

House Committee on Energy and Commerce

Markup of thirteen health bills

March 11, 2020

10:00AM, 2123 Rayburn House Office Building

Purpose:

The purpose of the proceedings was to markup thirteen health bills H.R. 5279, the "Cosmetic Safety Enhancement Act of 2019", H.R. 5668, the "Making Objective Drug Evidence Revisions for New Labeling Act of 2020" or the "MODERN Labeling Act of 2020", H.R. 5663, the "Safeguarding Therapeutic Act", H.R. 4866, the "National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act of 2019", H.R. 4712, the "Fairness in Orphan Drug Exclusivity Act", H.R. 2117, the "Food Allergy Safety, Treatment, Education, and Research Act of 2019" or the "FASTER Act of 2019", H.R. 2468, the "School-Based Allergies and Asthma Management Program Act", H.R. 2271, the "Scarlett's Sunshine on Sudden Unexpected Death Act", H.R. 4801, the "Healthy Start Reauthorization Act of 2019", H.R. 1379, the "Ensuring Lasting Smiles Act", H.R. 2477, the "Beneficiary Enrollment Notification and Eligibility Simplification Act of 2019" or the "BENES Act of 2019", H.R. 5534, the "Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act", H.R. 3935, the "Protecting Patients Transportation to Care Act"

Opening Statements:

Chairman Eshoo said today the Committee will mark up thirteen bills to improve Americans healthcare and expand access to affordable and safe products regulated by the FDA. Nearly every bill being considered today is bipartisan. Furthermore, the bills being considered span a wide range of healthcare topics, from updating food labeling requirements to improving healthcare transportation. Today's markup is bursting with common sense bills which will improve the lives of Americans.

Rep. Walden said that three of the bills being considered today are bipartisan pieces of legislation aimed to improve children's healthcare. Furthermore, several of the bills are designed to ensure the safety of Americas medical supply chain while increasing access to these products. Additionally, multiple bills seek to improve healthcare for Medicare and Medicaid beneficiaries by expanding access, communication and transportation.

Rep. Pallone said that today this committee is continuing its commitment to put American consumers first. Members on both sides of the aisle have worked hard to introduce these bipartisan pieces of legislation. It is crucial to ensure that the products Americans use every day are safe. Consumers must have confidence in their products. A number of bills seek to improve health outcomes for children.

Ranking Member Burgess said that HR 5534 would extended the coverage of immunosuppressant drugs for the duration of a Medicare beneficiary's lifetime. This bill will change the lives of patients with end stage renal disease. Several of the other bills being considered today are bipartisan and would improve health outcomes in America. It is crucial to

protect the medical supply chain in America and provide oversight mechanisms to the proper federal authorities.

Rep. Cardenas said that too often we talk about what divides us. Today, there is proof that Democrats and Republicans can work together to improve the lives of Americans. HR 3935 would change individual's lives by providing affordable and timely access to medical transportation.

Rep. Barragan said that HR 5279 will protect millions of consumers who would never think cosmetic products may be unsafe. It is important to provide FDA with the proper authority to conduct oversight of these products. Women of color tend to be the most affected by these products.

Rep. Kennedy said that HR 2271 is of crucial importance. Too many individuals have to live with the reality of sudden infant death. It is time to prioritize SID research.

Bill Consideration:

H.R. 5279 the "Cosmetic Safety Enhancement Act of 2019"

Rep. Pallone offered an amendment in the nature of a substitute (AINS). **Rep. Pallone** said that the AINS makes a number of changes including requiring the disclosure of fragrance allergens on cosmetic products, providing a time table for FDA's ingredient review process, building in the opportunity for FDA to meet with manufacturers to support the development of data collection and providing additional support to small businesses. **Chairman Eshoo** spoke in support of the bill.

