COMMITTEE ON
ENERGY & COMMERCE
CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

May 9, 2022

To: Subcommittee on Health Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Subcommittee Markup of Six Health Bills

On **Wednesday, May 11, 2022, at 10:15 a.m. (EDT) in the John D. Dingell Room, 2123 of the Rayburn House Office Building, and via Cisco Webex online video conferencing**, the Subcommittee on Health will hold a markup of the following six bills:

H.R. 7667, the "Food and Drug Amendments of 2022"; **H.R. 7666**, the "Restoring Hope for Mental Health and Well-Being Act of 2022"; **H.R. 7233**, the "Keeping Incarceration Discharges Streamlined for Children and Accommodating Resources in Education (KIDS CARES) Act"; **H.R. 623**, the "Gabriella Miller Kids First Research Act 2.0"; **H.R. 3771**, the "South Asian Heart Health Awareness Act of 2021"; and **H.R. 5585**, the "Advanced Research Project Agency-Health Act."

I. H.R. 7667, THE "FOOD AND DRUG AMENDMENTS OF 2022"

Reps. Eshoo (D-CA), Guthrie (R-KY), Pallone (D-NJ), and Rodgers (R-WA) introduced H.R. 7667 on May 6, 2022. This bill reauthorizes the Food and Drug Administration's (FDA) user fee programs and incorporates various programmatic improvements across the whole of FDA.

H.R. 7667 reauthorizes the prescription drug user fee program, the medical device user fee program, the generic drug user fee program, and the biosimilar user fee program through fiscal year (FY) 2027 to provide funding to FDA for the review of new drugs, devices, and biologics, postmarket safety activities, and to operate programs to promote the development of medical products. The legislation generally maintains the fee structures and congressional reporting requirements for all of these programs, though the device program does include a new performance improvement adjustment provision. The legislation also reauthorizes third-party 510(k) review of certain devices and program for accreditation of testing laboratories to assess conformance of a device with certain recognized standards. Although the biosimilar fee structure remains intact, the fees for biosimilar biological products do increase under this legislation.

H.R. 7667 also includes provisions to improve clinical trial diversity. The legislation would require sponsors of clinical investigations of new drugs or certain devices to submit a diversity action plan for trial enrollment. It also requires FDA to issue or update existing draft

guidance on the topic and expeditiously finalize that guidance. The legislation also requires FDA to: (1) evaluate the need for FDA authority to mandate postapproval studies or postmarket surveillance due to insufficient demographic subgroup data; (2) convene one or more public workshops to solicit input from stakeholders on increasing the enrollment of historically underrepresented populations in clinical trials; (3) provide a report to Congress on progress to increase diversity in clinical trials and studies; (4) convene a public meeting on clinical trial flexibilities initiated in response to the coronavirus disease of 2019 (COVID-19) pandemic; and (5) issue draft guidance that addresses considerations for decentralized clinical trials and expeditiously finalize that guidance.

H.R. 7667 also promotes competition for generic drugs by requiring FDA to increase transparency in generic drug applications with regard to the makeup of a generic drug's ingredients. It would also allow a generic drug to be approved and begin marketing if its proposed labeling differs from that of the brand drug on a temporary basis so long as such labeling does not differ with regard to the "warning" section of the label.

H.R. 7667 also includes a number of research, development, and supply chain improvements. It allows applicants for new drug approvals to use methods other than animal testing to support clinical testing and establish effectiveness. It also authorizes new programs to enhance drug development and manufacturing, including the Emerging Technologies Program and an advanced manufacturing technologies designation pilot program. It includes provisions to improve the treatment of rare diseases, advance antifungal research and development, and facilitate the development of cell and gene therapies.

The bill includes a number of provisions to increase FDA's inspections authorities, including codifying and clarifying FDA authority to inspect clinical study sites, creating a pilot program on unannounced foreign facility inspections, enhancing transparency of drug facility inspection timelines, and introducing new reporting requirements, including a Government Accountability Office (GAO) report on FDA inspections of foreign establishments manufacturing drugs.

Finally, H.R. 7667 includes a number of transparency, program integrity, and regulatory improvements, including requiring sponsors of biologics and biosimilars to report to FDA on the marketing status of their products. It includes a number of provisions to improve post-approval studies and program integrity for accelerated approval drugs, ensure cybersecurity of medical devices, clarify the application process for exclusive approval of drugs for rare diseases, and facilitate the exchange of product information prior to approval. It also requires FDA to issue guidance on the use of real-world evidence. The bill also clarifies that FDA is authorized to ban a particular use of a medical device and that all contrast agents, radioactive drugs, and over-the-counter monograph drugs are drugs and not medical devices.

