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HIF131140

MARKUP ON:

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 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 ARPA-H ACT

WEDNESDAY, MAY 11, 2022

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:19 a.m. in the John D. Dingell Room, 2123 of the Rayburn House Office Building, Hon. Anna Eshoo [chairwoman of the subcommittee], presiding.

Present: Representatives Eshoo, Butterfield, Matsui, Castor, Sarbanes, Welch, Schrader, Cardenas, Ruiz, Dingell, Kuster, Kelly, Barragan, Blunt Rochester, Craig, Schrier, Trahan, Fletcher, Pallone (ex officio); Guthrie, Upton,

Burgess, Griffith, Bilirakis, Long, Bucshon, Mullin, Hudson, Carter, Dunn, Curtis, Crenshaw, Joyce, and Rodgers (ex officio).

Staff Present: Lydia Abma, Fellow; Vincent Amatrudo FDA Detailee; Shana Beavin, Professional Staff Member; Jesseca Boyer, Professional Staff Member; Tania Calle, Fellow; Waverly Gordon, Deputy Staff Director and General Counsel; Tiffany Guarascio, Staff Director; Perry Hamilton, Clerk; Stephen Holland, Senior Health Counsel; Zach Kahan, Deputy Director Outreach and Member Service; Saha Khaterzai, Professional Staff Member; Una Lee, Chief Health Counsel; Aisling McDonough, Policy Coordinator; Meghan Mullon, Policy Analyst; Juan Negrete, Junior Professional Staff Member; Chloe Rodriguez, Clerk; Kylea Rogers, Staff Assistant; Rick Van Buren, Health Counsel; Charlton Wilson, Fellow; Caroline Wood, Staff Assistant; C.J. Young, Deputy Communications Director; Alec Aramanda, Minority Professional Staff Member, Health; Kate Arey, Minority Content Manager and Digital Assistant; Sarah Burke, Minority Deputy Staff Director; William Clutterbuck, Minority Assistant/Policy Analyst; Theresa Gambo, Minority Financial and Office Administrator; Seth Gold, Minority Professional Staff Member, Health; Grace Graham, Minority Chief Counsel, Health; Jack Heretik, Minority Press Secretary; Nate Hodson, Minority Staff

Director; Sean Kelly, Minority Press Secretary; Peter Kielty, Minority General Counsel; Emily King, Minority Member Services Director; Bijan Koohmaraie, Minority Chief Counsel, O&I Chief Counsel; Clare Paoletta, Minority Policy Analyst, Health; Kristin Seum, Minority Counsel, Health; Kristen Shatynski, Minority Professional Staff Member, Health; Olivia Shields, Minority Communications Director; Michael Taggart, Minority Policy Director; and Everett Winnick, Minority Director of Information Technology.

*Ms. Eshoo. Okay. Good morning, colleagues. Good morning, colleagues. I think that we have a quorum on the Democratic side; I think we have more that are online, but we are here today to mark up six bipartisan bills.

First is the Food and Drug Amendments of 2022, sponsored by myself and Mr. Guthrie.

Thank you, Mr. Guthrie.

This bill includes the user fee agreements for drugs and medical devices. So we are taking all of it up for reauthorization. It also includes rider legislation to speed the discovery of more cures, improve patient representation in clinical trials, and enhance the FDA's ability to fulfill their vital mission of ensuring the safety, efficacy, and quality of America's drugs and medical devices.

This package is an enormous legislative undertaking, and I fully appreciate the thoughtful work of subcommittee members on both sides of the aisle in putting forward their -- your ideas, and the committee staff for their work in drafting the bill.

One issue is that the bill clarifies congressional intent for FDA authority due to a few recent court rulings. These clarifications, I believe, should have gone through regular order and had a legislative hearing to avoid unintended consequences. For example, on the Genus decision the bill clarifies that contrast agents, radioactive drugs

and over-the-counter monograph drugs, should be treated as drugs, but left out ophthalmic products, eyedropper medications, which will now need to be treated as both drugs and devices because of the decision. This has to be reworked and corrected for the full committee markup.

The next bill is the Restoring Hope for Mental Health and Well-Being Act by Chairman Pallone and Ranking Member McMorris Rodgers. This legislation reauthorizes more than 30 important programs from SAMHSA and HRSA to supply more resources and support for mental health care and substance use disorder across the country.

