SUMMARY

The Energy and Commerce Subcommittee on Health held a markup for twelve pieces of legislation related to pre-existing conditions, Affordable Care Act (ACA) protections, protecting against short-term or associated health plans, and the rising cost of prescription drugs. All twelve bills were forwarded to the full committee, and no amendments introduced by Republicans during debates received approval.

At times, debate was interrupted by the topic of abortion and radically differing views on ACA history, the impact of the ACA, and the Administration's recent efforts against the law.

Opening Statements:

- Subcommittee Chair Anna Eshoo (D-CA): Focused on recent Administration action she believes is an attack on the ACA.

- Rep. G.K. Butterfield (D-NC): Spoke about colleagues across the aisle who are acting in an "unacceptable" manner, and called for more bipartisanship.

- Chairman Frank Pallone (D-NJ): Spoke on his beliefs that there is a danger posed by the Administration's efforts against the ACA, including protections of pre-existing conditions. He urged action on the bills before the subcommittee.

- Reps. Rush (D-IL), Blunt Rochester (D-DE), Lujan (D-NM) and Sarbanes (D-MD) expressed anger at the attempts by the administration to dismantle the ACA.

- Ranking Member Michael Burgess (R-TX) noted that a proposal from Rep. Eshoo to add consumer warnings to short-term plan was not on the list to be marked up. He said that his members would support such a bill and in fact, Rep. Carter offered a similar amendment on this in the markup.

- Ranking Member Greg Walden (R-OR): Spoke against the bills related to the ACA because he felt they were partisan and did not address the underlying issues.

Legislation:

* Note that Members with an asterisk next to their names introduced amendments to the corresponding bills.

- H.R. 1781, the "Payment Commission Data Act of 2019"

H.R. 1781, introduced by Reps. Carter (R-GA), O'Halleran (D-AZ), Rice (R-SC), Panetta (D-CA), Gianforte (R-MT), and Welch (D-VT), would provide the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access

Commission (MACPAC) with access to drug pricing and rebate data under Medicare Parts B and D, as well as under Medicaid. MedPAC and MACPAC are independent, nonpartisan commissions that advise Congress on issues affecting the Medicare and Medicaid programs. Currently, MedPAC and MACPAC lack access to this drug pricing data and are limited in their ability to analyze and provide information on related topics to Congress, such as issues related to prescription drug costs. H.R. 1781 would ensure the Commissions have access to this data in order to analyze and report to Congress on these issues.

Vote: No amendments. Voice Vote. Favorably reported to the full committee.

Spoke In favor: Reps Burgess (D-TX), Welch (D-VT), and Engel (D-NY)

Spoke Opposed: N/A

Comments on H.R. 1781:

Rep. Welch: Bill embraces the transparency needed to address rising drug costs.

- H.R. 938, the "Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act of 2019"

H.R. 938, introduced by Reps. Schrader (D-OR) and Carter (RGA) would discourage parking of 180-day exclusivity by a first generic applicant. It allows the Food and Drug Administration (FDA) to approve a subsequent generic application prior to the first applicant's first date of commercial marketing when the following four conditions have all been met: (1) the subsequent application is ready for full approval; (2) a minimum of 30 months has passed since at least one first applicant submitted their application for the drug; (3) any related patent litigation has been fully resolved; and (4) no first applicant has received final approval.

Vote: No amendments. Voice Vote. Favorably reported to the full committee.

Spoke In favor: Reps. Pallone (D-NJ) and Walden (R-OR)

Spoke Opposed: N/A

Comments on H.R. 938:

Rep. Schrader (D-OR): Bill estimated to save over $1.8 billion.

Rep. Pallone (D-NJ): Generic competition can be a huge factor in bringing down drug costs; this bill reemphasizes the impact that such competition can bring.

