



MEMORANDUM

May 16, 2022

To: Committee on Energy and Commerce Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Full Committee Markup of Six Health Bills

On Wednesday, May 18, 2022, at 10 a.m. (EDT) in the John D. Dingell Room, 2123 of the Rayburn House Office Building, and via Cisco Webex online video conferencing, the Committee on Energy and Commerce 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. Please refer to the memo¹ for the Subcommittee on Health’s markup on May 11, 2022, and to the section-by-section summary² released with the bill for more information.

On May 11, 2022, the Subcommittee on Health favorably forwarded H.R. 7667, amended, to the full Committee by a roll call vote of 30 yeas to 0 nays.

An amendment in the nature of a substitute (AINS) is expected to be offered to HR 7667. In addition to making technical changes, the AINS will include new provisions that would allow for a process by which sponsors of certain tests covered by emergency use authorization may

¹ House Committee on Energy and Commerce, Memorandum from Committee on Energy and Commerce Staff to the Subcommittee on Health Members and Staff (May 9, 2022) (energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Briefing%20Memo_HE%20Markup_2022.05.11.pdf).

² 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).

submit an application for approval concurrent with an application for a Clinical Laboratory Improvement Amendments (CLIA) waiver. The AINS will also extend FDA workforce enhancements included in the 21st Century Cures Act to additional areas in the agency.

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 reauthorizes mental health and substance use disorder programs at the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Health Resources and Services Administration (HRSA) for the purposes of addressing substance use disorder (SUD) and improving Americans’ mental health. Please refer to the memo³ for the Subcommittee on Health’s markup on May 11, 2022, and to the section-by-section summary⁴ released with the bill for more information.

On May 11, 2022, the Subcommittee on Health favorably forwarded H.R. 7666 to the full Committee, without amendment, by a roll call vote of 32 yeas to 0 nays.

An AINS is expected to be offered to H.R. 7666, which makes clarifying and technical changes to the underlying bill. In addition, the AINS includes provisions drawn from H.R. 7681, the “Preventing Overdoses and Saving Lives Act 2.0,” which support the development of strategic opioid crisis response plans and requires health care practitioners to prescribe an opioid reversal drug when also prescribing an opioid for certain patients. Amendments reflecting H.R. 1384, the “Mainstreaming Addiction Treatment (MAT) Act of 2021,” H.R. 2067, the “Medication Access and Training Expansion (MATE) Act of 2021,” H.R. 2929, the “Virtual Peer Support Act of 2021,” and an amended version of section 401 of H.R. 7232, the “9-8-8 and Parity Assistance Act of 2022,” are also expected to be offered.

III. H.R. 7233, THE “KEEPING INCARCERATION DISCHARGES STREAMLINED FOR CHILDREN AND ACCOMODATING RESOURCES IN EDUCATION (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. It would also direct the Centers for Medicare & Medicaid Services (CMS) to update its Medicaid school-based administrative claiming guide to help states submit claims for reimbursement for Medicaid-eligible services furnished in schools.

³ See note 1.

⁴ House Committee on Energy and Commerce, *The Restoring Hope for Mental Health and Well-Being Act of 2022 Section-by-Section* (May 5, 2022) (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).

On May 11, 2022, the Subcommittee on Health favorably forwarded H.R. 7233 to the full Committee, amended, by a roll call vote of 32 yeas to 0 nays.

An AINS is expected to be offered that would make technical corrections to the bill, as well as add a provision that would give states the option to continue to receive federal Medicaid funds to cover eligible juveniles who are being held in pre-trial detention.

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.

On May 11, 2022, the Subcommittee on Health favorably forwarded H.R. 623 to the full Committee, amended, by a voice vote.

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

Rep. Jayapal (D-WA) and 19 original cosponsors introduced H.R. 3771 on June 8, 2021. The legislation authorizes the Secretary of Health and Human Services (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.

On May 11, 2022, the Subcommittee on Health favorably forwarded H.R. 3771 to the full Committee, amended, by a voice vote.

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 fiscal year 2022 to be available until expended for ARPA-H.

On May 11, 2022, the Subcommittee on Health favorably forwarded H.R. 5585 to the full Committee, without amendment, by a voice vote.

An AINS is expected to be offered to make amendments to the legislation. These amendments would establish an independent ARPA-H within HHS; identify the goals and activities of the new agency; appoint a director with relevant duties and authorities; allow for

coordination with other federal agencies and external stakeholders; authorize personnel hiring, including program managers to lead ARPA-H projects; require milestone evaluation, reporting, and independent review; coalesce an ARPA-H Interagency Research Council; and authorize \$500 million annually for five fiscal years.