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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 OF 2014;

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

H.R. 4795, PROMOTING NEW MANUFACTURING ACT; AND

H.R. 4801, TO REQUIRE THE SECRETARY OF ENERGY TO PREPARE A REPORT ON THE IMPACT OF THERMAL INSULATION ON BOTH ENERGY AND WATER USE FOR POTABLE HOT WATER

MONDAY, JUNE 9, 2014

House of Representatives,

Committee on Energy and Commerce,

Washington, D.C.

The committee met, pursuant to call, at 4:10 p.m., in Room 2123,

Rayburn House Office Building, Hon. Fred Upton [chairman of the committee] presiding.

Present: Representatives Upton, Whitfield, Pitts, Burgess, Blackburn, Latta, Kinzinger, Pallone, and Welch.

Staff Present: Nick Abraham, Legislative Clerk; Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Charlotte Baker, Deputy Communications Director; Mike Bloomquist, General Counsel; Sean Bonyun, Communications Director; Matt Bravo, Professional Staff Director; Allison Busbee, Policy Coordinator, Energy & Power; Patrick Currier, Counsel, Energy & Power; Brenda Destro, Professional Staff Member, Health; Sydne Harwick, Legislative Clerk; Tom Hassenboehler, Chief Counsel, Energy & Power; Brittany Havens, Legislative Clerk; Kirby Howard, Legislative Clerk; Peter Kielty, Deputy General Counsel; Carly McWilliams, Professional Staff Member, Health; Brandon Mooney, Professional Staff Member; Mary Neumayr, Senior Energy Counsel; Katie Novaria, Professional Staff Member, Health; Graham Pittman, Staff Assistant; Charlotte Savercool, Legislative Coordinator; Heidi Stirrup, Health Policy Coordinator; Tom Wilbur, Digital Media Advisor; Ziky Ababiya, Minority Staff Assistant; Jen Berenholz, Minority Chief Clerk; Alison Cassady, Minority Senior Professional Staff Member; Hannah Green, Minority Staff Assistant; and Anne Morris Reid, Minority Senior Professional Staff Member.

The Chairman. The committee will come to order. And the chair will recognize himself for an opening statement.

The bills that we are going to consider this week continue our efforts to create jobs, build the architecture of abundance, improve public health, and modernize government for the innovation era.

The first bill that we are going to consider is H.R. 4795, the Promoting New Manufacturing Act, which is a simple process and transparency bill for EPA with an eye towards future job creation. It seeks to remove unnecessary uncertainty in the permitting of new manufacturing projects, thereby facilitating an American manufacturing renaissance.

A recent Goldman Sachs report noted the vast potential of our newfound energy abundance, but added that permitting delays and regulatory uncertainty are stalling the downstream investments in energy, infrastructure, and energy-intensive manufacturing. Without this architecture of abundance in place, many of the benefits of our domestic energy supply will indeed be squandered. But with it, America can capitalize on both the upstream and downstream opportunities for economic and job growth.

That is where the Promoting New Manufacturing Act really does come in. Its key provision requires that the necessary implementing regs and guidance be made available when a new air quality standard does take effect. In other words, the bill places a reasonable obligation

on EPA to do their job so that companies applying for permits can then do theirs. The result will be fewer delays for job-creating projects and, indeed, faster adoption of new air quality standards.

So let me emphasize again that no substantive environmental provisions are being changed. None. The only thing that changes is the speed by which new standards are implemented. And I want to thank in particular Steve Scalise for his sponsorship of H.R. 4795 and urge all my colleagues to support this job-creating measure.

We will also build on our bipartisan energy efficiency successes by considering a bill authored by Representatives Adam Kinzinger and Jerry McNerney that will identify cost- effective opportunities for Federal agencies to use energy and water more efficiently. The House has had a good record of success at promoting energy efficiency, and it is my hope that our approach will be embraced by Harry Reid in the Senate as a path forward to tangible events and results to advance the efficiency as part of our all-of-the-above efforts.

The committee will also consider a package of health bills that demonstrate the continued bipartisan accomplishments of the Health Subcommittee in their efforts to come together to improve the public health and safety for all Americans. H.R. 4299, the Improving Regulatory Transparency for New Medical Therapies Act, was introduced by Chairman Pitts and Mr. Pallone.

Currently, for a new drug that could be abused there is no deadline

for the DEA to make a scheduling decision after receiving FDA's recommendation. The delays in DEA's decisions have increased significantly in recent years, and this bill would fix the problem by providing more predictability and clarity around the DEA's review of scheduling decisions for these products.

H.R. 4709, the Ensuring Patient Access and Effective Drug Enforcement Act, was introduced by Representative Marino, Vice Chair Blackburn, Representative Welch, and Representative Chu. The bill would help us in our fight against the prescription drug abuse crisis by establishing a collaborative and coordinated approach among government agencies and stakeholders.