We will also mark up the KIDS CARES Act from Representatives Hudson and Kuster to improve mental health screening for children in institutions and in schools under the Medicaid program. I support this common-sense and bipartisan mental health package.

I caution that our work to address the mental health crisis is not done with the bills we are taking up today. Just this week -- I don't know how many of you viewed it -- 60 Minutes and The New York Times had really rather jaw-dropping coverage, and exposed how suicidal teens are not getting the care they need. Hundreds sleep in emergency rooms each night awaiting the help they need.

So I urge my colleagues to come together to support 7236, my Strengthen Kids' Mental Health Now Act. This is

bipartisan, and it is comprehensive. It addresses the full-blown pediatric mental health crisis our constituents are facing.

Today we move the ARPA-H Act forward. This bipartisan bill, as I have stated to so many of you, is a top legislative priority for me, and it advances the Advanced Research Projects Agency of Health as an independent agency within HHS. ARPA-H will embody the nimble spirit of the highly regarded and successful DARPA model to pursue large-scale, high-risk projects. Our committee needs to pass the ARPA-H legislation to provide the agency with the authorities it needs to be successful from day one, including ensuring that it will be a nimble, dynamic, and independent agency, and that it will not be duplicative.

I am pleased that Republican leader -- and grateful -- that the Republican Leader Rodgers is working with me to amend the bill during the full committee's markup to ensure that the legislation creates a responsible agency with strict deliverables and clear lanes of authority, as I said, to avoid duplication in our Federal research programs.

Finally, we are marking up two important bills focused on medical research: first, the South Asian Heart Health Awareness and Research Act works to close health disparities in heart disease; and the other is the Gabriella Miller Kids First Research Act 2.0. We are honored to -- we were honored

to hear testimony about this bill from Gabriella's mother, Ellen Miller, as you will all recall last year. And I am very proud that we are making good on our promise to Ellen to move this important bill.

This markup is the culmination of months of work by members of this subcommittee. So bravo to each one of you. I think that today we have crafted a set of bills that are worthy of the American people.

And with that the chair now recognizes the ranking member of our committee, Mr. Guthrie, for your opening statement.

*Mr. Guthrie. Thank you, Madam Chair, and today we are marking up bills that follow the legislative desires of a lot of us on our side of the aisle, and I know on your side, as well, increasing innovation in health care and fighting the rise of mental illness and substance abuse. And so I appreciate us working together, Madam Chair, and particularly your staff working with our staff. They have done a wonderful job being able to bring this to where we can -- close to having all these where we are -- bipartisan support. So we appreciate that.

H.R. 7667, the FDA Act of 2022, introduced by the chair and myself, along with leaders of the full committee, will reauthorize the user fee program at the FDA through 2027. The legislation will specifically promote lower drug costs,

while incentivizing biopharmaceutical innovation and protecting access to lifesaving therapies.

This legislative package also includes policies that promote the use of Real-World Evidence, protect access to accelerated approval pathway, and encourage greater transparency in the biologics marketplace to ensure patients have access to these critical and cost-effective therapies.

Our supply chain would also be more reliable and secure under this package through policies that promote the use of cutting-edge advanced manufacturing technologies. This will help reduce our dependance on foreign nations like China for our prescription drug needs in the United States, and ensure therapies are able to reach patients as quickly as possible.

And finally, the user fee agreement includes my legislation, the Pre-Approval Information Exchange Act, which would codify the 2018 FDA guidance, permitting information exchanges between product sponsors and payers by permitting the exchange of certain product information before the FDA approves the product or new uses of an approved product. Patients would ultimately be able to access breakthrough therapies more quickly once these products are approved by the FDA.

Combating substance use disorder is another core focus of today's hearing. Last year we saw the highest over-the-year increase in drug overdoses in the nation's history, a

majority of which were illicit fentanyl. That is why H.R. 7666, Restoring Hope for Mental Health and Well-Being Act, before us today is so important. This legislative package will enhance our behavioral health care workforce, bolster treatment and recovery resources to those seeking help to overcome their substance use disorder, and help our youth struggle with mental illness.

