RPTS JANSEN

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MARKUP OF:

H.R. 4299, IMPROVING REGULATORY TRANSPARENCY FOR NEW MEDICAL THERAPIES ACT;

H.R. 4709, ENSURING PATIENT ACCESS AND EFFECTIVE DRUG ENFORCEMENT ACT; AND

H.R. 4631, COMBATING AUTISM REAUTHORIZATION ACT OF 2014

WEDNESDAY, MAY 28, 2014

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 2 p.m., in Room 2123, Rayburn House Office Building, Hon. Joseph R. Pitts [chairman of the subcommittee] presiding.

Present: Representatives Pitts, Shimkus, Blackburn, Lance,

Guthrie, Griffith, Bilirakis, Upton (ex officio), and Pallone.

Staff Present: Nick Abraham, Legislative Clerk; Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Mike Bloomquist, General Counsel; Sean Bonyun, Communications Director; Matt Bravo, Professional Staff Member; Annie Caputo, Professional Staff Member; Noelle Clemente, Press Secretary; Brenda Destro, Professional Staff Member, Health; Sydne Harwick, Legislative Clerk; Robert Horne, Professional Staff Member, Health; Kirby Howard, Legislative Clerk; Peter Kielty, Deputy General Counsel; Carly McWilliams, Professional Staff Member, Health; Katie Novaria, Professional Staff Member, Health; Chris Sarley, Policy Coordinator, Environment and Economy; Charlotte Savercool, Legislative Coordinator; Heidi Stirrup, Health Policy Coordinator; John Stone, Counsel, Health; Tom Wilbur, Digital Media Advisor; Ziky Ababiya, Minority Staff Assistant; Jen Berenholz, Minority Chief Clerk; Stacia Cardille, Minority Chief Counsel; Eric Flamm, Minority FDA Detailee; Karen Nelson, Minority Deputy Committee Staff Director for Health; Anne Morris Reid, Minority Senior Professional Staff Member; and Rachel Sher, Minority Senior Counsel.

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

Today we are considering three important bipartisan bills: H.R. 4709, the Ensuring Patient Access and Effective Drug Enforcement Act, introduced by Representatives Marino, Blackburn, Welch, and Chu, which will facilitate greater collaboration between industry stakeholders and regulators in an effort to combat our Nation's prescription drug abuse epidemic.

H.R. 4631, the Combating Autism Reauthorization Act, introduced by Representatives Chris Smith and Doyle, which is important for all persons with an autism spectrum disorder and their family. In addition to reauthorizing existing provisions, the bill will require study on the needs of autistic youth transitioning into adulthood and the available services to help them as adults. We worked closely with our Senate colleagues to strengthen this bill and continue the important research to identify better prevention strategies, diagnostics, treatments, and even a cure.

And H.R. 4299, the Improving Regulatory Transparency for New Medical Therapies Act, which I and Ranking Member Pallone introduced. H.R. 4299 seeks to improve the transparency and consistency of DEA scheduling of new FDA-approved drugs under the Controlled Substances Act and its registration process for manufacturing controlled substances for use in clinical trials. Ultimately this will allow new and innovative treatments to get to patients who desperately need them

faster.

This committee has worked diligently in the last several years to ensure that the FDA has the resources that it needs to move new drugs more quickly through its approval process; however, newly approved drugs that contain substances that have not been previously marketed in the United States and that have abuse potential must also be scheduled under the Controlled Substance Act by the DEA before they could be marketed.

Unfortunately, under the CSA, there is no deadline for the DEA to make a scheduling decision, and the delays in DEA decisions have increased nearly fivefold since 2000. This lack of predictability in the timing of DEA scheduling decisions leads to unnecessary uncertainty in the drug-development process and needless delays in the patient's access to new therapies.

H.R. 4299 simply requires DEA to issue an interim final rule no later than 45 days after it receives FDA scheduling recommendation for a new drug, allowing patients access to new therapies, while still ensuring that appropriate controls are in place.

I would urge all my colleagues to support these three bills, and I yield back the remainder of my time and now recognize the gentleman from New Jersey Mr. Pallone for 3 minutes for his opening statement.

