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RPTR KERR

EDTR HUMKE

MARKUP OF

H.R. 639, IMPROVING REGULATORY TRANSPARENCY FOR NEW MEDICAL THERAPIES ACT (AMENDMENT IN THE NATURE OF A SUBSTITUTE);

H.R. 471, ENSURING PATIENT ACCESS AND EFFECTIVE DRUG ENFORCEMENT ACT OF 2015;

H.R.____, TRAUMA SYSTEMS AND REGIONALIZATION OF EMERGENCY CARE REAUTHORIZATION ACT; AND

H.R.____, ACCESS TO LIFE-SAVING TRAUMA CARE FOR ALL AMERICANS ACT
WEDNESDAY, FEBRUARY 4, 2015

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 2:04 p.m., in Room 2123, Rayburn House Office Building, Hon. Joseph R. Pitts [chairman of the subcommittee] presiding.

Present: Representatives Pitts, Guthrie, Murphy, Burgess,

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McMorris Rodgers, Griffith, Bilirakis, Long, Ellmers, Bucshon, Brooks, Collins, Upton (ex officio), Matsui, Schrader, and Pallone (ex officio).

Staff Present: Nick Abraham, Legislative Clerk; Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Charlotte Baker, Deputy Communications Director; Leighton Brown, Press Assistant; Karen Christian, General Counsel; Brittany Havens, Legislative Clerk; Kirby Howard, Legislative Clerk; Peter Kielty, Deputy General Counsel; Carly McWilliams, Professional Staff Member, Health; Katie Novaria, Professional Staff Member, Health; Tim Pataki, Professional Staff Member; Charlotte Savercool, Legislative Clerk; Adrianna Simonelli, Legislative Clerk; Heidi Stirrup, Health Policy Coordinator; John Stone, Counsel, Health; Ziky Ababiya, Minority Policy Analyst; Jen Berenholz, Minority Chief Clerk; Eric Flamm, Minority FDA Detailee; Hannah Green, Minority Policy Analyst and Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor.

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Mr. Pitts. The subcommittee will come to order.

The chair recognizes himself for an opening statement. Today we are considering four important bipartisan bills, but for the sake of time I will focus my remarks on H.R. 639, the Improving Regulatory Transparency for New Medical Therapies Act, which I introduced with Ranking Members Pallone and Green.

H.R. 639, as amended, seeks to improve the transparency and consistency of DEA's scheduling of new FDA-approved drugs under the Controlled Substances Act, CSA, 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 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 CSA by the DEA before they can 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 the year 2000. This bill would bring much needed certainty and predictability to the scheduling process and end the needless delays in patients' access to new therapies.

Senators Hatch and Whitehouse are working on companion

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legislation in the Senate, and we look forward to continuing conversations with them as well as FDA and the DEA as this process moves forward.

I would urge all my colleagues to support these bills, and I will yield back the remainder of my time.

And now recognize the ranking member of the full committee, Mr. Pallone, for 3 minutes.

[The prepared statement of Mr. Pitts follows:]

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Mr. Pallone. Thank you, Chairman Pitts, for holding this markup on four important public health bills.

The Improving Regulatory Transparency for New Medical Therapies Act would speed up Drug Enforcement Administration decisions on scheduling all new FDA-approved drugs containing controlled substances so that they could get to patients more quickly and would also speed up the DEA registration process, allowing the manufacture and distribution of controlled substances for use only in clinical trials.

The bill aims to bring better reliability and transparency to breakthrough therapies while continuing to ensure that they reach patients in need both safely and effectively.

I want to thank Chairman Pitts for working with me on this bill last Congress and committing to moving it forward early this Congress and thank to Mr. Green also for joining us on the bill.

The second bill, the Ensuring Patient Access and Effective Drug Enforcement Act, would add two definitions to the Controlled Substances Act to better focus DEA's enforcement activities. It would also require DEA to provide registrants an opportunity to submit an action plan to correct any violations for which DEA is considering revoking or suspending their controlled substance registration.

And the goal of this bill is help drug distributors, pharmacies, and others who work with DEA to achieve the difficult balance between keeping controlled substance prescription drugs away from drug abusers but not from patients who need them.

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And again, thank Representatives Blackburn, Marino, Welch, and Chu for introducing this legislation.

I know that Senators Whitehouse and Hatch are working to incorporate technical assistance they received from FDA and DEA on their melded versions of these two bills, and it is critical that the agencies responsible for implementing these programs have this input so that the intended policy goals we share are properly executed.

And I look forward to working with the administration, the Senate, and my House colleagues on a perfected version that we can markup the full committee after we pass these today.

Third are the two bills reauthorizing a number of trauma programs. The Trauma Systems and Regionalization of Emergency Care Reauthorization Act, which passed the House last year, aimed at planning, implementing trauma care systems in the States and establishing pilot projects for innovative models of regionalized trauma care. The second, Access to Life-Saving Trauma Care for All Americans, reauthorizes two additional trauma programs that expire this year that aim to increase the availability of trauma services.

And again, traumatic injury is the leading cause of death for children and adults under the age of 45, and it is critical that States are equipped to deliver these medical services. But none of these programs have received funding during the appropriations process in recent years, so I hope our consideration signals the importance of these programs to members.

