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RPTR MCCONNELL

EDTR WILTSIE

MARKUP OF:

H.R. 734, FEDERAL COMMUNICATIONS COMMISSION CONSOLIDATED REPORTING ACT OF 2015;

H.R. 639, IMPROVING REGULATORY TRANSPARENCY FOR NEW MEDICAL THERAPIES ACT;

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

H.R. 647, ACCESS TO LIFE-SAVING TRAUMA CARE FOR ALL AMERICANS ACT;

H.R. 648, TRAUMA SYSTEMS AND REGIONALIZATION OF EMERGENCY CARE REAUTHORIZATION ACT; AND

H.R. 212, DRINKING WATER PROTECTION ACT

WEDNESDAY, FEBRUARY 11, 2015

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

The committee met, pursuant to call, at 5:31 p.m., in Room 2123, Rayburn House Office Building, Hon. Fred Upton [chairman of the

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committee] presiding.

Present: Representatives Shimkus, Pitts, Burgess, Blackburn, Latta, Bilirakis, Pallone, Green, Tonko, Yarmuth, Clarke, and Loeb sack.

Staff Present: Nick Abraham, Legislative Clerk; Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Karen Christian, General Counsel; Jerry Couri, Senior Environmental Policy Advisor; Brittany Havens, Legislative Clerk; Kirby Howard, Legislative Clerk; Peter Kielty, Deputy General Counsel; David McCarthy, Chief Counsel, Environment/Economy; Carly McWilliams, Professional Staff Member, Health; Katie Novaris, Professional Staff Member, Health; John Ohly, Professional Staff, O&I; 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; Jeff Carroll, Minority Staff Director; Jacqueline Cohen, Minority Senior Counsel; Eric Flamm, Minority FDA Detailee; David Goldman, Minority Chief Counsel, Communications and Technology; Hannah Green, Minority Policy Analyst; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Rick Kessler, Minority Senior Advisor and Staff Director, Energy and Environment; Tim Robinson, Minority Chief Counsel; Ryan Skukowski, Minority Policy Analyst.

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Mrs. Blackburn. [Presiding.] The committee will come to order.

And I recognize myself -- it is on? It is on. I just need to talk into a little more closely.

Today we embark upon our first full committee markup of the new Congress. This committee is an ideas factory with the results to show for it. We racked up an impressive bipartisan record of success in the 113th Congress. Over 90 bills passed in the House and over 50 bills now law to promote jobs, modernize Government, protect families and communities. Today we will consider a half dozen bills as we look to build upon that solid foundation of results.

First, we have H.R. 734, the FCC Consolidated Reporting Act of 2015. It is authored by Majority Whip Scalise, Communications and Technology Subcommittee Chairman Walden, and Ranking Member Eshoo.

This good-government legislation reduces the reporting workload and increases efficiency at the FCC by consolidating eight separate congressionally mandated reports on the communications industry into a single comprehensive report. The streamlined report will give us important information about competition among technology platforms and the deployment of communications technologies to unserved communities.

Next, H.R. 212, the Drinking Water Protection Act. It is authored by Representative Bob Latta. This bill will give the EPA the tools they need to prevent future occurrences like the one that happened in Ohio. As the Cleveland Plain Dealer editorialized yesterday, this

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bill recognizes the urgency of addressing the public health threat presented by harmful algal blooms.

H.R. 471, the Ensuring Patient Access to Effective Drug Enforcement Act, one that I have authored in partnership with Representatives Moreno, Welch, and Chu, would help prevent prescription drug abuse. It is an issue that hits home for all of our communities.

The bill will establish clear and consistent enforcement standards and ensure patients have access to medications by promoting collaboration among Government agencies, patients, and industry stakeholders.

H.R. 639, the Improving Regulatory Transparency for New Medical Therapies Act, authored by Health Subcommittee Chairman Pitts, Subcommittee Ranking Member Green, and full Committee Ranking Member Pallone, would amend the CSA to improve and streamline the Drug Enforcement Agency's process for scheduling new drugs approved by the Food and Drug Administration.

And, last, the committee will consider two trauma bills led by Dr. Burgess and Ranking Member Green.

H.R. 647, the Access to Life-Saving Trauma Care for All Americans Act, reauthorizes language from the Public Health Service Act to aid hospitals in handling their uncompensated care costs from traumatic injury. The funding is set to expire in fiscal year 2015. All of us

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are concerned about Level I and Level II trauma centers, and we are pleased to have the bill before us.

H.R. 648, the Trauma Systems and Regionalization of Emergency Care Reauthorization Act, was passed through the full House in June 2014 and would help support State and rural development of trauma systems.

For a modernizing Government, for the innovation era to protecting public health, these are all important bills.

And I would like to submit for the record a letter from the chain drugstores supporting H.R. 471, the Ensuring Patient Access and Effective Drug Enforcement Act.