H.R. 4631, introduced by Representative Chris Smith and Representative Doyle, would continue important autism- related research, early identification and intervention, education, and the activities of the Interagency Autism Coordinating Committee. It is so important that we continue to support those with Autism Spectrum Disorders and their families by supporting this bill and passing H.R. 4631. We have been working closely with the Senate, very close, and we will have an amendment to the bill that reflects our work on that important legislation. I would urge all of my colleagues to support these commonsense energy and health bills.

Would recognize now the gentleman, my friend from New Jersey, for 5 minutes for an opening statement.

Mr. Pallone. Thank you, Mr. Chairman. I want to lend my support to three important bipartisan health bills being marked up today. And these bills continue the strong legislative record of the Subcommittee on Health. It is my hope that we can continue to work together to address critical public health issues in our communities.

H.R. 4299, Improving Regulatory Transparency for New Medical Therapies Act, is a bill that Chairman Pitts and I introduced, which includes two commonsense corrections to DEA scheduling authorities. It improves both the DEA's scheduling process for new FDA-approved drugs and the registration process for the use of controlled substances in clinical trials. Without weakening FDA oversight, the bill gives or will help give patients more timely access to the latest innovation therapies available.

In addition, we will mark up H.R. 4709, the Ensuring Patient Access and Effective Drug Enforcement Act of 2014, introduced by members of this committee, Representatives Blackburn and Welch, as well as Representatives Marino and Chu. We all agree that prescription drug abuse threatens the safety and health of too many people in this country. Like the Pitts-Pallone bill, this bill is not meant to impede DEA's critical mission of combating the abuse and diversion of drugs. However, it creates a more collaborative partnership between the DEA and legitimate supply chain players to limit unnecessary disruptions that may be affecting patient access to needed medications.

I am also pleased to support H.R. 4631, the Combating Autism Reauthorization Act of 2014, which after today's manager's amendment will hold a new title to better reflect the goals of the bill. The newly named Autism CARES -- Collaboration, Accountability, Research, Education and Support -- Act extends critical programs to help address supports and services of autism in this country.

Mr. Chairman, during subcommittee markup two issues remained outstanding, both of which will be addressed today in a manager's amendment: the title change, which I mentioned, as well as the scope of a report to Congress. I want to thank members for their strong efforts to get a consensus bill together. That includes Representatives Doyle and Smith, the bill's sponsors, and the leadership of this committee, Representatives Upton, Pitts, and Waxman, who worked with our Senate colleagues to ensure the bill moves forward expeditiously.

And lastly, Mr. Chairman, there are the two energy bills before the committee today. H.R. 4795, the Promoting New Manufacturing Act, has a title that highlights a worthy goal, but unfortunately the bill raises serious concerns. It weakens the Clean Air Act's preconstruction permitting process under the National Ambient Air Quality Standard, which could lead to more pollution and increase negative health impacts. I do, however, plan to support the other energy bill before the committee today, H.R. 4801, which requires a

report regarding how the Federal Government can better take advantage of thermal insulation to reduce energy consumption in Federal buildings.

Thank you, Mr. Chairman. I yield back.

Mr. Whitfield. [Presiding] Thank you, Mr. Pallone.

At this time, I recognize myself for a 3-minute opening statement.

As chairman of the Energy and Power Subcommittee, I am just going to address the Promoting New Manufacturing Act, H.R. 4795, which was introduced by Mr. Scalise of Louisiana. I think all of us are very much aware that one of the primary goals that we have in America today in our public policy is trying to expand our economy, create more jobs. And, unfortunately, the President in his first administration, with the billions of dollars spent in the stimulus package, many dollars went for renewable projects that were not ready for primetime. A lot of them went into bankruptcy. And that is one of the reasons, not the only reason, but one of the reasons we still have an economy that is sputtering along and our unemployment has remained higher than was anticipated for a long time.

This bill is so important because we are really surprised that EPA hadn't already adopted what this bill is requiring them to do. As you may or may not know, when EPA establishes a new standard today, which becomes effective immediately, EPA does not set out the guidelines until a much later period of time. So the entities that

are trying to comply with the new standard don't know what the guidelines are, and it is sort of like the IRS publishing its tax instructions but not setting out the standards for those instructions. And that is precisely what is happening at EPA regarding Ambient Air Quality Standard.

So what this bill would simply say is that when EPA establishes a new National Ambient Air Quality Standard they would concurrently provide implementing regulations and guidance so that the regulated community can expeditiously comply with the new standard, including the process for obtaining preconstruction permits.

This legislation requires transparency. It is a commonsense approach. It is a modest goal that nonetheless can bring us a long way toward facilitating an American industrial comeback. The Promoting New Manufacturing Act would be good news for the economy, create new jobs, strengthen the American consumers. And I would urge all my colleagues to support the bill.

