

House Energy and Commerce Committee, Subcommittee on Health

Markup of H.R. 1781, H.R. 938, H.R. 1520, and Other Related Bills

March 27, 2019

10:00 AM, 2123 Rayburn

Purpose

The purpose of this markup was to consider the following 12 bills: H.R. 1781, the “Payment Commission Data Act of 2019”; H.R. 938, the “Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act of 2019”; H.R. 1520, the “Purple Book Continuity Act of 2019”; H.R. 1503, the “Orange Book Transparency Act of 2019”; H.R. 1499, the “Protecting Consumer Access to Generic Drugs Act of 2019”; H.R. 965, the “Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019”; H.R. 1385, the “State Allowance for a Variety of Exchanges (SAVE) Act”; H.R. 1386, the “Expand Navigators’ Resources for Outreach, Learning, and Longevity (ENROLL) Act of 2019”; H.R. 1425, the “State Health Care Premium Reduction Act”; H.R. 987, the “Marketing and Outreach Restoration to Empower (MORE) Health Education Act of 2019”; H.R. 986, the “Protecting Americans with Preexisting Conditions Act of 2019”; and H.R. 1010, A bill to provide that the rule entitled “Short-Term, Limited Duration Insurance” shall have no force or effect.

Members Present

Chairman Eshoo, Ranking Member Burgess, Representatives Butterfield, Walden, Matsui, Pallone, Gianforte, Rush, Blunt Rochester, Lujan, Sarbanes, Carter, Welch, Engel, Schrader, Kelly, Guthrie, Dingell, Griffith, Upton, Bucshon, Castor, Shimkus, Kuster, Cardenas, Mullin, Kennedy, Barragan,

Opening Statements

Chairman Eshoo said that this markup is a significant step in the committee’s work to lower the cost of prescription drugs and reduce health care costs. Taken together, the six drug pricing bills being considered will lower prices and save tax payers billions of dollars. The committee is also considering six bills that will help Americans afford high quality health insurance. These bills are timely. Earlier this week, the President said that the entire Affordable Care Act (ACA) should be struck down in court. This is a monstrous attack on the health and wellbeing of Americas. The North Star for Democrats for decades has been universal coverage. Democrats are prepared to fight to for this issue.

Ranking Member Burgess said that Republicans are prepared to work on some of these bills in a bipartisan manner. There was a bill that Rep. Griffith and others wanted to work on along with Chairman Eshoo that would require further disclosure of information to consumers regarding STLDI plans. He is disappointed that this bill was not included in today’s markup. This bill would have provided members on both sides of the aisle with the opportunity to make sure that these plans, which are legal under the ACA, would be marketed appropriately. Republicans are also supportive of giving states the flexibility to lower health insurance costs through reinsurance and other programs. He introduced a bill on that issue, and hopes to continue working on it despite the fact that it is not included in this markup. Everyone also agrees that drug prices are too high. He looks forward to working in a bipartisan fashion on a number of these initiatives.

Rep. Butterfield said that Democrats are the party of universal coverage. If the ACA is overturned, millions of Americans will lose health coverage, and millions more will face higher premiums. Members of Congress need to work together to make health care more attainable and affordable.

Rep. Walden said that Republicans agree that Congress needs to do more to lower the cost of health care and prescription drugs. There has been bipartisan progress on several of the bills aimed at lowering drug prices. But he is disappointed that there has not been the same level of cooperation on the CREATES Act. Republicans have deeply held concerns about the potential consequences of a poorly written CREATES Act. However, they are willing to support this bill with two reasonable amendments. First, the bill currently allows for recapture of a company's revenue, rather than the profit, derived from anticompetitive behavior. This should be changed to either profit or treble damages, whichever is higher. Second, Republicans ask that the bill include an affirmative defense for license holders. He cannot support the CREATES Act as drafted. He is also concerned about H.R. 1499, which witnesses have testified would actually slow patient access to generic drugs. Unfortunately, the six ACA related bills are fairly partisan and fail to address the underlying problem of high health care costs.

Rep. Matsui said that Democrats are committed to reversing the sabotage that the Trump Administration has done against the ACA and lowering the cost of health care. These bills represent meaningful first steps towards these goals. A recent survey conducted by the Campaign for Sustainable Drug Pricing found that one in four Americans cannot afford their medicines. The cost of prescription drugs have skyrocketed and this is simply unacceptable.

Rep. Pallone said that taken together, these bills will strengthen the nation's health care system, reverse the Trump Administration's sabotage of the ACA, and help lower the cost of prescription drugs. This markup is even more critical given the Trump Administration's statement this week that the entire ACA should be overturned, stripping health care from millions of Americans. Many of the bills being considered aim to increase Americans' access to generic drugs, one of the best ways to lower prices. The second batch of bills will help lower health care costs, protect people with preexisting conditions, and strengthen the ACA.