More specific information about H.R. 7667 can be found in the section-by-section summary released with the bill.[1] An amendment in the nature of a substitute (AINS) is expected to be offered to make technical amendments to the legislation.

II. H.R. 7666, THE "RESTORING HOPE FOR MENTAL HEALTH AND WELL-BEING ACT OF 2022"

Reps. Pallone and Rodgers introduced H.R. 7666 on May 6, 2022. The legislation establishes a Behavioral Health Crisis Coordinating Office within the Substance Abuse and Mental Health Services Administration (SAMHSA) funded at $5 million annually for FY 2023 through FY 2027, establishes a Mental Health Crisis Response Partnership Pilot Program funded at $10 million annually for FY 2023 through FY 2027, and requires the Secretary of the Department of Health and Human Services (HHS) to establish standards for a continuum of care for use by health care providers and communities.

H.R. 7666 reauthorizes grants available through the Health Resources and Services Administration (HRSA) to establish, improve, or maintain programs for maternal mental health and substance use disorder screening, brief intervention, and treatment services for women who are postpartum, pregnant, or have given birth within the preceding 12 months and authorizes $24 million annually for FY 2023 through FY 2028 for such programs. It also reauthorizes seven SAMHSA programs to address mental health needs and prevent suicide among adults for FY 2023 through FY 2027. H.R. 7666 also establishes an authorization for the SAMHSA National Center of Excellence for Eating Disorders and authorizes it at $1 million annually for FY 2023 through FY 2027.

The legislation also reauthorizes the Community Mental Health Services Block Grants (MHBG) to states, territories, Tribes, and Tribal organizations to support community mental health services for adults with serious mental illness and children with serious emotional disturbance and to support the collection of performance and outcome data. The legislation requires five percent of the block grant funds be used for crisis-care services and allows for up to five percent of the funds to be used for early intervention activities. It authorizes $857.571 million annually for the MHBG for FY 2023 through FY 2027.

In addition, H.R. 7666 reauthorizes Section 506A of the Public Health Service Act (PHSA) and establishes funding to provide behavioral health and substance use disorder prevention, treatment and recovery services for American Indians and Alaska Natives modeled after the Special Diabetes Program for Indians. The legislation increases the existing funding level to $40 million and provides formula funding to Indian Tribes, Tribal organizations, and Urban Indian organizations.

H.R. 7666 also reauthorizes 11 SAMHSA programs that support mental health and substance use disorder prevention, treatment, and recovery services activities for FY 2023 through FY 2027. It also authorizes $5 million for the period of FY 2023 through 2027 for

[1] House Committee on Energy and Commerce, *The Food and Drug Amendments Section by Section Summary* (May 5, 2022) (energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Section%20by%20Section_The%20Food%20and%20Drug%20Amendments%20of%202022_5.4.2022.pdf).

SAMHSA to develop best practices and promote the availability of high-quality recovery housing for individuals with substance use disorders, award grants to states, tribal nations, territories, and localities to implement national recovery housing best practices, and authorizes $1.5 million for FY 2023 for the National Academies of Sciences, Engineering, and Medicine to conduct a related study of recovery housing best practices. The legislation also reauthorizes and renames SAMHSA's Substance Use Prevention, Treatment, Recovery Block Grant that provides states and Tribes with funding to plan, carry out, and evaluate substance use disorder prevention, treatment, and recovery support services, and authorizes $1.908 billion annually for the program for FY 2023 through FY 2027.

The legislation directs SAMHSA to assess flexibilities granted to Opioid Treatment Programs (OTP) during the COVID-19 public health emergency and increase access to substance use disorder services. Specifically, the legislation requires SAMHSA to issue a final rule that eliminates the requirement for patients to have an opioid use disorder for at least one year before being admitted for treatment by an OTP. It codifies Drug Enforcement Administration (DEA) regulations that allow OTPs to incorporate mobile medication units without a separate registration to provide maintenance treatment or detoxification treatment. It also requires SAMHSA to issue a final regulation on medication take-home requirements for patients who qualify for unsupervised treatment services.

H.R. 7666 amends Section 520K of the PHSA by reauthorizing a program that allows HHS to award grants to states that partner with a community program, a health center, or a primary health care physician practice to implement and evaluate evidence-based models of integrated behavioral health care services. The bill also provides grants to establish national and regional Technical Assistance Centers to help primary care practices implement the collaborative care model in their practices and authorizes $60 million annually for FY 2023 through FY 2027 for these purposes.