The package includes my legislation, the Substance Use Prevention, Treatment, and Recovery Support Services Act, and I thank Representatives Tonko, McKinley, and Wild for working on this reauthorization of this critical program, all of us working together. This would provide continued funding to states through 2027 to address the overdose epidemic by providing resources for prevention, treatment, and recovery services such as workforce training and peer support services.

I recently heard just how pervasive drug trafficking is in our communities, and specifically illicit fentanyl trafficking. During an addiction roundtable I held last week, our law enforcement partners expressed frustration with the inconsistency in which drug crimes are prosecuted. They specifically expressed frustrations about the current temporary scheduling of fentanyl analogues. And should the temporary scheduling expire, it would be more difficult and challenging to prosecute the criminals running these drug

enterprises, both domestically and abroad. And Congress must act to permanently place these dangerous substances in schedule I.

The family members impacted by illicit fentanyl overdoses that participated in the roundtable agreed with this assessment, and even called for stricter penalties against those trafficking these poisons into the United States. Family members also highlighted the real need for continued access to comprehensive treatment and recovery support services at the level -- at the local level, with real emphasis on the need for more flexibility in how funds are spent.

A two-pronged approach to combating substance use disorder, as outlined above, is undoubtedly needed. However, I am concerned that yet we are again failing to take a bipartisan vote on the HALT Fentanyl Act, which would be an essential step to getting illicit fentanyl off our streets and reversing this alarming drug overdose trend.

I am also concerned that we are missing an opportunity to better understand the toll COVID-19 lockdowns had on the mental health of our children and those dealing with substance use disorder who went months without critical in-person support services. I urge my colleagues to work with me on studying this issue more closely, and identifying policy solutions to help those in need resulting from these

ineffective lockdowns.

I would ultimately urge my colleagues to support the Restoring Hope for Mental Health and Well-Being Act. This legislation will ensure individuals seeking help overcoming substance use disorder or those battling mental illnesses can receive needed care as quickly as possible.

I look forward to advancing many of these important proposals before us today, and I yield back.

*Ms. Eshoo. Thank you, Mr. Guthrie. The Chair is now pleased to recognize the chairman of the full committee, Mr. Pallone, for his opening statement.

*The Chairman. Thank you, Chairwoman Eshoo. After months of work to craft legislation to reauthorize and improve programs at the FDA, improve our nation's response to mental health and substance use disorder, and authorize President Biden's groundbreaking ARPA-H initiative, I am pleased that members of the committee are coming together across party lines to find a bipartisan path forward today. This is what the committee does best: coming together to move legislation to address the nation's needs.

And we begin this markup by examining the bipartisan Food and Drug Amendments of 2022, introduced by Chairwoman Eshoo and Ranking Member Guthrie. This legislation would reauthorize FDA's user fee programs, which are critically important to ensure the agency has the funding it needs so

that Americans can continue to trust that the drugs and medical devices they use are safe and effective.

This comprehensive package also includes important provisions that will help lower drug costs for the American people by promoting competition for generic drugs. It helps bolster diversity in clinical trials, so that historically under-represented populations are included in trials. It also ensures a safe supply chain through enhanced inspection authorities. And it improves program integrity at the agency, including improvements to the accelerated approval program.

I wanted to mention to Congresswoman DeGette and Congressman Upton that, while Cures 2.0 was not noticed as part of today's markup, I am pleased to say that we have made progress on several of the priorities included in that bill, and the Food and Drug Amendments legislation we are considering today includes provisions on shared priorities such as advancing Real-World Evidence, developing endpoints for rare diseases, and increasing diversity in clinical trials. So these are some of the provisions in Cures, but we are going to continue to seek technical assistance from the Administration, and work on a bipartisan basis to advance the rest of the Cures 2.0 legislation.

We simply cannot delay in advancing this FDA bill. As we heard from FDA and other stakeholders during our hearings,

failure to pass these agreements would be detrimental to the agency's mission. It could lead to mass layoffs at the agency, and setback medical product development and innovation. So I look forward to advancing the bill, and continue to work with my colleagues on additional improvements that can be made before we markup in full committee. It is critical that we continue to move forward so that we can get a final bill to the President's desk by August.

