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## **House Energy & Commerce Health Subcommittee Advances Bipartisan User Fee, Mental Health and Research Bills to Full Committee**

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On Wednesday (May 11), the House Energy & Commerce Subcommittee on Health advanced six bipartisan health care bills to the full House Energy & Commerce Committee. Committee leaders expressed strong support for the bills and the importance of passing legislation to reauthorize the Food and Drug Administration's (FDA) user fee agreements, the Food and Drug Amendments of 2022 (H.R. 7667), before the current user fee agreements expire on Sept. 30. Committee Chair Frank Pallone (D-NJ) noted that while CURES 2.0 was not included in the markup, the committee was able to make progress on key priorities -- such as the Advanced Research Project Agency-Health Act, or the ARPA-H Act, (H.R. 5585) -- and that the committee will work to advance the rest of CURES 2.0 on a bipartisan basis.

Committee leaders also expressed their support for legislation to support mental health care and substance use disorders -- the Restoring Hope for Mental Health and Well-Being Act of 2022 (H.R. 7666) and the Keeping Incarceration Discharges Streamlined for Children and Accommodating Resources in Education Act, also known as the KIDS CARES Act, (H.R. 7233) -- with Subcommittee Chair Anna Eshoo (D-CA) noting the need to improve mental health screening for children in schools and Subcommittee Ranking Member Brett Guthrie (R-KY) discussing the impact of fentanyl overdoses on the country. Subcommittee Chair Eshoo (D-CA) also praised the committee's work on the South Asian Heart Health Awareness Act of 2021 (H.R. 3771) and Gabriella Miller Kids First Research Act 2.0 (H.R. 623).

- For more information: <https://energycommerce.house.gov/committee-activity/markups/markup-of-6-bills-subcommittee-on-health-may-11-2022>

### **Mark-up details**

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#### **H.R. 7667, the Food and Drug Amendments of 2022**

The bill would reauthorize FDA's drug and medical device user fee programs, which are set to expire on Sept. 30. In addition to setting new industry fees and hiring and review goals for the FDA, the bill also includes a number of policies to increase access to lower-cost generic drugs, bolster the FDA's authority to remove accelerated approval drugs from the market if they fail to show a clinical benefit or conduct required post-market studies, improve diversity in clinical trials, increase access to therapies and treatments for rare diseases, and improve the FDA's use of real-world evidence and patient feedback in its decision making.

During the markup, both subcommittee members praised the quick, bipartisan nature of the legislation. However, lawmakers from both sides of the aisle noted concerns they would like addressed in full committee. For example, Subcommittee Ranking Member Guthrie cited concerns about the bill's changes to regulating certain products as drugs; Rep. Kathy Castor (D-FL) said the bill could do more to ensure pregnant and lactating people are not left out of clinical research; Rep. Debbie Dingell (D-MI) said more must be done to improve post-market surveillance of medical devices; Rep. G. K. Butterfield (D-NC) urged committee members to include a bill to accelerate drugs for pediatric cancer patients, the Give Kids a Chance Act (H.R. 5416); Rep. Gus Bilirakis (R-FL) expressed disappointment the legislation does not include the Speeding Therapy Access Today Act (H.R. 1730); Rep. Larry

Bucshon (R-WI) expressed disappointment that the bill leaves out the VALID Act and suggested committee members clarify language on generic drug labelling for sponsors with pending applications; and several committee members discussed the need to clarify the definitions of remanufacturing and servicing in relation to medical devices.

Ultimately, the subcommittee voted 30-0 to advance the bill with an amendment in the nature of a substitute (AINS) offered by Subcommittee Chair Eshoo advancing, which made technical changes to the bill. Three other amendments were withdrawn.

#### **H.R. 7666, the Restoring Hope for Mental Health and Well-Being Act of 2022**

The bill reauthorizes more than 30 programs from Substance Abuse and Mental Health Services Administration (SAMHSA) and Health Resources and Services Administration (HRSA) to support mental health and substance use disorder care across the country, establishes a Behavioral Health Crisis Coordinating Office within SAMHSA, includes language to require self-funded health plans to comply with mental health parity laws, and provides funding for the 988 suicide prevention lifeline set to launch this summer.

During the markup, both bipartisan subcommittee members expressed support for the bill and its efforts to address the nation's mental health and substance use disorder crises. A few members noted the importance of building on these efforts. For example, Rep. Burgess called on the Biden administration to improve security at the Southern border to reduce the amount of fentanyl entering the United States and Rep. Lisa Blunt Rochester (D-DE) emphasized the importance of supporting programs that support the full spectrum of care to support the mental health needs of all children.

Ultimately, the subcommittee voted 32-0 to advance the bill to the full committee.

#### **H.R. 7233, the Keeping Incarceration Discharges Streamlined for Children and Accommodating Resources in Education Act (KIDS CARES Act)**

The bill would require Medicaid plans to cover health screenings and referrals for certain incarcerated children and require the Health and Human Services (HHS) Secretary to issue guidance on how Medicaid and the Children's Health Insurance Program (CHIP) can support health care and mental health care service delivery in schools.

During the markup, several subcommittee members offered amendments, including Rep. Richard Hudson (R-NC), Subcommittee Chair Eshoo, and Reps. Rochester and Burgess. The subcommittee voted by voice to adopt three amendments: An AINS from Rep. Hudson, which made technical changes; an amendment from Rep. Eshoo to instruct the HHS Secretary to issue guidance to states on how to expand behavioral health services under State plans; and an amendment from Rep. Rochester to instruct the HHS Secretary to update guidance to states to overcome barriers and increase access to telehealth under Medicaid and CHIP. Three amendments from Rep. Burgess were withdrawn.

Ultimately, the subcommittee voted 32-0 to advance the amended bill to the full committee.

#### **H.R. 623, the Gabriella Miller Kids First Research Act 2.0**

The bill would provide a new funding stream for the National Institutes of Health (NIH) to support research on pediatric diseases and disorders. The subcommittee adopted by voice vote an AINS by Rep. Castor.

Ultimately, the subcommittee advanced the amended bill to the full committee by voice vote.

#### **H.R. 3771, the South Asian Heart Health Awareness Act of 2021**

The bill would amend the Public Health Service Act to support research and improvement of cardiovascular health among the South Asian and other populations diversely impacted by cardiovascular disease. During the hearing,

Ranking member Guthrie expressed concerns about provisions in the bill and asked that those be addressed in the full committee.

The subcommittee adopted by voice vote a manager's amendment from Committee Chair Pallone to make clarifying edits to the legislation, and ultimately advanced the amended bill by voice vote to the full committee.

#### **H.R. 5585, the Advanced Research Project Agency-Health Act (ARPA-H Act)**

The bill establishes ARPA-H as an independent agency within NIH with an initial authorization of \$3 billion for FY 2022. During the hearing, Rep. Rodgers raised concerns about the new agency being duplicative of existing efforts.

Ultimately, the subcommittee by voice vote advanced the measure to the full committee.

*If you have questions, please contact [Heather Meade](#) or [Heather Bell](#).*

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