Rep. Gianforte said that he is pleased that there has been a quick markup of several bipartisan bills. Other bills, however, spend more money on failed programs, limit state flexibility, and do little to bring down costs. He looks forward to working to improve those bills.

Rep. Rush said that the President has declared war on the health of millions of Americans who rely on the ACA. This markup includes 12 important bills to strengthen the ACA and lower drug costs across the nation. He is glad that H.R. 1499 is being considered.

Rep. Blunt Rochester said that the Administration just announced its intent to pursue an entire takedown of the ACA. Millions of Americans will be harmed if the ACA is repealed. The bills before the committee will strengthen the ACA and lower costs. H.R. 987 will reverse the funding cuts to ACA marketing and outreach efforts, which will bring more young and healthy people into the market.

Rep. Lujan said that the administration's decision to abandon the ACA is an attack on Americans with preexisting conditions. Health care is a right, not a privilege.

Rep. Sarbanes said that Americans with preexisting protections must be protected.

Discussion

Chairman Eshoo called up H.R. 1781, the "Payment Commission Data Act of 2019." **Rep. Carter** said that the cost of drugs is a critical issue. These prices hurt patients, and lowering them should be a bipartisan effort. This bill gives MedPAC and MACPAC important data to aid their work and should be adopted. **Rep. Welch** said that this bill is a start to the effort to bring down drug prices. Transparency is incredibly important. **Rep. Walden** said that this is bill very important and will help Congress understand how to bring down drug prices. **Rep. Engel** said that he supports the bill as well.

The bill was reported favorably to the full committee by unanimous voice vote.

Chairman Eshoo called up H.R. 938, the "Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act of 2019." **Rep. Carter** said that this is a common sense, bipartisan bill to lower drug prices. It will allow new generic drugs to come to market while maintaining competition. **Rep. Schrader** said that said that this bill demonstrates the bipartisan work that can get done on the issue of drug costs. It is narrowly tailored to address the specific problem of patent parking, and it should become law. **Rep. Pallone** said that this bill reemphasizes the impact of generic competition on drug prices. **Rep. Butterfield** said that he is a little concerned about the potential for H.R. 1499 and H.R. 938 to delay patient access to affordable medicine. Prior to the full committee markup, Congress should clarify the forfeiture reforms that were passed as part of the MMA in 2003.

The bill was reported favorably to the full committee by unanimous voice vote.

Chairman Eshoo called up H.R. 1520, the "Purple Book Continuity Act of 2019." She offered an amendment to require publication of the patents of approved biologics in the Purple Book in a similar format to the Orange Book. She said that the Purple Book should be published electronically and kept up to date. **Ranking Member Burgess** said that he supports making the Purple Book more useful and easier to navigate. He asked to be added as a cosponsor to the bill.

The amendment was adopted by unanimous voice vote.

The bill was reported favorably to the full committee by unanimous voice vote.

Chairman Eshoo called up H.R. 1503, the "Orange Book Transparency Act of 2019." **Rep. Kelly** said that the Orange Book must be complete and accurate. She is willing to work with

members in the majority and minority to continue to improve this legislation. She offered an amendment to incorporate technical changes from the FDA and feedback from stakeholders. **Rep. Guthrie** said that it is important to make the Orange Book a useful tool for generic drug manufacturers, and he supports advancing it out of the subcommittee.

The amendment was adopted by unanimous voice vote.

The bill was reported favorably to the full committee by unanimous voice vote.

Chairman Eshoo called up H.R. 1499, the "Protecting Consumer Access to Generic Drugs Act of 2019." **Rep. Rush** offered an amendment to include technical changes recommended by FDA. **Ranking Member Burgess** said that Republicans received this amendment last night and are still evaluating it. He asked counsel to clarify the definition of an "authorized generic" in this amendment. **Counsel** responded that the definition is the same as under current law. **Rep. Pallone** said that patent settlements that delay generic market entry are a perversion of the Hatch-Waxman Act and have twisted the incentives in this space to extend market monopolies. H.R. 1499 will address this problem. **Rep. Griffith** said he has concerns about the retrospective nature of the bill. He asked if it is written as an ex post facto law in violation of the Constitution. **Counsel** responded that that is a question for the House General Counsel. **Rep. Griffith** asked if the law would invalidate already established contracts that do not meet the law's criteria. **Counsel** said yes. FTC would have the ability to take enforcement action to prove that those contracts were unlawful. **Rep. Dingell** said that she supports this legislation. Pay-for-delay agreements are wrong. Patients need access to affordable drugs. **Rep. Carter** said that members haven't had a chance to fully evaluate Rep. Rush's amendment. **Rep. Sarbanes** said that he supports Rep. Rush's amendment. Pay-for-delay agreements do not help consumers. **Rep. Welch** said that he supports the amendment and the bill. **Rep. Walden** said that he would like to work with Democrats between now and the full committee markup to better understand the amendment.

