief colloquies. We will try to get both of these done very quickly and have a roll call vote.

Mr. Markey.

Mr. Markey. Thank you, Mr. Chairman.

Mr. Chairman, we have an opportunity in the legislation that we are considering today to ensure that people with vision loss can access information on prescription drug labels. You shouldn't have to be able to see in order to be safe.

But today, more than 25 million Americans experience vision loss that makes it difficult, if not impossible, to read the small print on prescription drug labels. Given that the incidence of vision loss is expected to increase as the Baby Boomers age, the consequences of being able to read prescription information pose a looming public health challenge. People who are blind or visually impaired can mistakenly consume the wrong medication, an incorrect dose or expired drug because they are unable to read the label or to distinguish between medication containers.

They may be also unable to determine, to detect a pharmacy error, because they cannot verify the accuracy of a prescription label. Many blind or visually impaired are also forced to sacrifice their privacy and independence, relying on sighted family, friends, or even complete strangers to read the personal and sensitive information on their prescription bottles. All of these challenges lead to a loss of privacy, unnecessary illness, added emergency room visits, additional

expenses and increased anxiety.

In 2011, I introduced legislation to establish a working group of pharmacists, patient advocates and Federal regulators, who would issue best practices for pharmacies to ensure that people who are blind or are visually impaired have access to prescription drug labeling. Under the bill, the working group's guidelines will provide answers about which options could best address needs of the blind and visually impaired, such as large font labels or digital voice recorders attached to pill bottles. They will examine what options are feasible for pharmacies of different sizes, such as small, rural pharmacies.

Unfortunately, we were not able to address this issue in the House version of the FDA Reform Act up to this point, but there is comparable language in the Senate version of the FDA bill, which I support, which I would like to see reserved in on conference.

With millions of Americans with vision impairments, I believe that we should ensure that they know which medication they are taking or are helping to administer to a child.

Would the chairman be willing to commit to working with me to address this issue in conference?

The Chairman. If the gentleman will yield, the issue did come to a slate. As you noted, it is in the Senate language. I am very supportive of that concept, and we need a little time to examine the language more closely, but I absolutely commit to work with you and others on the committee that are interested in this and so we can move forward.

Mr. Markey. I thank the chairman.

And may I say that in the bill before us today, it misses a key opportunity as well. It is a different subject, but to improve the safety of medical devices.

I regret that the majority was unwilling to include any part of the legislation that I introduced with Mr. Waxman and Ms. Schakowsky to ensure that the FDA has the ability to reject devices if they are modeled after defective devices that have been recalled from the market. The Safety Of Untested and New Devices Act wouldn't have required the FDA to reject the new application, as we often heard from the bill's opponents, but rather, it would have given the FDA authority to reject a device if the company could not show that the new device avoided serious, previous loss.

Unfortunately, right now, FDA is legally obligated to clear a new medical device as long as the company shows it is similar to an earlier model, even if that model was recalled for serious safety problems.

Mr. Chairman, I ask unanimous consent to enter into the record this report prepared by my staff, which documents this problem and includes the stories of patients who suffered irreparable and avoidable harm as a result of these faulty devices.

[The information follows:]

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

Mr. Markey. It is disappointing that we were unable -- and the majority thus far has been unwilling to work with us to address this critical safety issue -- but this is something that I plan to continue working on addressing in the future. I just don't think that we can allow these medical devices to stay out on the marketplace knowing that they are defective, and I yield back the balance of my time.

The Chairman. The gentleman yields back.

The gentleman from Louisiana, Mr. Cassidy.

Dr. Cassidy. Yes, thank you, Mr. Chairman.

Mr. Chairman, the committee mark includes a provision related to valid prescription. While Federal law clearly defines a valid prescription as regards to controlled substances, no such definition exists for noncontrolled substances. The language in the bill, in the mark, is intended to close a statutory loophole being exploited by unscrupulous and dangerous online drug sites.

We discovered, however, that the bill as currently drafted may adversely impact legitimate telehealth services. To ensure that this legislation restricts illegal online prescriptions but not undermine access to legitimate telehealth services, and as we look to cut health care costs, we must not inadvertently constrict medical innovation. I will continue to work with members on both sides of the aisle to address this issue to reach a resolution before the House considers the user-fee package.

The Chairman. Would the gentleman yield?

Dr. Cassidy. I will yield.

The Chairman. I appreciate all the work that you have put into this issue for sure. I believe that we can collectively reach a resolution without adversely impacting innovation on the telehealth phase, and I will continue to work with you to find a solution as we continue to move through the process.

Will the gentleman yield back?

Dr. Cassidy. I yield back.

Thank you.

The Chairman. Are there other members wishing to speak?

Seeing none, the question now occur on favorably reporting H.R. 5651 to the House.

All those in favor will say aye.

Those opposed, no.

In the opinion of the chair, the ayes have it.

The bill is favorably reported.

The clerk will call the roll. I ask for a roll call vote.

The Clerk. Mr. Barton?

Mr. Barton. Aye.

The Clerk. Mr. Barton votes aye.