[The prepared statement of Mr. Pitts follows:]

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

Mr. Pallone. Thank you, Mr. Chairman.

Today we are marking up three important bipartisan health bills. I am proud to join with you on H.R. 4299, the Improving Regulatory Transparency for New Medical Therapies Act. The bill aims to improve the DEA's scheduling process for new FDA-approved drugs under the Controlled Substances Act and the registration process for the use of controlled substances in clinical trials.

Without weakening FDA oversight, the committee has worked together most recently on FDASIA, to give manufacturers and patient groups a more predictable process, allowing patients to get timely access to the latest innovation therapies available. Unfortunately we have learned that when a medicine has abuse potential, the DEA's authorities under the Controlled Substance Act are hindering this progress.

Our bill would require DEA to make a final determination 45 days after receiving FDA's scheduling recommendation for a new drug. Additionally, it would generate greater transparency in the application process for drugmakers who want to manufacture drugs for clinical trials.

We all agree DEA has an important role to play in combating the abuse and diversion of drugs, but in examining this problem during our subcommittee hearing, it seems to me that there is an unnecessarily repetitive process at the DEA for brand-new products. As a result there is a delay of critical drugs getting to patients who need them,

and I hope Members will support this commonsense correction to DEA authorities.

In addition, we will mark up H.R. 4709, the Ensuring Patient Access and Effective Drug Enforcement Act of 2014. This is an updated version of a bill the subcommittee examined in April. The bill aims to improve and better coordinate enforcement efforts within the drug supply chain regarding prescription drug diversion and abuse.

Prescription drug abuse threatens the safety and health of too many people in this country. Like the Pitts-Pallone bill, the goal of this legislation is not to impede DEA's critical mission of catching bad actors who break laws and divert dangerous drugs; however, by creating a more collaborative partnership between drug manufacturers, wholesalers, retail pharmacies, and the DEA, the bill seeks to limit unnecessary supply chain disruptions that may be affecting patient access to needed medications.

Specifically it would allow supply chain members an opportunity to submit a corrective action plan prior to having their license revoked or suspended by DEA. It also requires a report to Congress on the impact of enforcement activities and opportunities for agency and stakeholder collaboration to combat prescription drug abuse.

And, lastly, I am pleased to support H.R. 4631, the Combating Autism Reauthorization Act of 2014. Established over a decade ago, this longtime bipartisan effort was a direct response to the rising concern about the increased prevalence of autism in this country. In

fact, the most recent report by the Centers for Disease Control and Prevention on the prevalence of autism states that 1 in 68 children has autism. This new estimate is roughly 30 percent higher than the estimate for 2008. Meanwhile, in my home State of New Jersey, 1 in 45 children has autism, and now we don't know what one factor is causing this increase. Some of it may be due to the way children are identified or diagnosed and served in their local communities, but exactly how much is really unknown.

That is why extending the current programs already underway is still critical. These programs include research and surveillance activities, education, early detection and intervention efforts, and the work of the Interagency Autism Coordinating Committee.

In addition, today we will consider a manager's amendment with a number of updates to current law, and the amendment reflects ongoing bipartisan and bicameral efforts to achieve consensus legislation.

So I want to commend Congressman Smith, Congressman Doyle for sponsoring this legislation. I also want to acknowledge the ongoing efforts of our Senate colleagues, Senator Harkin, Alexander, Menendez, and Enzi, who continue to work with our staff and the staff of Congressmen Smith and Doyle to ensure the bill moves forward expeditiously. And I look forward to working with everyone to accomplish this goal.

Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Pallone follows:]

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Mr. Pitts. I now recognize the chairman of the full committee Mr. Upton for 3 minutes for his opening statement.

The Chairman. Thank you, Mr. Chairman.

You know, our committee has had great bipartisan success on the public health front, with more than a dozen committee bills already having become law in this Congress. And today we look to build upon that success as we consider three important bipartisan bills, which I, too, think will reach the President's desk.