At this time, I would call on the gentleman from Vermont for 3 minutes.

Mr. Welch. Thank you very much, Mr. Chairman. I want to thank you for marking up the Ensuring Patient Access and Effective Drug Treatment and Enforcement Act, H.R. 4709. And I want to thank Vice Chair Blackburn, Representative Tom Marino, and Representative Judy Chu for their cosponsorship and leadership on this legislation.

Vermont, like many States around the country, is facing an opiate epidemic. In addition to alarming increases in heroin treatment required, Vermont admissions for prescription drug abuse treatment has increased 361 percent from 2005, when we had 719 cases in our very small State, to 2013, when we had 2,596 cases. It is a full-blown public health crisis.

And to gather all of the stakeholders -- that is providers and public health officials, law enforcement, distributors and pharmacists -- obviously have to come together to tackle this problem head on. It requires communication, collaboration, and predictability. And I have heard from distributors and pharmacies in my own district, as have any colleagues on this legislation, that welcome the opportunity to come together to find ways to better prevent prescription drug abuse and diversion. They, too, see the impact that this epidemic is having on their communities.

And today distributors in my State of Vermont, like Burlington Drug Company and local pharmacies, face unpredictable enforcement from the DEA. These are good folks trying to do a good job, and they are in favor of enforcement, but it has got to be predictable. This can lead to disruptions in the supply chain, which can then limit patient access to legitimate prescription drugs.

This bill will encourage that collaboration between law enforcement, members of the supply chain, and public health providers

and officials, while ensuring that patients have access to the treatment their doctor has prescribed. I look forward to the markup of this important bill.

Mr. Chairman, I yield back.

Mr. Whitfield. Mr. Welch, thanks so much.

At this time, I recognize the chairman of the Health Subcommittee, Mr. Pitts, for a 3-minute opening statement.

Mr. Pitts. Thank you, Mr. Chairman.

I am very pleased that the three bipartisan bills the Health Subcommittee marked up on May 28 are being brought before the full committee for consideration. For the sake of time, I will limit my remarks to H.R. 4299, the Improving Regulatory Transparency for New Medical Therapies Act, which I and Ranking Member Pallone introduced on March 26 of this year.

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. It now takes on average well over a billion dollars and 14 years from the time a drug is discovered to the time of approval.

This committee has taken steps to provide more transparency and

consistency in the drug approval process through the Prescription Drug User Fee program and a commitment to review goals embedded in the PDUFA agreements. However, drugs that contain substances that have not been previously marketed in the U.S. and that have abuse potential must also be scheduled under the CSA by the DEA before they can begin marketing their product.

But under the Controlled Substances Act 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 patients' access to new therapies.

H.R. 4299 simply requires DEA to issue an interim final rule 45 days after it receives FDA's scheduling recommendation for a new drug, allowing patients access to new therapies 45 days after FDA approval. The DEA would retain its authority to subsequently transfer the drug between schedules under the section 201 of the CSA.

This bill also establishes a timeline for DEA to grant approval of manufacturers' applications to register controlled substances not yet approved by the FDA to be used in clinical trials, allowing companies to properly plan clinical trial schedules for prospective new therapies. This provision will get products to the market faster because innovators will be able to get clinical trials underway in a

timely and predictable way, which is critical to drug developers and patients alike.

So I urge support for all three bills. And I yield back.

Mr. Whitfield. Thank you, Mr. Pitts.

At this time, the chair recognizes the gentleman from Ohio, Mr. Latta, for a 3-minute open statement.

Mr. Latta. Thank you, Mr. Chairman. And thank you very much for holding the markup today.

I am especially pleased that H.R. 4795, the Promoting New Manufacturing Act, is one of the listed bills. I represent 60,000 manufacturing jobs in the northwest quadrant of Ohio. When I am back home, I spend a lot of my time visiting their operations, which range from metal casters that make pipes used in hydraulic fracturing to high-tech solar panels. These manufacturing institutions are true engines of economic growth in our country.

Unfortunately, under the current administration, we have seen regulatory proposal after regulatory proposal create a litany of unnecessary red tape on manufacturers. In fact, today there are an estimated $1.9 trillion worth of regulations covered entities must comply with. Instead of spending the money to expand new operations, hire new employees, or invest in local community initiatives, this money is spent complying with government regulations. In fact, many of the latest proposals create more questions than answers.

That is why H.R. 4795 is a very important piece of legislation. This bill simply brings a much-needed level of accountability into the preconstruction permitting process. Manufacturers that are required to get a preconstruction permit should be fully aware of their chances in obtaining it. This bill brings transparency and timeliness and a degree of public awareness that will undoubtedly improve this regulatory process. I thank Mr. Scalise for his leadership on the issue.