[The information follows:]

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Mrs. Blackburn. With that, I yield back the balance of my time.

And I now recognize my friend from New Jersey, Mr. Pallone, for 5 minutes for his opening statement.

Mr. Pallone. Thank you. I thank the chairwoman.

Today we will consider a number of bills which all passed the respective subcommittees. And I want to thank our ranking members for their leadership as well as the staff, who have collaborated along the way to ensure consensus.

Over the years, Congress has tasked the FCC with compiling many individual reports about different sectors of the communications marketplace, and these reports provide the public and policymakers the insight we need to better understand the market.

Nonetheless, we have a bipartisan interest in rationalizing these requirements and allowing the agency to use its resources more efficiently. To accomplish this goal, the Communications and Technology Subcommittee reached an agreement last week to update the FCC Consolidated Reporting Act. Together we were able to find a way to preserve transparency for consumers and maintain the FCC's authority.

Two more bills relate to trauma. The traumatic injury -- well, since now traumatic injury is the leading cause of death for children and adults under the age of 45, it is critical that States are equipped to deliver medical services for traumatic injury. And that is why,

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with the leadership of Mr. Green and Dr. Burgess, we are considering two bills that reauthorize a number of important trauma programs.

The first, the Trauma Systems and Regionalization of Emergency Care Reauthorization Act, allows for planning and implementing trauma care systems in the States. The bill would also establish pilot projects for innovative models of regionalized trauma care.

The second bill, the Access to Life-Saving Trauma Care for All Americans Act, reauthorizes two additional trauma programs that will increase the availability of trauma services.

Our next bill is the Improving Regulatory Transparency for New Medical Therapies Act. It aims to bring better reliability and transparency to medical therapies while continuing to ensure that they reach patients in need quickly, but most importantly, safely and effectively.

And the fifth bill, Ensuring Patient Access and Effective Drug Enforcement Act, would help drug distributors, pharmacies, and others 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. And I am glad that we have been able to work with both the DEA and the FDA, our Senate counterparts, and the bill's sponsors to ensure that the goals of these bills are met.

And the last bill is the H.R. 212, the Drinking Water Protection Act. I believe it is a step forward. Safe drinking water should be

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a bipartisan issue and should be a priority for this committee. Harmful algal blooms are a serious and growing threat to public health. They also carry serious economic impacts affecting fishing, recreation, and tourism.

I am happy to say that the bill we will consider reflects several changes sought by Democratic Members of the subcommittee. I thank the chairman, Mr. Latta, and the majority staff for working with us to improve the bill.

And I will add that not all of our changes were accepted. So the bill still lacks an authorization of appropriations. Without funding for implementation, I am concerned that the strategic plan will have little impact.

In addition, harmful algal blooms are just one of many threats facing our drinking water systems. More and more communities around the Nation are experiencing the significant disruption that results when safe drinking water is suddenly not available, and serious threats include aging infrastructure, climate change, fracking, drought, and terrorism.

The committee should be doing more to ensure access to safe and affordable drinking water, and we should be doing it in a bipartisan manner. I hope this bill will be the start rather than the end of our drinking water work.

But, Madam Chairwoman, I urge my colleagues to support passage

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of these bills today. And I yield back.

[The prepared statement of Mr. Pallone follows:]

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Mrs. Blackburn. The gentleman yields back.

At this time I recognize Mr. Pitts for 3 minutes.

Mr. Pitts. Thank you, Madam Chairman.

Today we are considering four bipartisan health 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 U.S. 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.

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This bill would bring much-needed certainty and predictability to the scheduling process and end the needless delays in patients' access to new therapies. So I would urge all of my colleagues to support these bills.

And I yield back the remainder of my time.

[The prepared statement of Mr. Pitts follows:]

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Mrs. Blackburn. The gentleman yields back.

At this time Mr. Green is recognized for 3 minutes.

Mr. Green. Thank you, Madam Chairman. I appreciate the committee's leadership for having this markup today.

Of the bills that come out of the Health Subcommittee, all four 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 the FDA recommendations has lengthened in recent years, which delays the availability of new therapies.

This legislation will improve patient access by bringing clarity and transparency to the process of scheduling a new FDA-approved therapy. I was pleased to join Chairman Pitts and ranking member of the full committee, Frank Pallone, in supporting this legislation so we continue the great work they started last Congress.

Two other bills that are being marked up today are H.R. 648, the Trauma Systems and Regionalization of Emergency Care Reauthorization Act, and H.R. 647, the Access to Life-Saving Trauma Care Act. My good friend and fellow Texan, Dr. Mike Burgess, and I are sponsors of these bills.

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H.R. 647 and 648 will reauthorize important grant programs that are designed to ensure the availability and effective use of trauma care. Trauma will continue to occur despite our best prevention efforts.

