COMMITTEE ON
ENERGY & COMMERCE
CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

March 9, 2020

To: Subcommittee on Health Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Subcommittee Markup of Thirteen Health Bills

On **Wednesday, March 11, 2020, at 10 a.m. in the John D. Dingell Room, 2123 of the Rayburn House Office Building**, the Subcommittee on Health will hold a markup of the following 13 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 Therapeutics 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"; and **H.R. 3935**, the "Protecting Patients Transportation to Care Act".

I. H.R. 5279, THE "COSMETIC SAFETY ENHANCEMENT ACT OF 2019"

The "Cosmetic Safety Enhancement Act of 2019", introduced by Chairman Pallone (D-NJ), would require cosmetics manufacturers to register their facilities and comprehensive cosmetic ingredient statements with the Food and Drug Administration (FDA). H.R. 5279 would also require cosmetic manufacturers to notify FDA of adverse events associated with their cosmetic products within 15 days of learning of such events. Cosmetic manufacturers would be required to substantiate the safety of their products. In addition, the bill would empower FDA to conduct safety reviews of cosmetic ingredients and mandate recalls of products associated with serious adverse health events. It also requires cosmetic manufacturers to provide more transparency about their products on their labels. FDA would be required to develop and implement good manufacturing practices (GMPs) for cosmetic products within three years of enactment, and FDA would be authorized to collect fees annually to carry out the new regulatory authorities and responsibilities.

An amendment in the nature of a substitute (AINS) is expected to be offered that would modify requirements for safety substantiation, require disclosure of fragrance allergens on the label of cosmetic products, make improvements to the ingredient review program, clarify the registration and foreign supplier verification program requirements, as well as other technical changes.

II. H.R. 5668, THE "MAKING OBJECTIVE DRUG EVIDENCE REVISIONS FOR NEW LABELING ACT OF 2020" OR THE "MODERN LABELING ACT OF 2020"

H.R. 5668, the "MODERN Labeling Act of 2020", was introduced by Reps. Matsui (D-CA) and Guthrie (R-KY). This bill gives authority to FDA to require modifications of outdated labeling for generic drugs and requires that FDA report any actions taken under the bill's auspices to update labeling for covered drugs, including the number of drugs, description of the changes and the rationale, as well as any FDA recommendation to modify the program, among other items.

An amendment is expected to be offered that would incorporate technical changes.

III. H.R. 5663, THE "SAFEGUARDING THERAPEUTICS ACT"

H.R. 5663, the "Safeguarding Therapeutics Act", introduced by Reps. Guthrie and Engel (D-NY), would extend FDA's administrative destruction authority to medical devices. This would allow FDA to destroy certain imported medical devices in instances where FDA believes such medical devices are adulterated, misbranded, or unapproved and may pose a threat to the public health as they currently do for drugs.

IV. H.R. 4866, THE "NATIONAL CENTERS OF EXCELLENCE IN CONTINUOUS PHARMACEUTICAL MANUFACTURING ACT OF 2019"

H.R. 4866, the "National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act of 2019", was introduced by Chairman Pallone and Rep. Guthrie. This bill would amend the 21st Century Cures Act to direct FDA to designate National Centers of Excellence in Continuous Pharmaceutical Manufacturing (NCEs). NCEs would work with FDA and industry to craft a national framework for continuous manufacturing implementation, including supporting additional research and development of this technology, workforce development, standardization, and collaborating with manufacturers to support adoption of continuous manufacturing. The bill authorizes $80 million annually for NCEs from fiscal years 2021 through 2025.

An amendment is expected to be offered that would incorporate technical changes.

V. H.R. 4712, THE "FAIRNESS IN ORPHAN DRUG EXCLUSIVITY ACT"

H.R. 4712, the "Fairness in Orphan Drug Exclusivity Act", introduced by Reps. Dean (D-PA), Veasey (D-TX), Carter (R-GA), and McKinley (R-WV), updates the Orphan Drug Act to

require drug manufacturers seeking orphan drug designations to demonstrate the absence of any reasonable expectation of recovering the costs they incur in developing and making those drugs available in the United States for such disease or condition, and to make such demonstrations annually for the duration of the seven-year period of market exclusivity of an approved orphan drug. The bill directs FDA and the drug manufacturer to take into consideration the sales of all drugs for the rare disease or condition developed by the same manufacturer as well as all drugs containing the same active molecular components.

An amendment is expected to be offered that would incorporate technical changes.

VI. H.R. 2117, the "FOOD ALLERGY SAFETY, TREATMENT, EDUCATION, AND RESEARCH ACT OF 2019" or the "FASTER ACT OF 2019"

H.R. 2117, the "FASTER Act of 2019", introduced by Rep. Matsui, would require the Centers for Disease Control and Prevention (CDC) to expand the collection of information as to the prevalence of food allergies for specific allergens and to include that information in reports to Congress. The bill would also amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to include sesame as a major allergen and allow FDA, through regulation, to add other food ingredients as major allergens based on the prevalence and severity of allergic reactions to the food ingredient. Additionally, the bill would require FDA to include patient experience data on treatments for patients with food allergies in its reports on patient experience data as well as a study by the National Academies of Sciences, Engineering, and Medicine on the economic costs of food allergies.

An amendment is expected to be offered that would incorporate technical changes.