I also support the health-related bills before us today. Especially I am pleased to see the movement of H.R. 4709, which will create more collaboration between the DEA, FDA, and HHS in addressing the prevention of prescription drug abuse. This is an ever-growing problem not only in Ohio, but across the country. We need to be looking at all avenues to help end this epidemic.

I urge my colleagues' support on all these bills before us today. I thank the chairman. I yield back.

Mr. Whitfield. Thank you, Mr. Latta.

At this time, the chair will recognize the gentleman from Illinois, Mr. Kinzinger, for 3 minutes. And he is one of the authors of H.R. 4801, which will be marked up tomorrow.

Mr. Kinzinger. Well, thank you, Mr. Chairman. And I want to thank the chairman, ranking member, and their respective staffs for helping Congressman McNerney and myself bring forward the Thermal

Insulation Efficiency Improvement Act. They have been extremely helpful throughout this whole process.

Today millions of gallons of water and energy are wasted due to heating and cooling losses that could be prevented through the increased use of thermal insulation. And I believe a major part of our job in this committee is to help identify opportunities in which we can maximize energy and water efficiency through the minimization of waste, especially in our Federal facilities.

With the Federal Government being the single largest consumer of energy in the country, the potential savings from the increased use of thermal insulation are significant and enough to warrant some attention. For example, we have seen the benefits of mechanical insulation maintenance in commercial buildings, we have seen what that benefit can be, with savings potentially topping $4.8 billion dollars annually. That is enough energy savings to light nearly 4 million homes per year. Up to this point, there have been some small-scale studies showing the benefits such insulation can have on water and energy resources that are otherwise being wasted. The potential increase in energy efficiency is tremendous and can be seen with mechanical insulation, but this has not yet been demonstrated on a large scale.

That is why I introduced H.R. 4801 with my friend from California. This legislation takes a step in the right direction to show not only

the private sector the benefits of thermal insulation, but to show the Federal Government how it could increase the energy efficiency and cost savings of these systems in Federal facilities. It does this by having the Department of Energy compile a study on the impact of thermal insulation on both energy and hot and cold water systems in Federal buildings. I believe the addition of thermal insulation to the proper systems in our Federal facilities is both a relatively simple yet cost-effective way to reduce heat gains and losses.

Estimates also show that thermal insulation saves up to 500 times more energy over its lifespan than its cost, which translates into fairly generous returns on energy efficiency. Simply put, thermal insulation saves energy, water, and money.

Lastly, I want to thank Congressman McNerney for his work on this legislation, and I urge its passage. And I yield back.

Mr. Whitfield. Thank you very much.

At this time, the chair will recognize the vice chairwoman of the full committee, Ms. Blackburn of Tennessee, for 3 minutes.

Mrs. Blackburn. Thank you, Mr. Chairman. And I want to thank our subcommittee chairs and Chairman Upton for going ahead and scheduling this markup.

We know there are some bills that do need to come forward. It is nice that we have bipartisan bills, and the prescription drug abuse bill is one of those. H.R. 4709 is bipartisan. I have been pleased

to work with my colleagues Marino, Welch, and Chu in offering this, the Ensuring Patient Access and Effective Drug Enforcement Act of 2014.

Our legislation specifies that the phrase, and I am quoting, "consistent with the public health and safety," end quote, corresponds to a substantial relationship to preventing diversion and abuse of controlled substances. We also further define imminent danger by providing clarification and harmonizing the Controlled Substances Act with other statutes using imminent danger standard, such as the Federal Mine Safety and Health Act.

Why do definitions matter? Because Congress and this committee has a responsibility to make sure that the law is crystal clear for both DEA and legitimate businesses who want to understand what the rules are so they can do the right thing. This bill will ensure that everyone is on the same page.

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. Our bill lists that other public healthcare providers should be consulted in preparation for the report. I would like to encourage DEA to reach out to long-term care providers and other specialty care groups so that they can report the patient access issues that these different entities face.

I yield back my time, and I thank you for yielding.

Mr. Whitfield. Gentlelady yields back the balance of her time.

And seeing no one seeking recognition for an opening statement, the chair would now call up H.R. 4795 and ask the clerk to report.

The Clerk. H.R. 4795, To promote new manufacturing in the United States by providing for greater transparency and timeliness in obtaining necessary permits and for other purposes.

Mr. Whitfield. Without objection, the first reading of the bill is dispensed with.

[The bill follows:]

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Mr. Whitfield. And the bill will be open for amendment at any point. So ordered.

Now, for the information of members and staff, we are now on H.R. 4795. The committee will reconvene tomorrow at 10 a.m., and I would remind members that the chair at that time will give priority recognition to amendments offered on a bipartisan basis. So I look forward to seeing all of you tomorrow. And without objection, the committee now stands in recess.

[Whereupon, at 4:33 p.m., the committee recessed, to reconvene at 10:00 a.m., Tuesday, June 10, 2014.]