COMMITTEE ON
ENERGY & COMMERCE
CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

April 1, 2019

To: Committee on Energy and Commerce Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Full Committee Markup of H.R. 1644, H.R. 1781, H.R. 938, H.R. 1520, H.R. 1503, H.R. 1499, H.R. 965, H.R. 1385, H.R. 1386, H.R. 987, H.R. 1010, H.R. 986, H.R. 1425, and H.R. 9

On **Wednesday, April 3, 2019, at 9:30 a.m. in the John D. Dingell Room, 2123 of the Rayburn House Office Building**, the Committee on Energy and Commerce will hold a markup of the following bills: **H.R. 1644**, the "Save the Internet Act of 2019"; **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. 987**, the "Marketing and Outreach Restoration to Empower (MORE) Health Education Act of 2019"; **H.R. 1010**, A bill to provide that the rule entitled "Short-Term, Limited Duration Insurance" shall have no force or effect; **H.R. 986**, the "Protecting Americans with Preexisting Conditions Act of 2019"; **H.R. 1425**, the "State Health Care Premium Reduction Act"; and **H.R. 9**, the "Climate Action Now Act."

I. H.R. 1644, THE "SAVE THE INTERNET ACT OF 2019"

On March 8, 2019, Rep. Doyle (D-PA) introduced H.R. 1644, the "Save the Internet Act of 2019," with 132 original co-sponsors. Specifically, H.R. 1644 would repeal the RIF Order[1] that was adopted by the Commission in December 2017 and reinstate and codify the FCC's 2015 Order.[2] The legislation would also restore and place into effect as of January 19, 2017, the Report and Order on Remand, Declaratory Ruling, and Order adopted by the FCC in February 2015. It would also restore as in effect on January 19, 2017, Part 8 of title 47, Code of Federal

[1] Federal Communications Commission, *Restoring Internet Freedom*, Declaratory Ruling, Report and Order, and Order, WC Docket No. 17-108, FCC 17-166 (rel. Jan. 4, 2018) (RIF Order).

[2] Federal Communications Commission, *Protecting and Promoting the Open Internet*, Report and Order, GN Docket No. 14-28, FCC 15-24 (rel. Mar. 12, 2015) (2015 Order).

Regulations. Finally, it would restore as in effect on January 19, 2017, any other rule that the RIF Order modified or repealed.

On March 26, 2019, the Subcommittee on Communications and Technology met in open markup session and favorably forwarded H.R. 1644, without amendment, to the full Committee by a roll call vote of 18 yeas to 11 nays.

II. H.R. 1781, THE "PAYMENT COMMISSION DATA ACT OF 2019"

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

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1781, without amendment, to the full Committee by a voice vote.

III. H.R. 938, THE "BLOCKING ACT OF 2019"

H.R. 938, the "Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act of 2019", introduced by Reps. Schrader (D-OR) and Carter (R-GA), 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 are all 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.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 938, without amendment, to the full Committee by a voice vote.

IV. H.R. 1520, THE "PURPLE BOOK CONTINUITY ACT OF 2019"

H.R. 1520, the "Purple Book Continuity Act of 2019", introduced by Rep. 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.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1520, amended, to the full Committee by a voice vote. An amendment was adopted by voice vote that incorporates technical feedback from the FDA and clarifies that the Purple Book should be published in a searchable electronic format and that exclusivities for biological products should be listed.

V. H.R. 1503, THE "ORANGE BOOK TRANSPARENCY ACT OF 2019"

H.R. 1503, the "Orange Book Transparency Act of 2019", introduced by Rep. Kelly (D-IL), 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.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1503, amended, to the full Committee by a voice vote. An amendment was adopted by a voice vote that incorporates technical feedback from FDA and clarifies that removal of patents found to be invalid through a decision by the Patent trial and Appeal Board only occurs after no appeal has been or can be taken.

VI. H.R. 1499, THE "PROTECTING CONSUMER ACCESS TO GENERIC DRUGS ACT OF 2019"

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

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1499, amended, to the full Committee by a voice vote. An amendment was adopted by a voice vote that incorporates technical feedback from FDA, including ensuring reverse payment settlements amongst any type of manufacturer, including two generics, are unlawful, and extending the scope of unlawful agreements to include those that include a generic forgoing development of their own product in lieu of marketing or selling a brand's authorized generic.

VII. H.R. 965, THE "CREATES ACT OF 2019"

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

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 965 to the full Committee, amended, by a voice vote. An amendment was adopted by a voice vote that incorporates technical feedback from FDA, including clarifying language regarding products that are subject to a shortage, and clarifies the ability of generic manufacturers to share separate REMS.

VIII. H.R. 1385, THE "SAVE ACT"

H.R. 1385, the "State Allowance for a Variety of Exchanges (SAVE) Act", introduced by Reps. Kim (D-NJ) and Fitzpatrick (R-PA), would provide states with $200 million in federal funds to establish state-based marketplaces.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1385, without amendment, to the full Committee by a voice vote.

IX. H.R. 1386, THE "ENROLL ACT OF 2019"

H.R. 1386, the "Expand Navigators' Resources for Outreach, Learning, and Longevity (ENROLL) Act of 2019", 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.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1386, without amendment, to the full Committee by a voice vote.

X. H.R. 987, THE "MORE HEALTH EDUCATION ACT OF 2019"

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

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 987, without amendment, to the full Committee by a voice vote.

XI. HR 1010, A BILL 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, rendering it without 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.

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1010, without amendment, to the full Committee by a roll call vote of 19 yeas to 13 nays.

XII. H.R. 986, THE "PROTECTING AMERICANS WITH PREEXISTING CONDITIONS ACT OF 2019"

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

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 986, without amendment, to the full Committee by a roll call vote of 19 yeas to 13 nays.

XIII. H.R. 1425, THE "STATE HEALTH CARE PREMIUM REDUCTION ACT"

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

On March 27, 2019, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1425 to the full Committee by a roll call vote of 18 yeas to 13 nays. An amendment in the nature of a substitute was adopted by roll call vote of 18 yeas to 12 nays. The amendment incorporates technical feedback from CMS and streamlines the federal default reinsurance program.

XIV. H.R. 9, THE "CLIMATE ACTION NOW ACT"

On June 1, 2017, the Trump Administration announced its intent to withdraw from the Paris Agreement reached by the Conference of the Parties (COP) to the United Nations Framework Convention on Climate Change (UNFCCC) on December 12, 2015, which, under the terms of the Agreement, cannot occur until November 4, 2020.[3] In response, on March 27, 2019, Rep. Castor (D-FL) introduced H.R. 9, the "Climate Action Now Act." The bill was introduced with 71 original co-sponsors.

H.R. 9 seeks to ensure the United States honors its commitments under the Paris Agreement to limit global temperature rise to between 1.5 and two degrees Celsius above pre-industrial levels.[4] The bill achieves this by prohibiting the use of funds to advance the withdrawal by the United States from the Agreement. The bill also requires the President to submit to the appropriate Congressional Committees and make public a plan for the United States to meet its Nationally Determined Contribution (NDC) under the Paris Agreement to Congress 120 days after enactment. In its initial NDC, the United States committed to reducing greenhouse gas emissions 26-28 percent below 2005 levels by 2025. Finally, H.R. 9 requires the President to file with Congress and make public annual updates to the plan.

[3] The White House, Statement by President Trump on the Paris Climate Accord (June 1, 2017) (www.whitehouse.gov/briefings-statements/statement-president-trump-paris-climate-accord).

[4] The Paris Agreement, United Nations Framework Convention on Climate Change (2015).