The legislation reauthorizes several key behavioral training and workforce programs at HRSA as well as extends the volunteer health professional liability protections at health centers for an additional five years through October 21, 2027. H.R. 7666 also requires self-funded, non-federal governmental plans to comply with mental health parity requirements.

H.R. 7666 reauthorizes HRSA's Pediatric Mental Health Care Access grant program that promotes behavioral health integration into pediatric primary care by supporting pediatric mental health care telehealth access programs in states at $14 million annually for FY 2023 through FY 2025 and $30 million annually for FY 2026 through FY 2027. It reauthorizes SAMHSA's Infant and Early Childhood Mental Health Grant Program, which is intended to improve outcomes for children from birth to age 12 by developing, maintaining, or enhancing mental health promotion, intervention, and treatment services, at $50 million for the period of FY 2023 through FY 2027. The legislation reauthorizes the Comprehensive Community Mental Health Services for Children with Serious Emotional Disturbances Grants at $125 million annually for FY 2023 through FY 2027 and the Enhancement and Expansion of Treatment and Recovery Services for Adolescents, Transitional Aged Youth, and their Families (Youth and Family TREE) at $29.605 million annually for FY 2023 through FY 2027. Finally, the legislation reauthorizes four SAMHSA

programs that support adolescent and young adult mental and behavioral health for FY 2023 through FY 2027.

More specific information about H.R. 7666 can be found in the section-by-section summary released with the bill.[2]

III. H.R. 7233, THE "KEEPING INCARCERATION DISCHARGES STREAMLINED FOR CHILDREN AND ACCOMODATING RESOURCES IN EDUCATION ACT" (KIDS CARES ACT)

Reps. Hudson (R-NC) and Kuster (D-NH) introduced H.R. 7233 on March 28, 2022. The legislation requires state Medicaid programs to have in place medical and behavioral health screenings for eligible juveniles upon their release from incarceration. The legislation would permit states to conduct such screenings before their release. It would also direct the Centers for Medicare & Medicaid Services to update its Medicaid school-based administrative claiming guide to help states submit claims for reimbursement for Medicaid-eligible services furnished in schools.

An AINS to make technical changes and additional amendments are expected to be offered.

IV. H.R. 623, THE "GABRIELLA MILLER KIDS FIRST RESEARCH ACT 2.0"

Rep. Wexton (D-VA) and 17 original cosponsors introduced H.R. 623 on January 28, 2021. The legislation reauthorizes the Gabriella Miller Kids First Pediatric Research Program (Kids First) program for an additional five years and increases the funding authorization to $25 million annually.

An AINS is expected to be offered to make technical amendments to the legislation.

V. H.R. 3771, THE "SOUTH ASIAN HEART HEALTH AWARENESS ACT OF 2021"

Rep. Jayapal (D-WA) and 19 other original cosponsors introduced H.R. 3771 on June 8, 2021. The legislation authorizes the Secretary of HHS to award grants to states for the purpose of promoting awareness of the increasing prevalence of heart disease, including when appropriate, its relationship to type 2 diabetes in communities disproportionately affected by heart disease such as South Asian communities in the United States. It authorizes $1 million annually for FY 2023 through FY 2027 for these purposes. In addition, the legislation calls on the Secretary to conduct or advance research and related activities regarding cardiovascular disease and type 2 diabetes among at-risk populations, including South Asian communities in the United States, and to establish an internet clearinghouse to catalog existing evidence-based heart

[2] House Committee on Energy and Commerce, *The Restoring Hope for Mental Health and Well-Being Act of 2022 Section-by-Section* (May 5, 2022) (https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Section%20by%20Section_HE_Restoring%20Hope%20for%20Mental%20Health%20and%20Well-Being%20Act%20of%202022_Final.pdf).

health research and treatment options for communities disproportionately affected by heart disease. The legislation authorizes $1 million annually for FY 2023 through FY 2027 for these purposes.

A manager's amendment will be offered to make clarifying edits to the legislation.

VI. H.R. 5585, THE "ADVANCED RESEARCH PROJECT AGENCY-HEALTH ACT"

Rep. Eshoo introduced H.R. 5585 on October 15, 2021. The legislation authorizes the Advanced Research Projects Agency for Health (ARPA-H) within HHS to accelerate innovation in health and medicine by investing in high-risk, high-reward research projects. It establishes the goals and methods for the new agency; defines the role and authorities of the director and program managers; creates a research council; and authorizes hiring, awards, cooperative agreements, and other transactions, among other authorities. The bill authorizes $3 billion in funding for FY 2022 to be available until expended for ARPA-H.