Rep. Butterfield (D-NC): Would like sponsors to work with Rep. Butterfield for clarifications before full committee markup; supports bill, wants to make constructive suggestions (with support by Rep. Eshoo)

- H.R. 1520, the "Purple Book Continuity Act of 2019"

H.R. 1520, introduced by Subcommittee Chair Eshoo (D-CA), would amend the Public Health Service Act to codify publication of approved biological products in the Purple Book in a similar format and with similar requirements to the Orange Book, specify that the Purple Book should be published electronically on FDA's website and updated routinely, and direct FDA to consider the types of patents that should be listed in the Purple Book.

Vote on Eshoo Amendment: Voice Vote. Passed.

Technical amendment proposed (specify that Purple Book should be published on the FDA website and updated regularly),

Vote on Bill: Voice Vote. Favorably reported with Eshoo amendment to full committee.

Spoke in Favor: Rep. Burgess (addition of co-sponsorship)

Spoke Opposed: N/A

Comments on H.R. 1520:

Rep. Burgess (R-TX): Appreciated amendment from Rep. Eshoo; supported it, asked to be a co-sponsor on the bill.

- H.R. 1503, the "Orange Book Transparency Act of 2019"

H.R. 1503, introduced by Rep. Kelly (DIL), would help to ensure that the Orange Book is accurate and up-to-date, by requiring manufacturers to share complete and timely information with FDA, as well as ensuring that patents listed in the Orange Book are relevant to the approved drug product. Patents found to be invalid through a court decision or a decision by the Patent Trial and Appeal Board would be required to be removed promptly. FDA is also directed to reconsider the types of patents that should be listed in the Orange Book within one year of enactment.

Vote on Bill: No amendments. Voice Vote. Favorably reported to full committee.

Comments on H.R. 1503:

Rep. Kelly (D-IL): Will work with Members to improve this legislation related to technical changes, before full committee markup.

- H.R. 1499, the "Protecting Consumer Access to Generic Drugs Act of 2019"

H.R. 1499, introduced by Rep. Rush (D-IL), would make it illegal for brand name and generic drug manufacturers to enter into agreements in which the brand-name drug manufacturer pays the generic manufacturer to keep a generic equivalent off the market.

** Rep. Rush offered an amendment that was based on technical advice from the FDA. It was provided to Members at least 2 hours before the mark up (as per the rules), but some Members said the amendment was highly technical and expressed a need for more time to understand it. There was confusion and major disagreement on whether to move forward with the bill or postpone the vote.

Vote on Rush Amendment: Voice Vote. Passed.

Addition of technical advice from the FDA.

Vote on Upton Amendment: Failed (11-19)

Amendment to eliminate the retroactive nature of the bill, which would make cases settled retroactively unlawful as far back as June 17, 2013 (FTC v. Actavis).

Vote on Bill: Favorably reported with Rush amendment to full committee.

Spoke in Favor: Reps. Dingell (D-MI), Sarbanes (D-MD), Welch (D-VT)

Spoke Opposed: Reps. Griffith (R-VA) and Carter (R-TX)

Comments on H.R. 1499:

*****Rep. Upton (R-MI): Introduction of amendment; to eliminate the retroactive nature of the bill. Rep. Rush asked for Rep. Upton to withdraw this amendment to further work together, because penalties are prospective. Rep. Griffith is concerned that the unlawful nature is still retrospective.

Rep. Burgess (R-TX): Seeking clarification on definitions, satisfied with response.

Rep. Pallone (D-NJ): This bill is the most important bill considered today; this bill will help prevent monopolization and promote competition.

Rep. Griffith (R-VA): Concern with retroactive nature of the bill violating the Constitution (as it addresses cases as far back as 2013); Counsel asks Rep. Griffith look to House Counsel, under the legislation today addressing any older agreements would be done by the FTC and not the parties involved (if legal enforcement were to take place)

Rep. Dingell (D-MI): In favor; some cases on just one drugs take 10 years to settle; pay for delay is anti-competitive.

Rep. Carter (R-GA): The rush amendment was introduced to the subcommittee the night before, and not fully understood, and that is why he is not in favor.