Now, we are also moving on another critical bipartisan bill, a package that will continue our efforts to combat our nation's mental health and substance use disorder crisis. The COVID-19 pandemic has heightened the need for high-quality mental care -- mental health care and substance use disorder treatment across the country. So myself and Ranking Member Rodgers were able to come to a bipartisan agreement on a package that includes so many provisions from members of the committee on both sides of the aisle, both on mental health and also dealing with opioids.

The Restoring Hope for Mental Health and Well-Being Act aims to help those in need by providing access to critical mental health and substance use disorder support. The bill reauthorizes more than 30 programs set to expire this September. These programs support mental health awareness, education, and prevention initiatives, care and crisis

services, and workforce training. The programs target those in greatest need, with interventions for children and young adults, those living in rural areas, tribal communities, and individuals experiencing housing insecurity. This bill strengthens our mental health parity laws so that more people have access to these critical services.

Now, there are two pieces of legislation that are not in this package that I would like to mention: the MAT Act and the MADE Act. These bills would provide critical tools in addressing the devastating opioid and substance use crisis by removing barriers to medication-assisted treatment. And they would also provide eligible practitioners with important training and education on treating and identifying substance use disorders.

I hope to keep working on these critical pieces of legislation with my Republican colleagues, so that we can reach agreement on these and include them in full committee.

The subcommittee is also going to vote on the bipartisan Keeping Incarcerated Discharges Streamlined for Children and Accommodating Resource in Education Act, led by Representatives Hudson and Kuster; the Gabriella Miller Kids First Research Act 2.0 from Representatives Wexton and Cole; and the South Asian Heart Health Awareness and Research Act from Representatives Jayapal and Fitzpatrick.

And finally, the subcommittee will vote on the Advanced

Research Project Agency Health Act, or ARPA-H, as ably led by Chairwoman Eshoo. This bill will authorize an independent ARPA-H that accelerates biomedical innovation in order to make transformative breakthroughs on how we detect and treat the deadliest diseases affecting Americans.

So all six of these bills have bipartisan support. I look forward to advancing them to the full committee.

I want to again thank our Ranking Member Rodgers for working so closely with us to make this bipartisan markup a reality.

And with that, I yield back to Chairwoman Eshoo.

*Ms. Eshoo. Thank you, Mr. Chairman. And I just want to add that it is -- let me put it this way -- music to my ears that some of the policies in Cures 2.0 are going to be taken up today.

But your commitment to see the broader legislation be taken up -- yes, there is work being done, but your cooperation and that of the committee staff on both sides of the aisle -- this is legacy legislation, not only for the work that Mr. Upton has done, but as a follow-on on the highly successful and impactful Cures 1.0. So thank you for that, and we look for an early date for markup on that.

And with that, the chair now recognizes the gentlewoman from Washington State, the ranking member of our full committee, Mrs. Rodgers.

*Mrs. Rodgers. Thank you, Madam Chair. And as you said, this is an enormous legislative undertaking. I am grateful for your leadership as chair of this subcommittee, the chairman of the full committee, Mr. Pallone, as well as my colleagues on both sides of the aisle for tremendous work that has been done over the last few weeks to bring these bipartisan solutions forward today.

We are addressing the mental health crisis, ensuring America's leadership in medical innovation, honoring the rich history of this committee. We are taking urgent action to help communities provide lifesaving mental health care to people in need, especially our children and those suffering from severe mental illness.

Just this morning, CDC announced overdose deaths again rose to record levels in 2021: 108,000. Communities are overwhelmed by adolescent self-harm, attempted suicide, and children desperate for mental health.

On Monday, 60 Minutes featured children in crisis. I encourage everyone to watch. There is a story of Austin, a nine-year-old boy who struggled to cope when his school was closed and his parents were going through a divorce. He was socially isolated, didn't know where to turn, and slipped into depression. When he confessed suicidal thoughts to his mom, they faced a long waiting lists and no beds for the care he needed. Cases like Austin's can't be ignored. Parents

are talking about this everywhere I go.

The Restoring Hope for Mental Health and Well-Being Act is the most comprehensive effort to date to revive hope and healing since COVID-19 and the policies that were put in place, including shutdowns, that added to the enormous mental health and overdose crisis in America. It includes many bipartisan solutions, and to -- including my own legislation to reauthorize the Garrett Lee Smith Memorial Act, which supports community-based youth and young adult suicide prevention programs.