Mr. Stearns?

Mr. Stearns. Aye.

The Clerk. Mr. Stearns votes aye.

Mr. Whitfield?

Mr. Whitfield. Aye.

The Clerk. Mr. Whitfield votes aye.

Mr. Shimkus?

Mr. Shimkus. Aye.

The Clerk. Mr. Shimkus votes aye.

Mr. Pitts?

Mr. Pitts. Aye.

The Clerk. Mr. Pitts votes aye.

Mrs. Bono Mack?

Mrs. Bono Mack. Aye.

The Clerk. Mrs. Bono Mack votes aye.

Mr. Walden?

Mr. Walden. Aye.

The Clerk. Mr. Walden votes aye.

Mr. Terry?

Mr. Terry. Aye.

The Clerk. Mr. Terry votes aye.

Mr. Rogers?

[No response.]

The Clerk. Mrs. Myrick?

Mrs. Myrick. Aye.

The Clerk. Mrs. Myrick votes aye.

Mr. Sullivan?

[No response.]

The Clerk. Mr. Murphy?

Mr. Murphy. Aye.

The Clerk. Mr. Murphy votes aye.

Mr. Burgess?

[No response.]

The Clerk. Mrs. Blackburn?

Mrs. Blackburn. Aye.

The Clerk. Mrs. Blackburn votes aye.

Mr. Bilbray?

Mr. Bilbray. Aye.

The Clerk. Mr. Bilbray votes aye.

Mr. Bass?

Mr. Bass. Aye.

The Clerk. Mr. Bass votes aye.

Mr. Gingrey?

Dr. Gingrey. Aye.

The Clerk. Mr. Gingrey votes aye.

Mr. Scalise?

Mr. Scalise. Aye.

The Clerk. Mr. Scalise votes aye.

Mr. Latta?

Mr. Latta. Aye.

The Clerk. Mr. Latta votes aye.

Mrs. McMorris Rodgers?

Mrs. McMorris Rodgers. Aye.

The Clerk. Mrs. McMorris Rodgers votes aye.

Mr. Harper?

Mr. Harper. Aye.

The Clerk. Mr. Harper votes aye.

Mr. Lance?

Mr. Lance. Aye.

The Clerk. Mr. Lance votes aye.

Mr. Cassidy?

Dr. Cassidy. Aye.

The Clerk. Mr. Cassidy votes aye.

Mr. Guthrie?

Mr. Guthrie. Aye.

The Clerk. Mr. Guthrie votes aye.

Mr. Olson?

Mr. Olson. Aye.

The Clerk. Mr. Olson votes aye.

Mr. McKinley?

Mr. McKinley. Aye.

The Clerk. Mr. McKinley votes aye.

Mr. Gardner?

Mr. Gardner. Aye.

The Clerk. Mr. Gardner votes aye.

Mr. Pompeo?

Mr. Pompeo. Aye.

The Clerk. Mr. Pompeo votes aye.

Mr. Kinzinger?

Mr. Kinzinger. Aye.

The Clerk. Mr. Kinzinger votes aye.

Mr. Griffith?

Mr. Griffith. Aye.

The Clerk. Mr. Griffith votes aye.

Mr. Waxman?

Mr. Waxman. Aye.

The Clerk. Mr. Waxman votes aye.

Mr. Dingell?

Mr. Dingell. Aye.

The Clerk. Mr. Dingell votes aye.

Mr. Markey?

Mr. Markey. Aye.

The Clerk. Mr. Markey votes aye.

Mr. Towns?

[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. Gonzalez?

Mr. Gonzalez. Aye.

The Clerk. Mr. Gonzalez votes aye.

Ms. Baldwin?

[No response.]

The Clerk. Mr. Ross?

[No response.]

The Clerk. Mr. Matheson?

Mr. Matheson. Aye.

The Clerk. Mr. Matheson votes aye.

Mr. Butterfield?

[No response.]

The Clerk. Mr. Barrow?

Mr. Barrow. Aye.

The Clerk. Mr. Barrow votes aye.

Ms. Matsui?

Ms. Matsui. Aye.

The Clerk. Ms. Matsui votes aye.

Mrs. Christensen?

[No response.]

The Clerk. Ms. Castor?

Ms. Castor. Aye.

The Clerk. Ms. Castor votes aye.

Mr. Sarbanes?

[No response.]

The Clerk. Chairman Upton?

The Chairman. Aye.

The Clerk. Chairman Upton votes aye.

The Chairman. Are there any members who wish to cast a vote?

Mr. Towns?

Mr. Towns. Aye.

The Clerk. Mr. Towns votes aye.

The Chairman. Any other members?

Seeing none, the clerk will report the tally.

The Clerk. Mr. Chairman, on that vote, there were 46 ayes, zero nays.

The Chairman. 46 ayes, zero nays. The bill is passed. And without objection, the staff is authorized to make technical and conforming changes to H.R. 5651, approved by the committee today, so ordered.

The chair thanks all members and the staff.

Without objection, the committee stands adjourned.

[Whereupon, at 10:34 a.m., the committee was adjourned.]