Rep. Sarbanes (D-MD): Authority to handle the retroactive nature of cases should be in the hands of the FTC.

Rep. Welsh (D-VT): Addressed Rep. Griffith's concerns as ones to be discussed in full committee; reiterated HHS Secretary Alex Azar's support of this bill.

Rep. Walden (R-OR): Want to better understand Rep. Rush' amendment. Asked for a revenue vs. profit clarification in bill, as currently revenue is taxed and stifles innovation.

Rep. Upton (R-MI): Speaking on behalf of his amendment, said perhaps a voice vote would forward the bill to full committee, giving more time to work on the bill.

- H.R. 965, the "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019"

H.R. 965, introduced by Reps. Cicilline (D-RI), Sensenbrenner (R-WI), Nadler (D-NY), Collins (R-GA), Welch (D-VT), and McKinley (R-WV), would establish a process by which generic manufacturers could request that FDA authorize them to obtain sufficient quantities of samples for testing. The bill would allow a generic manufacturer facing delay tactics to bring an 3 action in federal court to obtain the samples it needs. Courts would be authorized to award monetary damages sufficient to deter future gaming. It would also clarify FDA's discretion to allow generic manufacturers to operationalize equivalent safety protocols in a separate system instead of entering a shared safety protocol with brand manufacturers, provided that such separate protocol meets the same safety standard as the original system.

Vote on Gianforte Amendment: Voice Vote. Failed.

Amendment to ensure that this bill is consistent with penalties in current law; do not need an unprecedented increase in damages.

Vote on Welch Amendment: Voice Vote. Passed.

FDA technical feedback; clarifies when "shortage" should be included in technical language – clarifies to avoid exacerbation of shortage; generic companies can work together and stream line as well.

Vote on Bucshon Amendment: Voice Vote. Failed.

Amendment would protect potential product developers with an affirmative defense under the law.

Vote on Bill: Voice Vote. Favorably reported with Welch amendment to the full committee.

Comments on H.R. 965

*****Rep. Welch (D-VT): Introduction of amendment; FDA technical feedback to sponsors, addresses some concern from colleagues that would want FDA input. Rep. Walden still

finds fundamental concerns with the bill, though supportive of overall intent and amendment.

*Rep. Gianforte (R-MT): Introduction of amendment to ensure that this bill is consistent with penalties in current law; do not need an unprecedented increase in damages; ensures bill meets Constitutional muster; willing to meet Democrats on this bill with adoption of amendment.

*Rep. Bucshon (R-IN): Introduction of amendment; cannot support bill on reverse litigation; amendment would protect potential product developers with an affirmative defense under the law; otherwise, frivolous litigation would overshadow innovation. Rep. Burgess is in support.

Rep. Pallone (D-NJ) opposes this amendment strongly – this amendment would lead to smaller windows of time for shared samples to generics, lessening competitive ability. Rep. Gianforte strongly for this amendment.

Rep. Welch (D-VT): Noted that this bill was considered in the Senate Judiciary Committee before; disagrees with Rep. Gianforte's amendment.

Rep. Walden (R-OR): Also concerned that penalties are unprecedented and could have a detrimental effect to startups/new drug manufacturers.

Rep. Eshoo (D-CA): Questioning if the bill is designed as a deterrent; Rep. Welch answers that this is an effective deterrent according to the FDA, CBO, etc.

Rep. Pallone (D-NJ): Opposes Gianforte amendment; this legislation gives a clear deterrent to delay in competition from coming to the market.

Rep. Dingell (D-MI): Aggressively against the Gianforte amendment, sees the amendment as a push to "gut" this bill.

- H.R.1385, the "State Allowance for a Variety of Exchanges (SAVE) Act"

H.R. 1385, introduced by Reps. Kim (D-NJ) and Fitzpatrick (R-PA), would provide states with $200 million in federal funds to establish state-based marketplaces.

Vote on Bucshon Amendment: Failed (10-18)

Funds should only be available to states who cannot pay for their exchanges.