First, Subcommittee Chairman Pitts and Ranking Member Pallone have introduced H.R. 4299, the Improve Regulatory Transparency for New Medical Therapies Act. Under current law, for a new drug with potential for abuse, there is no deadline, no deadline for the DEA to make a scheduling decision after receiving a recommendation from the FDA. Recently the delays in the DEA's decisions have increased significantly, and this legislation would provide more predictability and clarity around their review of scheduling decisions for these new drug products.

Second, we are going to look at H.R. 4709, the Ensuring Patient Access and Effective Drug Enforcement Act, authored by Representatives Marino, Vice Chair Blackburn, Welch, and Chu. This bill would aid in the fight against prescription drug abuse by establishing a strong, collaborative and coordinated approach among government agencies and stakeholders. Such a cooperative approach would also ensure the patients still have access to necessary medications.

And, finally, we are going to consider H.R. 4631, the Combating Autism Reauthorization Act, introduced by Chris Smith and Mike Doyle. This important bill will, in fact, continue autism-related research, early identification and intervention, education, and the activities of the Interagency Autism Coordinating Committee.

In the face of growing prevalence, it is certainly critical that we continue to support those with autism spectrum disorders and their families by supporting autism research and passing this bill. The amendment in the nature of a substitute offered to the bill reflects our continued work in cooperation with the Senate on this priority.

I commend you, Chairman Pitts, for your leadership as our work to improve the public health continues and yield back the balance of my time.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Upton follows:]

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

Mr. Pitts. The chair reminds Members that, pursuant to committee rules, all Members' openings statements will be made a part of the record.

Are there further opening statements?

The chair recognizes the vice chair of the full committee Mrs. Blackburn, 1 minute for opening statement.

Mrs. Blackburn. Thank you, Mr. Chairman. I appreciate the comments of my colleagues, and I think that we all realize that prescription drug abuse is an epidemic that is in need of a solution in this country. There needs to be a clear distinction between the legitimate pharmaceutical supply chain that directly serves patients and the criminals who are diverting and selling illegal drugs.

Supply chain stakeholders need further guidance on how to collaborate more effectively with law enforcement. Stated simply, their obligation to prevent diversion is only achievable if to the DEA and other regulators will work with them to get this done.

I have been so pleased to work with my colleagues Marino, Welch, and Chu in crafting H.R. 4709, the Ensuring Patient Access and Effective Drug Enforcement Act of 2014. This legislation does clarify and harmonize definitions to make sure the law is clear for both the DEA and legitimate businesses who want to understand what the rules are so that they can do the right thing.

We also require a report which will give government, public policy, and industry the ability to collaborate and provide

recommendations to Congress on initiatives to reduce prescription drug diversion and abuse.

I thank the chairman, and I would also like to ask permission to submit for the record four letters that we have received in support of this legislation: the Healthcare Distribution Management Association, the National Community Pharmacists Association, National Association of Chain Drug Stores, and Alliance to Prevent the Abuse of Medicines.

Mr. Pitts. Without objection, so ordered.

[The letters follow:]

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

Mrs. Blackburn. Yield back.

Mr. Pitts. Are there any other further opening statements?

If not, the chair calls up H.R. 4299, and asks the clerk to report.

The Clerk. H.R. 4299, to amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors --

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

[The information follows:]

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

Mr. Pitts. Are there any bipartisan amendments to the bill?

Are there any other amendments to the bill?

The question now occurs on forwarding H.R. 4299 to the full committee. All those in favor, say aye.

Those opposed, no.

The ayes appear to have it, the ayes have it, and the bill is agreed to.

Mr. Pitts. The chair calls up H.R. 4709 and asks the clerk to report.

The Clerk. H.R. 4909, to improve enforcement efforts related to prescription drug diversion and abuse, and for other purposes.

Mr. Pitts. 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 1-2 ********

Mr. Pitts. Are there any bipartisan amendments to the bill?

Are there any other amendments to the bill?

The question now occurs on forwarding H.R. 4709 to the full committee. All those in favor, say aye.

Those opposed, no.

The ayes appear to have it, the ayes have it, and the bill is agreed to.

Mr. Pitts. The chair calls up H.R. 4631 and asks the clerk to report.

The Clerk. H.R. 4631, to reauthorize certain provisions of the Public Health Service Act relating to autism, and for other purposes.