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And I would like to thank Mr. Green and Dr. Burgess, who are both leaders on trauma care, for their work on these bills.

As you said, many of these bills passed our committee in the House last Congress with broad bipartisan support. And I look forward to working with my colleagues to do the same this year.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Pallone follows:]

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Mr. Pitts. The chair thanks the gentleman.

And now recognizes the gentleman from Michigan, the chairman of the full committee, Mr. Upton, for 3 minutes for his opening statement.

The Chairman. Thank you, Mr. Chairman.

You know, in the last Congress, the Health Subcommittee, this one, established an impressive record of success, with over two dozen bipartisan bills signed into law. The new laws will help local communities by improving the public health across the country, and today we are going to build upon the success of what I like to call the public health Congress by considering four bills to expand access to trauma systems and improve the Controlled Substances Act.

The subcommittee will consider two trauma bills led by Dr. Burgess and Ranking Member Green. The Trauma Systems and Regionalization of Emergency Care Reauthorization Act was passed through the full House in June last year, and would help support State and rural development of trauma systems.

The second bill, the Access to Life-Saving Trauma Care for All Americans Act, will reauthorize language from the Public Health Service Act to aid hospitals in handling their uncompensated care costs from traumatic injuries.

We are also going to consider two bills related to the Controlled Substances Act. The Improving Regulatory Transparency for New Medical Therapies Act, led by Chairman Pitts, full committee Ranking Member Pallone, and subcommittee Ranking Member Green, would amend the CSA

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to improve and streamline the DEA's process for scheduling new drugs approved by the FDA.

Lastly, the Ensuring Patient Access and Effective Drug Enforcement Act, led by Vice Chair Blackburn and Representatives Marino, Welch, and Chu, would help prevent prescription drug abuse, establish clear and consistent enforcement standards, and ensure that patients have access to medications by promoting collaboration among government agencies, patients, and industry stakeholders.

These are four very important bills. I urge their swift approval, and I yield back the balance of my time.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of The Chairman follows:]

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Mr. Pitts. And now I recognize the gentleman from Texas, Mr. Green, for 3 minutes for his opening statement.

Mr. Green. Thank you, Mr. Chairman. I apologize for being late. We had a Texas delegation luncheon, and I was worried they were going to talk about redistricting.

But I want to thank the committee leadership for having this markup today. All four bills being considered address public health needs, and remind us of what we can accomplish when we work together to improve the health and safety of the American people.

H.R. 639, the Improving Regulatory Transparency for New Medical Therapies Act, provides a solution to current delays experienced by patients in need. The amount of time the DEA has taken before acting on FDA recommendations has lengthened in recent years, which delays the availability of new therapies. This legislation would improve patient access by bringing clarity and transparency to the process of scheduling a new FDA-approved therapy.

I am pleased to join Chairman Pitts and ranking member of the full committee Pallone in supporting this legislation so we can continue the great work they started last Congress.

Representative Marino, Welch, Blackburn, and Chu introduced H.R. 471, the Ensuring Patient Access and Effective Drug Enforcement Act. The legislation would promote patient access to medically necessary controlled substances and protect DEA's authority for public safety and health.

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The final two bills being marked up today are H.R. 648, The Trauma Systems and Regionalization of Emergency Care Reauthorization Act, and the H.R. 647, the Access to Life-Saving Trauma Care Act. My good friend and fellow Texan, Dr. Mike Burgess and I, are a sponsor of these bills. I want to thank him and his staff for their dedication hard work on these legislative efforts.

H.R. 647 and H.R. 648 will reauthorize important grant programs that are designed to ensure the availability and effective use of trauma care. Investing in trauma centers and trauma systems will save lives, improve patient outcomes, and lead to downstream cost savings within the healthcare system.

Thank you again, Dr. Burgess, for your partnership on this, and Mr. Chairman, for bringing these bills before the subcommittee today.

I thank all my colleagues from both sides of the aisle for putting forward these thoughtful proposals and for your commitment to improving access and delivery of healthcare. I look forward to seeing these important pieces of legislation move forward, and I hope we continue to work on a bipartisan basis.

And I yield back the time.

Mr. Pitts. The chair thanks the gentleman.

[The prepared statement of Mr. Green follows:]

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

Are there further opening statements? In the Republican side?
In the Democratic side?

The chair recognizes Ms. Matsui 1 minute for opening statement.

Ms. Matsui. Thank you.

Thank you, Mr. Chairman, for holding this markup, and Ranking Member Green.

Investment in public health programs and infrastructure is critical to our Nation's health and wellbeing. All too often I have seen cases of disease outbreaks like Ebola or measles and with other epidemics that plague our Nation. We expect the public health system to respond robustly, and it should. However, it is unrealistic to have that expectation if we don't provide long-term stable funding for public health programs, even in the absence of immediate crises.

I appreciate the efforts of this committee to advance public health legislation. I support the movement of this legislation, and I support including resources the agencies need to implement changes.

I yield back the balance of my time.

Mr. Pitts. The gentlelady yields back.