VII. H.R. 2468, THE "SCHOOL-BASED ALLERGIES AND ASTHMA MANAGEMENT PROGRAM ACT"

H.R. 2468, the "School-Based Allergies and Asthma Management Program Act", introduced by Rep. Hoyer (D-MD), would add a preference for grants to those states that have additional access to certain healthcare professionals and programs. To be eligible for this preference, states would have to require: (1) the presence of a school nurse or other trained personnel on school premises during school operating hours; (2) that there be a school-based allergies and asthma program, including a method to identify all students in the school with a diagnosis of allergies and asthma; (3) an individual student allergies and asthma action plan for each student with a diagnosis of allergies and asthma; (4) education for staff about allergies and asthma; (5) efforts to reduce environmental triggers of allergies and asthma; and (6) a coordinated support system for students.

An amendment will be offered that will make technical and conforming changes.

VIII. H.R. 2271, the "SCARLETT'S SUNSHINE ON SUDDEN UNEXPECTED DEATH ACT"

H.R. 2271, the "Scarlett's Sunshine on Unexpected Death Act", introduced by Rep. Moore (D-WI), would require the CDC to revise the Sudden Unexplained Infant Death Investigation Reporting Form to include doll re-enactments and scene investigation information on sleep-related deaths of children under the age of five, and to align the form with the National Fatality Review Case Reporting System. The bill also authorizes the CDC to make grants to improve the completion of comprehensive death scene investigations for Sudden Unexpected Infant Death (SUID) and Sudden Unexplained Death in Children (SUDC), to increase the rate of comprehensive, standardized autopsies in cases of SUID and SUDC, and to train medical examiners, coroners, death scene investigators, law enforcement personnel, and health professionals on standard death scene investigation protocols.

The bill also authorizes grants through the Administration for Children and Families (ACF) to assist states in investing in core capacity to review 100 percent of all infant and child deaths, and to develop review programs and prevention strategies. Additionally, the bill authorizes grants through the Health Services and Resources Administration (HRSA) to develop and implement educational programs and outreach related to sleep-related SUID, and programs to develop and deploy support services for families who have had a child die of SUID or SUDC. Finally, the bill states that it is the sense of Congress that additional research is needed to improve the understanding of epidemiology of SUID and SUDC and requires the Department of Health and Human Services (HHS) to report data on SUID and SUDC.

An AINS will be offered that will make technical and conforming changes.

IX. H.R. 4801, THE "HEALTHY START REAUTHORIZATION ACT OF 2019"

H.R. 4801, the "Healthy Start Reauthorization Act of 2019", introduced by Rep. Ryan (D-OH), would reauthorize the Healthy Start Program at $135 million annually for five years, an increase of $15 million per year above the last authorized level. The bill also makes technical changes to require HRSA to consider social determinants of health, high infant mortality rates, and poor perinatal health outcomes when awarding grants. The bill would also require the HHS Secretary to ensure coordination between the Healthy Start program and other HHS programs that aim to reduce infant mortality and improve perinatal outcomes. Finally, the bill requires the Government Accountability Office (GAO) to report to Congress on the Healthy Start program.

X. H.R. 1379, THE "ENSURING LASTING SMILES ACT"

H.R. 1379, the "Ensuring Lasting Smiles Act", introduced by Rep. Peterson (D-MN), would require all individual and group market health insurance plans to cover medically necessary treatment resulting from congenital abnormalities or birth defects. The bill requires plans to provide coverage for any service or treatment that is medically necessary to restore or achieve a normal appearance or function of the body.

XI. H.R. 2477, THE "BENEFICIARY ENROLLMENT NOTIFICATION AND ELIGIBILITY SIMPLIFICATION ACT OF 2019" OR THE "BENES ACT OF 2019"

H.R. 2477, the "BENES Act of 2019", introduced by Rep. Ruiz (D-CA), would improve beneficiary outreach and education, reduce gaps in coverage, and simplify the Medicare part B enrollment process.[1] The BENES Act would require the Federal Government to send advance notice about the enrollment process to individuals approaching Medicare eligibility (aged 60-65). It would also require that part B coverage begin during the first month after an individual enrolls, through either the initial enrollment period or general enrollment period. The bill would further align the general enrollment period with the annual enrollment period for Medicare Advantage (MA) and part D prescription drug plans and would also allow for the creation of a new part B special enrollment period for "exceptional circumstances."

An AINS will be offered that strikes the requirement to align the part B general enrollment period with the annual enrollment period for MA and part D and instead requires the HHS Secretary to submit a report to Congress on how to effectively coordinate these enrollment periods with the goals of maximizing coverage continuity, choice, and ease of beneficiary transition. The AINS also requires that notices containing information about enrollment be sent to individuals aged 63-65 (instead of 60-65) and makes other technical and conforming changes.

XII. H.R. 5534, THE "COMPREHENSIVE IMMUNOSUPPRESSIVE DRUG COVERAGE FOR KIDNEY TRANSPLANT PATIENTS ACT OF 2019"

H.R. 5534, the "Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2019", introduced by Rep. Kind (D-WI), would permanently remove the 36-month limit for Medicare coverage of immunosuppressive drugs following a kidney transplant.

An AINS will be offered that would add a requirement for GAO to conduct a report on the implementation of the new policy and makes other technical and conforming changes.

XIII. H.R. 3935, THE "PROTECTING PATIENTS TRANSPORTATION TO CARE ACT"

H.R. 3935, the "Protecting Patients Transportation to Care Act", introduced by Rep. Carter (R-GA), would amend the Medicaid statute to include non-emergency medical transportation (NEMT) in the list of mandatory Medicaid benefits by codifying current Medicaid NEMT regulations. The bill would also require state Medicaid programs to have in place a prior authorization or utilization management process for the benefit.

[1] Medicare Rights Center, *Congress Must Streamline and Simplify Medicare Enrollment* (2019) (www.medicarerights.org/pdf/2019-benes-act-factsheet-long.pdf).