Mr. Pitts. 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 1-3 ********

Mr. Pitts. The chair recognizes himself to offer an amendment in the nature of a substitute, and the clerk will report the amendment.

The Clerk. Amendment in the nature of a substitute to H.R. 4631 offered by Mr. Pitts. Strike all after the enacting clause and insert the following:

Section 1. Short Title. This act may be cited as the "Combating Autism Reauthorization Act of 2014."

Section 2. National Autism Spectrum Disorder Initiative.

Mr. Pitts. Without objection, the reading of the amendment is dispensed with.

[The amendment in the nature of a substitute of Mr. Pitts follows:]

******** INSERT 1-4 ********

Mr. Pitts. And I will recognize myself 5 minutes in support of the amendment.

This amendment represents a collective effort of the House and Senate to reauthorize this law quickly to continue the important activities, to study autism spectrum disorders, and it provides services and supports. And we will continue to work with our colleagues in the Senate to pass a bill that will help the Americans who live with this disorder.

The chair recognize the ranking member Mr. Pallone, 5 minutes.

Mr. Pallone. Thank you, Chairman Pitts. I am glad the bill is being marked up at subcommittee today because it gives us an opportunity to identify where we have already reached agreement on issues and where there is still some work left to be done. And I also think it would be important for the Department to have the opportunity to provide additional technical assistance as we move the bill forward.

The current manager's amendment reflects ongoing bipartisan and bicameral efforts to achieve consensus legislation.

The underlying bill extends the programs already underway to ensure there is no lapse in authorization, and, like I mentioned in my opening, there is critical work being done at the Federal level on research and surveillance, as well as education, early detection, and intervention efforts.

In addition, the bill extends the activities of the Interagency Autism Coordinating Committee and the requirement that HHS submit a

report on autism activities.

The manager's amendment does include a number of changes to current law. Specifically it designates an official within HHS to oversee all of these programs, ensuring their implementation is taking into account the strategic plan developed by IACC, and that HHS and other Federal autism activities are not unnecessarily duplicative.

It would also codify the participation of HHS agencies and Federal departments currently on IACC, and affirm the importance of the participation of the public membership of the IACC.

Mr. Chairman, I know Members and staff on both sides of the aisle and in both Chambers have been working hard on this manager's amendment. I understand there are two issues still left to resolve. The first is on what government entity will be responsible for conducting the assessment about the needs for children and adolescents with autism transitioning into adulthood and what information is required for reporting. And the second is finalizing whether the legislation continues to be called the "Combating Autism Act," or if we call it another name.

There is clear agreement that we need to better understand the needs of individuals with autism as they age out of school-based services, and I think evaluating this issue is an important part of the reauthorization effort.

On the bill title, I understand there are some in the autism community who think there are more appropriate terms Congress could

use in conveying its support for ongoing autism and developmental disability activities.

So both issues, I believe, are resolvable. I hope we can continue to work collaboratively to resolve these outstanding issues between subcommittee and full committee.

We all share the goal of advancing legislation that can pass both the House and the Senate as soon as possible and well before the current authorization for these activities lapse, and, therefore, I urge support of the manager's amendment.

Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman.

Is there further discussion of the amendment?

The vote occurs on the amendment in the nature of a substitute. All those in favor shall signify by saying aye.

All those opposed, no.

The ayes have it. The amendment is agreed to.

Are there any bipartisan amendments to the amendment?

Are there any other amendments?

The question now occurs on forwarding H.R. 4631 to the full committee as amended. All those in favor, say aye.

Those opposed, no.

The ayes appear to have it, the ayes have it, and the bill is agreed to.

Without objection, I would like to ask unanimous consent to insert

a letter from the Epilepsy Foundation in support of H.R. 4299 into the record.

Without objection, so ordered.

[The Epilepsy Foundation letter follows:]

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

Mr. Pitts. Without objection, the staff is authorized to make technical and conforming changes to the legislation considered by the subcommittee today. So ordered.

Without objection, the subcommittee stands adjourned.

[Whereupon, at 2:20 p.m., the subcommittee was adjourned.]