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[The prepared statement of Ms. Matsui follows:]

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Mr. Pitts. Any other opening statements?

If not, the chair now calls up H.R. 639 and asks the clerk to report.

The Clerk. H.R. 639, 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 with. The bill will be open for amendment at any point. So ordered.

[The information follows:]

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Mr. Pitts. The chair recognizes himself for the purpose of offering 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. 639 offered by Mr. Pitts of Pennsylvania.

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

[The information follows:]

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

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Mr. Pitts. This amendment amends the bill text so that it is identical to H.R. 4299 as introduced by Mr. Pallone and myself during the 113th Congress.

Is there discussion of the amendment?

Are there any bipartisan amendments to the amendment?

Are there any other amendments?

If there are no more amendments, 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, and the amendment is agreed to.

Are there other amendments?

The question now occurs on forwarding H.R. 639, as amended, 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.

Chair now calls up H.R. 471 and asks the clerk to report.

The Clerk. H.R. 471, 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, and the bill will be open for amendment at any point. So ordered.

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[The information follows:]

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

Are there any other amendments?

Question now occurs on forwarding H.R. 471 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.

The chair now calls up the discussion draft entitled, "Trauma Systems and Regionalization of Emergency Care Reauthorization Act" and asks the clerk to report.

The Clerk. Discussion draft to amend Title XII of the Public Health Service Act to reauthorize certain trauma care programs and for other purposes.

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

[The information follows:]

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

Are there any other amendments?

The chair recognizes --

Mr. Burgess. Mr. Chairman, I would like to strike the requisite number of words, please.

Mr. Pitts. The chair recognizes the gentleman.

Mr. Burgess. Thank you, Mr. Chairman.

I just want to speak briefly on this bill and a bill that is very similar, the reauthorization for both trauma centers and the grants.

This is an issue worthy of our consideration because trauma is the leading cause of death under the age of 65. It is expensive, costing nearly \$400 billion a year, third only to heart disease and cancer. It affects individuals of all ages, 35 million Americans, or a person every 15 minutes.

Over several years, Mr. Green and I have worked closely on this issue to update the law and ensure reauthorization of crucial trauma grant programs. As a result of this coordination today, we will be voting on two bills that continue our long bipartisan record of support for the efforts to shore up our Nation's trauma systems.

The Trauma Systems and Regionalization of Emergency Care Reauthorization Act, H.R. 648, is identical to H.R. 4080 that passed this subcommittee and the full Energy and Commerce Committee unanimously last year. That bill also passed the House on a voice vote. This reauthorization allows funding for trauma systems, development,

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and the regionalization of emergency care.

Many members of this subcommittee have trauma systems in their districts or ones nearby that are able to serve their constituents. Regionalizing emergency care allows States to coordinate their resources and helps first responders act faster.

The second, the Access to Life-Saving Trauma Care for All Americans Act, will reauthorize two additional grants that will expire this year that provide critically needed funding to help cover uncompensated costs in trauma centers and to support the core mission of trauma services.

Trauma can happen at any time to anyone. We all watched in horror last night with the live footage of the train that hit the car at the railroad crossing in New York. Certainly underscores that it can happen at any time to anyone. Trauma centers must be available for all victims of traumatic injury. Getting a trauma victim to a trauma center right away is the first step in saving his or her life.

These bills draw support from the American Association of Neurological Surgeons, the American Association of Orthopaedic Surgeons, the American Burn Association, the American College of Emergency Physicians, the American College of Surgeons, the American Trauma Society, the Congress of Neurological Surgeons, the Association of Critical Care Transport, the American Heart Association, the American Stroke Association, the Emergency Nurses Association, Society of Trauma Nurses, American Association for Surgery of Trauma, Eastern

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Association for the Surgery of Trauma, National Association for Emergency Medical Technicians, and the Orthopaedic Trauma Association, and the Trauma Center Association of America.

I thank the chairman for allowing these bills to be considered today, and look forward to their passage through the subcommittee.

I thank you, and I will yield back.

Mr. Pitts. The chair thanks the gentleman.

Now recognizes the gentleman, Mr. Green, 5 minutes for discussion of the bill.

Mr. Green. Mr. Chairman, I just -- and my colleague actually mentioned these two bill numbers, H.R. 647 and 648, so the record reflects it. It is not a draft, and -- but again, we have worked on this legislation for a number of reauthorization periods, and I appreciate Congressman Burgess working with us, and I won't list a supporting of it.

And I yield back my time.

Mr. Pitts. The chair thanks the gentleman.

Anyone else seek recognition?

If not, the question now occurs on forwarding the discussion draft 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.

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The chair now calls up the discussion draft entitled, "Access to Life-Saving Trauma Care for All Americans Act," and asks the clerk to report.

The Clerk. Discussion draft to amend Title XII of the Public Health Service Act to reauthorize certain trauma care programs 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:]

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

Are there any other amendments?

Does anyone seek recognition?

If not, the question now occurs on forwarding the discussion draft 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.

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

So ordered.

Ends another productive bipartisan committee meeting.

Without objection, this subcommittee stands adjourned.

[Whereupon, at 2:24 p.m., the subcommittee was adjourned.]