Our work cannot end here. We must build on it, and do everything that we can to turn despair into hope for people and their families again.

In addition to mental health, I am pleased that we are delivering a comprehensive and bipartisan package to reauthorize the FDA user fee agreements. The FDA Act of 2022, H.R. 7667, includes provisions to lower costs, spur more lifesaving innovation, secure our supply chains, and protect access to breakthrough drugs and therapies.

My Republican colleagues are leading on specific solutions to promote the use of cutting-edge health technologies to advance rare disease research. We are also leading to make FDA inspections of foreign and domestic manufacturing facilities more timely and dependable. And we are requiring FDA to provide an improved guidance on how

remote tools can be used to ensure more inclusive clinical tests.

Chairman Pallone and I also reached consensus on ways to preserve the promise and the hope of accelerated approval pathway, and what it brings to patients and their families, while ensuring studies require post-approval are conducted in a timely manner.

Thank you again, Chairman Pallone, Chair Eshoo, Ranking Member Guthrie, for all the hard work on this user fee package. We still have some work ahead to ensure these agreements are authorized on time, and I am committed to doing so.

Regarding ARPA-H, I have raised concerns about duplication, lack of accountability, unclear priorities, and mission. We all share the goal of making sure that the money for research is targeted and spent wisely for results and more cures. I have asked the chair, Chair Eshoo, for more time to work together to find a path forward. And I want to thank Chair Eshoo and Chairman Pallone that we have been working tirelessly, and keeping the lines of communication open, and I am hopeful that by next week we will have a substitute amendment, and be able to move a bipartisan bill.

To conclude, I want to thank again everyone for their hard work that has led to today's markup and next week's full committee markup. There is a lot to be proud of in these

bills.

And just to finish on ARPA-H, Chair Eshoo, I share the commitment to make sure that these funds are authorized for this new agency with a focus and a transparency and accountability.

There is a lot of bills in front of us today. It includes more than 40 ideas and solutions that were led by those of us on this side of the aisle. But -- both Republicans on and off the Energy and Commerce Committee that are included to advance in the FDA Act, as well as the mental health package. This is what is possible when we come together and do the hard work necessary to find a bipartisan agreement that is going to address important issues for our nation and, ultimately, improve people's lives.

Thank you, Madam Chair. I yield back.

*Ms. Eshoo. The gentlewoman yields back.

With four of us having made an opening statement, these are -- as each member has said, this is a huge and very important package. So I want to invite any other member that would want to seek recognition to make an opening statement and make time for it.

Yes, the gentlewoman from New Hampshire, Ms. Kuster.

*Ms. Kuster. Thank you so much, Chairwoman Eshoo --

*Ms. Eshoo. If you can hold it to three minutes, it would be great.

*Ms. Kuster. I will.

*Ms. Eshoo. Okay.

*Ms. Kuster. Characterizing our work today as six bills is quite an understatement. It includes comprehensive legislation on drug regulation, investing in biomedical research, and mental health and substance use disorder. It also includes my legislation to remove barriers in generic drug approvals, the Increasing Transparency in Generic Drug Applications Act.

The cost of prescription drugs is a near-constant concern when I speak with my constituents, and I am committed to bringing down the cost of prescription drugs so that folks in New Hampshire and across the country can afford their lifesaving medication. My legislation included in the Food and Drug Amendments Act today would bring lower cost generic drugs to market faster, so that Americans can pay less for their prescriptions and at the pharmacy counter. It is this type of common-sense legislation that we should all support and advance.

I am also pleased to see the commitment of this committee to turning the tide on the addiction and mental health crisis with the comprehensive Restoring Hope for Mental Health and Well-Being Act and my legislation with Congressman Hudson, the KIDS CARES Act. This bill is a critical step to addressing serious gaps in our mental health

and criminal justice system by allowing Medicaid mental health screenings for incarcerated children.

By meeting children where they are and ensuring they have adequate care, we can give them a chance and end the vicious cycle of recidivism.

Thank you, Chairwoman Eshoo. I yield -- for including this legislation, and I yield back.