Unfortunately, the access to trauma care is threatened by losses associated with high cost of treating severely injured patients, uncompensated care, and a growing shortage of trauma-related physicians. Investing in trauma centers and trauma systems will save lives, improve patient outcomes, and lead to cost savings within the healthcare systems.

I want to thank Dr. Burgess for being a champion and partner on this effort.

I also want to thank J.P. with Dr. Burgess' office and the committee staff for their hard work to move these bills forward.

I also support the environment and technology bills being considered today. Federal Communications Commission Consolidated Reporting Act, H.R. 734, is commonsense bipartisan legislation that will eliminate outdated FCC studies and consolidate the remaining into a report that will focus on the current marketplace.

I want to thank Chairman Shimkus for accepting many of the Democratic's suggestions to the Drinking Water Protection Act, H.R. 212.

Safe drinking water is a basic right for all Americans, no matter

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their income or where they live. I will support this bill and hope the Environment Subcommittee will examine this important issue further over the next 2 years.

I look forward to seeing these important pieces of legislation before and will continue to work in a bipartisan manner.

I yield back the balance of my time.

[The prepared of Mr. Green follows:]

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Mrs. Blackburn. I thank the gentleman.

And at this time, Mr. Bilirakis, you are recognized for 3 minutes.

Mr. Bilirakis. Thank you, Madam Chairwoman. I appreciate it very much. Thank you for allowing us to consider these very important bills.

Today we will be looking at several bills. Most of them passed the House during the last session, although in the 113th Congress, they died in the Senate. I am glad we are starting this year with these bipartisan bills, and I am hopeful that they will become law.

There are four public health bills which builds on the bipartisan record of the success for this committee. Hospital trauma centers play an important role in our healthcare system. When we get into a severe accident, we all hope that we will be sent to a quality trauma center to handle our emergency. These trauma bills will help hospitals keep their trauma center funded and ensure quality care.

The other two health bills deal with the Drug Enforcement Agency, DEA, and controlled substances, which is a particularly important issue for my district. The Improving Regulatory Transparency for New Medical Therapies Act, H.R. 639, will have a DEA schedule of new drugs more quickly so these treatments can get to market faster.

Delaying the scheduling of recent FDA-approved drugs only hurts patients who may need these breakthrough treatments.

Lastly, H.R. 471, the Ensuring Patient Access and Effective Drug

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Enforcement Act, would provide better guidance and communication between pharmaceutical wholesalers and the DEA. We need to protect against prescription drug fraud while ensuring people in legitimate pain with legitimate prescriptions have access to their medications.

This legislation is a good first step. By providing drug wholesalers with a timely and accurate guidance, the DEA pharmacists and wholesalers will be able to work together and make substantive progress on this issue.

As a new member of the Communications and Technology Subcommittee, I am excited that we are quickly considering the Federal Communications Commission Consolidated Reporting Act, which has a long history of bipartisan support.

Oversight of the FCC is a significant task of this committee. It is essential that reporting requirements are tailored and consolidated to ensure efficiency and accountability.

I am pleased about the addition of the communications marketplace report to this bill. This report focuses on the state of competition in the communications marketplace with an eye on combating barriers to entry and expansion. Such barriers disproportionately burden small- and medium-sized businesses.

This bill is a product of bipartisanship over the course of multiple Congresses. I hope it will stand as an early example of meaningful legislation produced by this committee when we put

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partisanship aside.

Thank you, Madam Chair. And I yield back the balance of my time.

[The prepared statement of Mr. Bilirakis follows:]

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Mrs. Blackburn. The gentleman yields back.

And at this time, Mr. Tonko from New York, you are recognized for 3 minutes.

Mr. Tonko. Thank you, Madam Chair.

Tomorrow morning we will report out H.R. 212, the Drinking Water Protection Act authored by our colleague from Ohio, Representative Latta.

I wanted to thank Representative Latta and Chairman Shimkus for working with us on this legislation.

H.R. 212 addresses a serious drinking water problem that impacts human health, the environment, drinking water utilities, and many other businesses across our country, harmful algal blooms.

This bipartisan bill is the result of the leadership of Representative Latta and Representative Kaptur and their desire to address the water quality problems of their area. Toledo, Ohio, made the headlines when the water utility had to shut down the water system for several days last year. But this problem is not unique to Lake Erie.

H.R. 212 does not provide instant relief for the problem of harmful algal blooms, but it does lay out a process for addressing the many facets of the problem. It is a good bill, and I urge our colleagues to support it.

Communities, large and small, across this country are

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experiencing problems with their drinking water infrastructure. We have allowed the to-do list on drinking water systems to outpace the resources for getting these jobs done. This approach does not save money. It only leads to damage and expensive repairs. Those costs are inflicted on individual families, individual businesses, individual local governments, and certainly individual water utilities.