The amendment was adopted by voice vote.

Rep. Upton said that, as currently drafted, this bill would not only deem all future pay-for-delay settlements unlawful, it would also call into question agreements that were entered into legally over the past six years. He offered an amendment to strike the retroactive language from the bill. **Rep. Rush** said his bill gives the FTC the discretion to pursue enforcement action against agreements entered into in the past; it does not mandate action. The penalties are only prospective. **Rep. Griffith** said he is still concerned about the retroactive illegality. **Rep. Walden** said that passing the retroactive language could lead to generics that are already on the market being withdrawn. That is an important consideration, and there should be more time to evaluate the implications.

The amendment was defeated by a vote of 19 to 11.

The bill was reported favorably to the full committee by voice vote.

Chairman Eshoo called up H.R. 965, the "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019." **Rep. Gianforte** offered an amendment to change the provision for recapture of a company's revenue to recapture of profit or treble damages,

whichever is higher. The change would make the CREATES Act consistent with existing law and the Constitution. **Rep. Welch** said that the bill as written was considered by the Senate Judiciary Committee, and the damage structure was based on recommendations by the FDA, FTC, and CBO. **Rep. Walden** said that this bill has the potential to be passed in a bipartisan fashion. But there is a big difference between revenue and profit. A recapture of revenues would be unprecedented and could have a detrimental effect on small businesses. **Chairman Eshoo** said that this is an important consideration. Whatever is ultimately agreed to will serve as a deterrent to anti-competitive behavior. **Rep. Pallone** said that he does not believe the CREATES Act does anything to violate the Constitution. **Rep. Gianforte** said that he is concerned that this damages provision will encourage frivolous litigation and could stifle innovation.

The amendment was defeated by a voice vote.

Rep. Welch offered an amendment to incorporate technical feedback received from FDA. **Rep. Walden** said that Republicans support the amendment, but unfortunately it does not address their concerns with the underlying bill.

The amendment was adopted by unanimous voice vote.

Rep. Bucshon said that he wants to be able to support the CREATES Act, but cannot support a bill that perversely incentivizes litigation. He offered an amendment to ensure that if a brand manufacturer makes a commercially reasonable, market-based offer to sell a sufficient quantity of a product to a potential product developer, the manufacture would have an affirmative defense under the law. **Ranking Member Burgess** said that he supports the amendment. The ability for affirmative defense will be critical to the success of this program. **Rep. Pallone** said that he strongly opposes this amendment. It would weaken the bill's deterrent effect. **Rep. Welch** said that the burden on manufacturers to provide samples is not unreasonable.

The amendment was defeated by a voice vote.

The bill was reported favorably to the full committee by voice vote.

Chairman Eshoo called up H.R.1385, the "State Allowance for a Variety of Exchanges (SAVE) Act." **Rep. Bucshon** said that this partisan bill is aimed at earmarking money to allow states to create their own marketplaces. He offered an amendment to stipulate that grants may only go to states that demonstrate an inability to fund their state exchange. **Rep. Pallone** said that the original intention of the ACA was to encourage states to create their own exchanges. This bill reiterates that goal and will help reverse the sabotage of the Trump Administration. **Ranking Member Burgess** said that many states could not set up exchanges when the ACA went into effect because they were only given a week after the rules for essential health benefits were made public.

The amendment was defeated by a vote of 18 to 10.

The bill was reported favorably to the full committee by voice vote.

Chairman Eshoo called up H.R.1386, the "Expand Navigators' Resources for Outreach, Learning, and Longevity (ENROLL) Act." **Rep. Castor** said that the Trump Administration's

sabotages against the ACA have raised costs for American families. The ENROLL Act will restore funding for the independent navigators that help keep the insurance pool broad and stable. Many Americans are still unaware of the ACA requirements and options. This speaks to the failure of the Trump Administration to properly educate the public. **Rep. Shimkus** said that the economy is growing, and more and more people have employer-sponsored health insurance. For plan year 2017, navigators received \$62.5 million in grants, but accounted for less than one percent of enrollees. Agents and brokers are far more effective. **Rep. Pallone** said that the navigators fill the void that agents and brokers leave. They are critical for outreach to low-income and under-served communities. **Rep. Walden** offered an amendment to codify the Trump Administration's proposed exchange user fee reduction for the next three plan years. This would provide certainty to insurance issuers and help lower premiums for consumers. **Rep. Pallone** said that navigators are necessary to reach low-income, uninsured, and non-English speaking communities. He does not believe that the administration is using the exchange user fee for its intended purpose. This amendment would make it harder for Americans to access quality and affordable health care.