*Ms. Eshoo. The gentlewoman yields back. It is my understanding that Dr. Joyce would like to be recognized.

*Mr. Joyce. Yes, Madam Speaker.

*Ms. Eshoo. Speaker? My goodness.

[Laughter.]

*Ms. Eshoo. I don't want the job.

*Mr. Joyce. You caught me off guard there.

*Ms. Eshoo. Let's just have that on the record, no thank you.

*Mr. Joyce. Madam Chair --

*Ms. Eshoo. No, thank you, but thank you for the compliment.

[Laughter.]

*Mr. Joyce. Thank you, Madam Chair. Thanks for yielding, and thanks for having a sense of humor on this day. But it is an important day. It is important legislation that we are marking up. And briefly, I would like to highlight two of the bills before us today.

First, H.R. 7667, the user fee reauthorization, which addresses safe and prompt approval of new drugs, biologics, generics, and biosimilars that are critical to health of all of our constituents. Reauthorizing these agreements before us today on time will be critical as we seek to continue the innovation that we have seen in this space, innovation that Americans have come to expect, innovation that leads to cures.

To that end, I would like to thank the committee leadership for including H.R. 6988, the Drug Manufacturing Innovation Act, which builds on the FDA's emerging technology program, which seeks to speed the approval of drugs made using novel manufacturing technologies by providing more regulatory certainty for the drug sponsors. The use of these new technologies will ultimately lower costs for patients and address future supply chain issues.

I would also like to thank Representative Levin for working with me on this issue.

Second, I would like to commend both Chair Pallone and Ranking Member McMorris Rodgers for H.R. 7666, the Restoring Hope for Mental Health and Well-Being Act, which is truly comprehensive medicine, and a comprehensive package that will reauthorize key programs at the Substance Abuse and Mental Health Services Administration and the HSA.

This bill will begin to get at the mental health crisis

that was created in many American communities due to the response to COVID-19 during lockdowns and unnecessary, prolonged school closures. Children and pediatric populations have been particularly impacted by this crisis.

And I thank the committee for including H.R. 7248, the Controlling Systems of Care for Children Act, which I introduced with Representative Sarbanes, that will reauthorize two crucial programs, one aimed at providing children and their families better access to mental health care support services, and to expand comprehensive treatment and recovery services. I look forward to the committee moving these bills forward and continuing to work next week at our full committee meeting.

And with that, I yield back, Madam Chair. Thank you.

*Ms. Eshoo. Thank you, Dr. Joyce. The chair is pleased to recognize the gentlewoman from California, Ms. Matsui, for three minutes for an opening statement.

*Ms. Matsui. Thank you very much, Madam Chair. I am really pleased that this subcommittee was able to reach agreements on several of our most important priorities, including legislation to invest in mental health services, bolster public health, and safeguard drugs and biologics.

As we work to advance much-needed legislation that addresses our nation's mental health crisis, it is important that we keep a focus on strengthening system capacity and

addressing behavioral health workforce shortages. We need to put physical and mental health on equal footing once and for all, and advancing my Excellence in Mental Health and Addiction Expansion Act, H.R. 4323, is a step in the right direction.

This legislation, which I introduced with my colleague from Oklahoma, Representative Markwayne Mullin, would expand the availability of integrated, community-based programs. Critically, this legislation authorizes a SAMHSA line item for Certified Community Behavioral Health Clinic Expansion Grants. These SAMHSA grants helped establish hundreds of clinics that deliver 24/7 care to millions of Americans dealing with drug and mental health crises.

The results of the expansion grant program have been nothing short of outstanding. According to HHS reports, CCBHC participants showed a 72 percent decrease in mental health care hospitalization in the past 30 days, and a 69 percent decrease in emergency room visits. To date, these grants have provided 431 CCBHCs across the country with an opportunity to dramatically expand access to comprehensive and evidence-based mental health and addiction care by offering a wide array of integrated services.

As the legislation we are considering today moves to the floor, particularly the mental health package, I look forward to working with you, Representative Guthrie, Chairman

Pallone, and Ranking Member McMorris Rodgers to ensure that this valuable and innovative program receives a five-year authorization.

Thank you, Madam Chair, and I yield back.