Rep. Burgess offered an amendment to the AINS. **Rep. Burgess** said there are some concerns that very small business will face a large regulatory burden. These regulatory restrictions could obstruct some small business from entering the market. This amendment would exclude manufacturers with gross annual sales of under \$1 million dollars from the requirements in the bill. **Rep. Pallone** said there have been special accommodations made for small businesses in the original bill.

Rep. Burgess withdrew the amendment.

Rep. Rush offered an amendment to the AINS. **Rep. Rush** said that African American women are at a higher risk to use cosmetic products contaminated with harmful ingredients. This amendment would ensure that the Office of Minority Health is consulted on which ingredients should be reviewed in cosmetic products. **Rep. Blunt-Rochester** spoke in support of the bill.

Rep. Rush's amendment to the AINS was approved by a voice vote.

Rep. Dingell offered an amendment to the AINS. **Rep. Dingell** said that the amendment would require the FDA to prioritize the review of PFAS ingredients in cosmetic products. These forever chemicals are dangerous to human health. This amendment would empower the FDA to remove this deadly chemical from consumer products. **Rep. Kuster and Pallone** spoke in support of the amendment. **Rep. Shimkus and Bucshon** spoke in opposition to the amendment.

Rep. Dingell's amendment to the AINS was approved by a voice vote.

Rep. Dingell offered an amendment to the AINS. **Rep. Dingell** said that the amendment would require companies to utilize the modern testing methods recommended by the FDA's inner agency working group on products containing talc intended for children. If they don't, they must place a warning label alerting consumers that asbestos may be present in the product.

Rep. Dingell withdrew the amendment.

The amendment in the nature of a substitute to H.R. 5279, as amended, was agreed to by a voice vote.

H.R. 5279, The Cosmetic Safety Enhancement Act of 2019, as amended, was reported favorably to the full House by a voice vote.

H.R. 5668, the "Making Objective Drug Evidence Revisions for New Labeling Act of 2020" or the "MODERN Labeling Act of 2020"

Rep. Matsui offered a manager's amendment to H.R. 5668. **Rep. Matsui** said that the amendment includes a new provision to clarify that the process created under this bill to update labels cannot be used as alternative pathway to update safety changes. Safety changes must continue to go through the regular FDA process. **Chairman Eshoo, Rep. Guthrie and Pallone** spoke in support of the amendment.

The manager's amendment to H.R. 5668, as amended, was agreed to by a voice vote.

H.R. 5668, the "Making Objective Drug Evidence Revisions for New Labeling Act of 2020" or the "MODERN Labeling Act of 2020" was reported favorably to the full House by a voice vote.

H.R. 5663, the "Safeguarding Therapeutic Act"

Rep. Guthrie and Engel spoke in support of the bill.

H.R. 5663, the "Safeguarding Therapeutic Act" was reported favorably to the full House by a voice vote.

H.R. 4712, the "Fairness in Orphan Drug Exclusivity Act"

Chairman Eshoo offered a manager's amendment to H.R. 4712. **Chairman Eshoo** said that the amendment require drug manufacturers to show that they will not recoup costs each year in order to achieve the orphan drug designation. **Ranking Member Burgess, Rep. Carter and Kuster** spoke in support of the amendment.

The manager's amendment to H.R. 4712, as amended, was agreed to by a voice vote.

H.R. 4712, the "Fairness in Orphan Drug Exclusivity Act" was reported favorably to the full House by a voice vote.

H.R. 2117, the "Food Allergy Safety, Treatment, Education, and Research Act of 2019" or the "FASTER Act of 2019"

Rep. Matsui offered an AINS to H.R. 2117. **Rep. Matsui** said that the amendment incorporates technical feedback from HHS, FDA and CDC, that will allow the bill to be implemented in a way that best achieves the goals of safety and collect more food allergy patient data.

The AINS to H.R. 2117, as amended, was agreed to by a voice vote.

H.R. 2117, the "Food Allergy Safety, Treatment, Education, and Research Act of 2019" or the "FASTER Act of 2019" was reported favorably to the full House by a voice vote.