H.R. 212 is a good beginning. I hope we will continue to work on these issues and address the many other outstanding problems with drinking water very soon.

I look forward to working with Chairman Shimkus and all of the Members of our committee on other legislation so that we can meet our commitment to deliver clean and safe drinking water to every citizen.

With that, I thank you, Madam Chair, and yield back.

[The prepared statement of Mr. Tonko follows:]

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Mrs. Blackburn. I thank the gentleman for yielding back.

And at this time the author of H.R. 212, Mr. Latta, you are recognized for 3 minutes.

Mr. Latta. Well, thank you, Madam Chair.

I am pleased that the committee is marking up a bill I introduced, H.R. 212, the Drinking Water Protection Act. This bipartisan bill will put forth a strategic plan for assessing and managing risks associated with cyanotoxins and algal toxins in drinking water provided by public water systems.

Cyanotoxins and algal toxins in public drinking water produced from harmful algal blooms are presenting serious concerns for our Nation's health.

Last August a half a million people in the Toledo area, including many of my constituents, were unable to utilize their public drinking water for over 2 days without risking potentially negative health effects due to a high level of cyanotoxins, microcystine-LR detected in the city's public water supply.

During that time, concerns and questions were and have since been raised about the health effects data, testing protocols, treatment processes, and appropriate short-term responses.

Furthermore, witnesses before this committee have testified about further complexity of this issue due to the numerous other algal toxins and variants that may have potential negative health effects

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when present in public drinking water.

I believe H.R. 212 takes a robust and strong scientific approach. We need to protect the health and safety of our public drinking water and better understand these issues short and long term.

I am also pleased that we are marking up the FCC Consolidated Reporting Act, which would initiate much needed bookkeeping reforms at the FCC by modernizing existing law to reduce the agency's reporting workload.

I urge my colleagues to support these bills as well as all of the bills before the committee today.

And, Madam Chair, I thank you. And I yield back the balance of my time.

[The prepared statement of Mr. Latta follows:]

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Mrs. Blackburn. The gentleman yields back.

At this time are there any other statements from the Democratic side?

None? All right.

Dr. Burgess, you are recognized for 3 minutes.

Dr. Burgess. I thank the chair for the recognition.

And I certainly want to thank Chairman Upton and Ranking Member Pallone for holding the markup tomorrow.

And I do plan on supporting all of the bills before our committee tomorrow.

I also want to thank the committee for recognizing two bills relating to Federal support for trauma care. As I mentioned at the subcommittee markup, trauma is the leading cause of death under the age of 65. It is expensive, costing over \$400 billion per year.

Over many years, Ranking Member Green and I have worked closely on this issue to update the law and ensure reauthorization of crucial trauma grant programs, the Trauma Systems and Regionalization of Emergency Care Reauthorization Act.

H.R. 648 is identical to H.R. 4080, which passed the full Energy and Commerce Committee unanimously last year. That bill later passed the House on a voice vote. This reauthorization allows funding for trauma systems development and for the regionalization of emergency care.

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Also, the Access to Life-Saving Trauma Care for All Americans Act, H.R. 647, will reauthorize two additional grants that expire this year. They provide critically needed funding to help cover uncompensated costs in trauma centers.

Trauma centers must be available for all victims of traumatic injury. A study released last year found that patients living near a recently closed trauma facility were 21 percent more likely to die from their traumatic injuries.

These bills draw wide support from organized medicine in the trauma community. I will enter those records in through the record at tomorrow's markup.

I thank the gentlelady for the recognition. I yield back the balance of my time.

[The prepared statement of Dr. Burgess follows:]

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Mrs. Blackburn. The gentleman yields back.

At this time I recognize Ms. Clarke from New York for a request for a UC.

Ms. Clarke. Thank you very much, Madam Chair.

On behalf of Mr. Rush of Illinois, there is a motion at the table requesting unanimous consent for the statement to be placed into the record.

Mrs. Blackburn. The gentleman's statement will be entered into the record.

[The prepared statement of Mr. Rush follows:]

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Mrs. Blackburn. Okay. There are no other opening statements. At this time the chair calls up H.R. 734, and asked the clerk to report.

The Clerk. H.R. 734, to amend the Communications Act of 1934, to consolidate the reporting obligations of the Federal Communications Commission in order to improve congressional oversight and reduce reporting burdens.

[The information follows:]

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

For the information of Members, we are now on H.R. 734. The committee will reconvene at 10:00 a.m. And I remind Members that the chair will give priority recognition to amendments offered on a bipartisan basis.

I look forward to seeing everyone at 10:00 a.m. And at this point, without objection, the committee stands in recess.

[Whereupon, at 5:54 p.m., the committee was adjourned.]