*Ms. Eshoo. The gentlewoman yields back. Is there anyone that seeks to be recognized?

Okay, then we will begin. That concludes our opening statements. At this time the chair will begin -- we will begin bill consideration.

The chair calls up H.R. 7667, the Food and Drug Amendment of 2022, and the clerk will report the title of the bill, please.

*The Clerk. H.R. 7667, a bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user fee programs for prescription drugs --

*Ms. Eshoo. Without objection, the first reading of the bill will be dispensed with. The bill is now considered as read.

[The bill follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. I recognize myself to strike the last word and speak on the underlying bill.

I am so proud, along with Representatives Guthrie, Pallone, and McMorris Rodgers, to sponsor the strong, bipartisan FDA user fee bill. With today's markup we are on track to pass this bill through the House with plenty of time before the September 30th user fee deadline.

Our nation is an international leader for impressive biomedical innovation. But with that achievement comes an increasingly complex FDA review process for drugs and devices. Over the past few decades, the user fee agreements have evolved to make sure that the FDA has the resources necessary so that its reviews for drugs and devices are prompt, transparent, and predictable.

The agreements included in our bill are the latest evolution, and will, in total, provide FDA billions of dollars over the next five years, and will allow FDA to hire hundreds of new, full-time employees. I hope these resources will help the FDA recover from the pandemic, and pick up its regular day-to-day work even more effectively, including by more often meeting with drug sponsors face to face to discuss FDA feedback.

Beyond the user fee agreement, the bill includes several important legislative riders. It includes key portions of my DEPICT Act, which I introduced with Representatives Kelly and

Fitzpatrick. FDA data shows that, for the drugs approved in 2020, 75 percent of clinical trial participants were White. Only 8 percent of trial participants were African American, and 11 percent Hispanic. The DEPICT Act included in this overall bill will statutorily require drug companies to show how they will include diverse populations in their clinical trials by reporting to FDA a "Diversity Action Plan,'' with targets by demographic subgroups. As we heard from Dr. Mesa during our hearing, diverse clinical trials are not only fair and just; it is good science.

H.R. 7667 also includes important reforms to the FDA's inspections program, based on bills introduced by Representative Griffith and Welch, as well as myself and Representative Hudson. These provisions will help the FDA catch up from a two-year inspection backlog due to the pandemic, and conduct a pilot program of unannounced foreign inspections, something members on both sides of the aisle have raised over and over and over again.

The legislation also includes targeted reforms to improve the accelerated approval program, so that drugs approved under that program ultimately show their clinical effectiveness.

The bill reauthorizes the Best Pharmaceuticals for Children Act, which I first authored in 1997. It doesn't seem that long ago, but it is. Thanks to the BPCA and its

partner, the Pediatric Research Equity Act, or PREA, 900 drugs newly have pediatric use information. Last month the FDA said it is concerned that the orphan exemption under PREA may be limiting evidence-based data for drugs for children with rare diseases, which is something I hope our subcommittee can work to improve.

Overall, this is a very strong bill with many worthy, worthy reforms, and I, with confidence, call on colleagues on both sides of the aisle to move it forward to the full committee.

Okay, all right. Now -- yes.

*Voice. You now recognize Mr. Guthrie.

*Ms. Eshoo. Yes, the chair now is pleased to recognize the ranking member of the -- of our subcommittee to speak.

*Mr. Guthrie. Thank you, Madam Chair. I was seeking to move to strike the last word.

And I am proud, as well, for all the work that we put in together, and our staffs have put in together, as I said, because what this does is secures our supply chain, some areas that we saw earlier moving forward; it increases biopharmaceutical innovation, and it protects access to lifesaving therapies with clinically unmet -- diseases with clinically unmet needs. And most importantly, the user fee authorization package before us today will help to get more cures to the market sooner and at lower costs.

And I am happy to report that my bill, the Pre-Approval Information Exchange Act, is included in the base bill. This will help reduce the time in which patients wait for a drug or device to be covered by their insurer after it is approved by the Food and Drug Administration.

The PIE Act specifically builds off the important work the FDA did over the course of several years, and in partnership with industry leaders, to codify the guidance permitting the exchange of certain product information before an investigational product or investigational use of approved product is approved by the FDA. I look forward to work with my colleagues to get this provision signed into law.