The amendment was defeated by a voice vote.

The bill was reported favorably to the full committee by voice vote.

Chairman Eshoo called up H.R. 1425, the "State Health Care Premium Reduction Act." **Rep. Pallone** said that this bill is an important step to strengthen the ACA. Reinsurance pays for the costs of people with serious medical conditions, and helps reduce premiums for everyone in the individual market. A sustained federal commitment is needed to help lower costs for all Americans. He is disappointed that this bill is not receiving bipartisan support. Attempts to make this debate about Hyde restrictions shows that Republicans are not committed to lowering health care costs. **Rep. Walden** said that the Hyde amendment is not unprecedented. Democrats and Republicans have supported it for years. As for sabotage, the Trump Administration has taken many steps to increase approval of state innovation waivers and increase patient choice. **Chairman Eshoo** said that Democrats are willing to work across the aisle with Republicans on health care issues, but the landscape changed dramatically when the President made the statement this week that the ACA should be repealed. **Rep. Shimkus** said that he does not stand with the President when it comes to eliminating preexisting condition protections, and many other Republicans have said the same thing. **Rep. Kuster** said that she commends Republicans for breaking with the President when he said that preexisting condition protections should be eliminated. Reinsurance is a tool that can help defray high costs for insurers and lower premiums for everyone. **Rep. Cardenas** said that the ACA has allowed more Americans to have insurance than ever before. Strengthening the individual market is critical. **Rep. Mullin** said that this bill does not include the longstanding requirement that federal dollars not be used for abortion services. **Rep. Kennedy** said that millions of Americans will lose coverage and access to care if the ACA is overturned. **Rep. Pallone** offered an amendment to make technical changes to the bill with respect to the state allocation amounts and application deadlines. **Ranking Member Burgess** offered an amendment to the amendment to add Hyde language to the bill. **Rep. Pallone** said that he opposes this amendment as unnecessary. **Rep. Lujan** said that this amendment is designed to incentivize insurance carriers to drop abortion coverage in all insurance products. Congress should be expanding access to care, not restricting it.

The amendment to the amendment was defeated by a vote of 17 to 12.

The amendment was adopted by a vote of 18 to 12.

The bill was reported favorably to the full committee by a vote of 18 to 13.

Chairman Eshoo called up H.R. 987, the “Marketing and Outreach Restoration to Empower Health Education Act of 2019” or the “MORE Health Education Act.” **Rep. Blunt Rochester** said that marketing and outreach for the ACA gives Americans critical information about their health care options. Funding for outreach and marketing is efficient and effective. In order for the ACA to benefit Americans, they need to know when and how to sign up. **Rep. Shimkus** offered an amendment to extend the marketing and outreach provisions to advertisement of STLDI and association health plans. He said it is important to inform consumers of all their options. **Rep. Castor** said that this amendment is a recipe for higher costs. Not only has the administration drastically cut funding for outreach, now Republicans want to advertise junk plans. **Ranking Member Burgess** said that every individual should be able to choose from a variety of health plans. Choice and competition are what produce better products. STLDI or association plans may be better options for some people, and they should be informed about them. **Rep. Pallone** said that people might choose these plans because they’re cheaper, but they’re cheaper because they’re junk.

The amendment was defeated by a voice vote.

Rep. Carter offered an amendment to allow funding for marketing and outreach regarding STLDI plans. The more informed patients are, the more informed decisions they will make. **Rep. Sarbanes** said that tax payer money should not be used to lure people in junk plans. **Rep. Barragan** said that there has been story after story of people buying these plans not realizing that they don’t cover necessary services until it’s too late.

The amendment was defeated by a voice vote.

The bill was reported favorably to the full committee by a voice vote.

Chairman Eshoo called up H.R. 986, the “Protecting Americans with Preexisting Conditions Act of 2019.” **Rep. Kuster** said that this bill is narrow in scope and aims to crack down on the prevalence of junk health plans by protecting Section 1332 of the ACA. **Rep. Pallone** said this is one of the most important bills before the committee. STLDI plans discriminate against people with preexisting conditions and raise costs.

The bill was reported favorably to the full committee by a vote of 19 to 13.

Chairman Eshoo called up H.R. 1010, To provide that the rule entitled “Short-Term, Limited Duration Insurance” shall have no force or effect. **Rep. Castor** said that this is another bill aiming to help those with preexisting conditions. **Rep. Pallone** said that he believes the administration’s authorization of STLDI plans violates the law. **Rep. Shimkus** said that he rejects the implication that Republicans don’t want to protect people with preexisting conditions. People are struggling with the cost of ACA plans. It is important that they have options.

The bill was reported favorably to the full committee by a vote of 19 to 13.