Vote on Bill: Voice Vote. Favorably reported to the full committee.

Spoke in Favor: Rep. Pallone (D-NJ)

Spoke Opposed: Rep. Burgess (R-TX)

Key Comments:

*Rep. Bucshon (R-IN): Introduction of amendment; funds should only be available to states who cannot pay for their exchanges. Rep. Pallone greatly opposes this, and instead should be empowering all states to move forward with exchanges by 2024.

- H.R.1386, the "Expand Navigators' Resources for Outreach, Learning, and Longevity (ENROLL) Act"

H.R. 1386, introduced by Rep. Castor (D-FL), would fund the Navigator program for the federally facilitated Marketplace (FFM) at $100 million per year. The bill would require the Department of Health and Human Services (HHS) to ensure that Navigator grants are awarded to organizations with a demonstrated capacity to carry out the duties specified in the ACA and would reinstate the requirement that there be at least two Navigator entities in each state. The legislation would further give Navigators new duties pertaining to enrolling individuals in Medicaid and the Children's Health Insurance Program, and it would allow Navigators to provide their services year-round. Lastly, the bill would prohibit HHS from taking an entity's capacity to provide information regarding association health plans or short-term, limited duration insurance (STLDI) into account in awarding grants.

Vote on Walden Amendment: Voice Vote. Failed.

Vote on Bill: Voice Vote. Favorably reported to the full committee.

Spoke in Favor: Reps. Pallone (D-NJ) and Kennedy (D-MA)

Spoke Opposed: Rep. Shimkus (R-IL)

Comments on H.R. 1386:

Rep. Pallone (D-NJ) argues that most people will not know the insurance available to them without this bill.

*Rep. Walden (R-OR): Introduction of amendment; codify the exchange user fee reduction proposed by the administration; achieves shared bipartisan goal before the need to bail out the "failed navigators."

Rep. Shimkus (R-IL): Does not agree with president on eliminating pre-existing condition protections.

Rep. Lujan (D-NM): Concerned about Republican response of using short-term or "junk" health plans.

- H.R. 1425, the "State Health Care Premium Reduction Act"

H.R. 1425, introduced by Reps. Craig (D-MN) and Peters (D-CA), would provide $10 billion annually to states, with the option for states to establish a state reinsurance program or to provide financial assistance for individuals enrolled in qualified health plans by reducing their out-of-pocket costs. The bill further requires the Centers for Medicare and Medicaid Services (CMS) to establish and implement a reinsurance program in states that do not apply for federal funding. The bill sets a state's allocation amount based on the state's share of claims of high-cost enrollees.

Note: Debate on this bill included an intense divide on the inclusion of Hyde language, and the use of federal dollars on abortion services.

Vote on Pallone Amendment: Passed (18-12)

Reduction of CMS' financial contribution, makes technical change to state allocation amount, makes technical change of the state application deadline to a timely manner.

Vote on Burgess Amendment: Failed (12-17)

"Hyde Amendment" language to be added to bill; confirm that federal dollars do not pay for abortion services.

Vote on Bill: Favorably reported with Pallone amendment to the full committee (18-13).

Spoke in Favor: Rep. Pallone (D-NJ)

Spoke Opposed: Rep. Walden (R-OR)

Comments on H.R. 1425:

*Rep. Pallone (D-NJ): Introduction of amendment; technical changes to the bill – reduction of CMS' financial contribution, makes technical change to state allocation amount, makes technical change of the state application deadline to a timely manner.

*Rep. Burgess (R-TX): Introduction of amendment; add back protections that are not new, confirm that federal dollars should not pay for abortion services; Rep. Pallone and Rep. Lujan against this. Rep. Shimkus emphasizes that the only thing wrong with the bill for the minority party is the push to use federal dollars toward abortion services.

Rep. Blunt Rochester (D-DE): Never-made-public study from CMS that proves that marketing/advertising is effective (re: lowering advertisement for ACA enrollment, a major issue); asked for this study to be released.