H.R. 2468, the "School-Based Allergies and Asthma Management Program Act"

Chairman Eshoo offered a manager's amendment to H.R. 2468. **Chairman Eshoo** said that the amendment makes technical changes to improve the legislations implementation. **Rep. Shimkus** spoke in support of the amendment.

The mangers amendment to H.R. 2468, as amended, was agreed to by a voice vote.

H.R. 2468, the "School-Based Allergies and Asthma Management Program Act" was reported favorably to the full House by a voice vote.

H.R. 4866, the "National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act of 2019"

Rep. Pallone offered a manager's amendment to H.R. 4866. **Rep. Pallone** said the amendment incorporates technical assistance and feedback from stakeholders to clarify the intent of the bill. **Chairman Eshoo and Rep. Guthrie** spoke in support of the manager's amendment.

The manager's amendment to H.R. 4866, as amended, was agreed to by a voice vote.

H.R. 4866, the "National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act of 2019" was reported favorably to the full House by a voice vote.

H.R. 2271, the "Scarlett's Sunshine on Sudden Unexpected Death Act"

Rep. Blunt-Rochester offered an AINS to H.R. 4866. **Rep. Blunt-Rochester** said that the AINS makes technical changes based on feedback from HHS. It also makes bipartisan conforming changes to better align this text with the accompanying Senate bill. **Rep. Kuster** spoke in support of the ANS.

The AINS to H.R. 2271, as amended, was agreed to by a voice vote.

H.R. 2271, the "Scarlett's Sunshine on Sudden Unexpected Death Act" was reported favorably to the full House by a voice vote.

H.R. 4801, the "Healthy Start Reauthorization Act of 2019"

H.R. 4801, the "Healthy Start Reauthorization Act of 2019" was reported favorably to the full House by a voice vote.

H.R. 1379, the "Ensuring Lasting Smiles Act"

Chairman Eshoo, Rep. Bilirakis and Pallone spoke in favor of the bill. **Ranking Member Burgess** spoke in support of the bill, but raised concerns about budgetary challenges. **Rep. Griffith** spoke in support of the bill but raised concerns about how broad the benefits are and how it may become increasingly expensive.

H.R. 1379, the "Ensuring Lasting Smiles Act" was reported favorably to the full House by a voice vote.

H.R. 2477, the "Beneficiary Enrollment Notification and Eligibility Simplification Act of 2019"

Rep. Ruiz offered an AINS to H.R. 2477. **Rep. Ruiz** said that the AINS reflects input from other committees as well as provides technical assistance from CMS and the social security administration. The AINS pushes back the enactment date to 2022. The AINS also removes a requirement to align the Medicare part B enrollment period with other open enrollment periods under Medicare. **Ranking Member Burgess** spoke in support of the AINS, but wanted to ensure that Medicare Advantage plans be offered to eligible enrollees. **Rep. Bilirakis** spoke in support of the AINS.

Rep. Schrader offered an amendment to the AINS. **Rep. Schrader** said that the amendment creates a new special enrollment period for seniors who maintain COBRA coverage after the age of 65. **Ranking Member Burgess** spoke in support of the amendment.

Rep. Schrader withdrew the amendment.

The AINS to H.R. 2477, as amended, was agreed to by a voice vote.

H.R. 2477, the "Beneficiary Enrollment Notification and Eligibility Simplification Act of 2019" was reported favorably to the full House by a voice vote.

H.R. 5534, the "Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act"

Ranking Member Burgess offered an AINS to H.R. 5534. **Ranking Member Burgess** said that the AINS makes technical changes to incorporate initial feedback from CMS and the social security administration.

The AINS to H.R. 5534, as amended, was agreed to by a voice vote.

H.R. 5534, the "Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act" was reported favorably to the full House by a voice vote.

H.R. 3935, the "Protecting Patients Transportation to Care Act"

Rep. Carter spoke in support of the bill.

H.R. 3955, the "Protecting Patients Transportation to Care Act" was reported favorably to the full House by a voice vote.