Rep. Pallone (D-NJ): Modeled after a bill supported by Republicans in the REPEAL bill last year; hoping for bipartisan agreement on reinsurance; the minority party will not support the bill without restrictions on abortion rights.

- H.R. 987, the "Marketing and Outreach Restoration to Empower Health Education Act of 2019" or the "MORE Health Education Act"

H.R. 987, introduced by Rep. Blunt Rochester (D-DE), would require HHS to conduct consumer outreach and enrollment educational activities for the ACA marketplaces. The legislation would fund these activities at $100 million per year. The bill further prohibits HHS from expending the funds on promoting plans that do not provide comprehensive consumer protections, including STLDI plans and association health plans.

Vote on Shimkus Amendment: Voice Vote. Failed.

Vote on Carter Amendment: Voice Vote. Failed.

Vote on Bill: Voice Vote. Favorably reported to the full committee.

Spoke in Favor: Reps. Pallone (D-NJ) and Castor (D-FL)

Spoke Opposed: Would gain minority support with addition of Shimkus amendment.

Comments on H.R. 987:

*Rep. Shimkus (R-IL): Introduction of amendment; this amendment would help advertise all the options, including short-term and associated health plans. Rep. Castor in opposition, Rep. Burgess heavily for amendment. Rep. Shimkus argues these plans are in fact compliant with the ACA.

*Rep. Carter (R-GA): Introduction of amendment; small changes to language. Rep. Carter used this time to support Rep. Shimkus, and to argue his amendment as a method of expanding plans to be advertised (again including short-term and associated health plans) into the bill. Rep. Sarbanes is aggressively against this, and Rep. Pallone sees it as deceptive.

> Rep. Walden (R-OR) supports Rep. Carter. Further argues these "junk plans" are technically legal under the ACA, and that there should be no concern. Anything misleading is in the hands of the insurance commissioners and the state AGs. Rep. Barragán (D-CA) only sees this as the use of federal dollars for misleading advertisement.

The minority party mainly argues for short-term and associated plans to be included in health care options – this is not a new stance. The majority party continues to argue against short-term plans, known as "junk" plans, as a further need to protect the ACA. Rep. Pallone emphasized investigation into associated plans/short-term plans, calling these plans deceptive.

Rep. Castor (D-FL): The use of these funds for "junk" plans will not help lower costs for consumers. Rep. Pallone agrees – "junk" plans or associated plans, there is no difference to Rep. Pallone, they are not comprehensive and should not be marketed.

- H.R. 986, the "Protecting Americans with Preexisting Conditions Act of 2019"

H.R. 986, introduced by Reps. Kuster (D-NH), Beyer (D-VA), and Courtney (D-CT), would revoke the Section 1332 guidance issued by the Trump Administration on October 2018. The bill would also prevent the Secretaries of HHS and Treasury from promulgating any substantially similar guidance or rule.

Vote on Bill: No amendments. Favorably reported to full committee. (19-13)

Spoke in Favor: Rep. Pallone (D-NJ)

Spoke Opposed: Rep. Burgess (R-TX) holding comments until full committee.

Comments on H.R. 986:

As expected, the majority party banded together to support this bill, looking to protect coverage for Americans with pre-existing conditions.

- H.R. 1010, To provide that the rule entitled "Short-Term, Limited Duration Insurance" shall have no force or effect

H.R. 1010, introduced by Reps. Castor (D-FL) , Barragán (D-CA), Horsford (D-NV), Moore (D-WI), Underwood (D-IL), and DeSaulnier (D-CA), would overturn the STLDI final rule, giving it no force or effect. These plans are not required to comply with any of the ACA's consumer protections, such as guaranteed issue, community rating, and essential health benefits, and expanding them raises premiums and undermines the individual market.

Vote on Bill: No amendments. Favorably reported to full committee. (19-13)

Key Comments:

Rep. Shimkus (R-IL): Responded to Democratic Members that he is sent to Congress by the people of his state, and is focused on his constituency.