Other important highlights include policies that promote greater use of Real-World Evidence of products granted Emergency Use Authorization by the FDA during the COVID-19 public health emergency that I know Dr. Burgess has worked very hard to champion. The collection of -- use of Real-World Evidence of products authorized under EUA could streamline the process when drug and device manufacturers are seeking full approval of their products from the FDA. It is critical that FDA provide further guidance on how this type of data can be appropriately used to get more products approved quickly.

The Manufacturing API Drugs and Excipients Act in America Act, or MADE in America Act, is also an important

piece to the FDA. I hear about this a lot when I am home. People say, "Why don't we manufacture more of our pharmaceuticals in America?'' This legislation will help reduce the drug shortages, and facilitate the use of advanced manufacturing technologies, promoting more domestic manufacturing and reducing our reliance on foreign nations for our pharmaceutical needs.

I do know that this is an iterative process, and this is just the first step to reauthorization of the user fee programs. While there are a lot of beneficial policies in this package, I know there are still some issues being worked out, and recognize this bill isn't perfect.

I would like to submit a letter for the record citing concerns about section 803 of the bill. I understand there are concerns about the policy, and especially because some of these were not discussed in the subcommittee until today. So I have a letter I would like to submit for the record.

Ultimately, for -- I look forward to working with my colleagues throughout the next week and months to ensure a bill gets signed into law that is -- ultimately promotes access to cures more quickly, at a lower cost, and encourages innovation.

Ultimately, I urge my colleagues to support this legislation, and I yield back.

*Ms. Eshoo. The gentleman yields back. Are there any

other members?

*Mrs. Rodgers. Madam Chair?

*Ms. Eshoo. Oh, I will -- we will accept the letter without objection, Mr. Guthrie.

[The information follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. Are there --

*Voice. Ms. Castor.

*Mrs. Rodgers. Madam Chair?

*Ms. Eshoo. Yes. The Chair recognizes the gentlewoman from Florida, Ms. Castor.

*Ms. Castor. Thank you, Madam Chair.

H.R. 7667 is a good, bipartisan bill. It is going to help our neighbors with access to safe and effective drugs and biologics and devices, and make sure -- it will ensure that the FDA has the tools and resources it needs to do its job.

The bill contains strong provisions addressing diversity and equity in the biopharmaceutical development process, but there is an important population that also must be considered in any effort to advance innovation, and that is pregnant and lactating people. Each year in the U.S., six million women become pregnant and more than three million initiate breastfeeding. Almost 90 percent of U.S. women will give birth during their lifetime.

And despite how common it is and how critical the pregnant and postpartum periods are for mothers and babies, there is very little information on the safety of therapeutics and vaccines in pregnancy, and even less on the safety for the baby while breastfeeding. And we saw this failure most recently with the COVID-19 vaccine, where

developers originally chose to exclude pregnant people from their trials, leading many who are at higher risk for severe illness or death from COVID-19 to forgo the protection of vaccines.

Now, prior to that, I was proud to sponsor legislation that was included in 21st Century Cures with Congresswoman Herrera Beutler that created the preg lac task force. That task force met, it issued 15 recommendations and a detailed implementation plan to ensure that we protect pregnant and lactating people through research and not from it.

Their number-one recommendation was to include and integrate pregnant and lactating people in the clinical research agenda by including -- by harmonizing FDA regulations with a common rule to remove pregnant women as a vulnerable population in research. And in January of 2019, HHS and other Federal agencies implemented these changes to the common rule regulations to protect human subjects in research, removing pregnant people as an example of a vulnerable population that requires additional ethical scrutiny prior to participating in research.

But the FDA has yet to act. And in our committee hearing in March I asked the witnesses how we could better include pregnant and lactating people in clinical trials and research. Both witnesses, one in industry and one in academia, stated that clear FDA guidance was needed, and they

recommended that FDA develop a framework.

The presumption that the use of medications throughout pregnancy and lactation is unhealthy is inaccurate in many cases, and it may actually endanger the health of mothers and children. And this danger applies to treatments for conditions arising directly from pregnancy, and even more so for the treatment of a multitude of conditions that occur in reproductive-aged women, whether pregnant, lactating, or neither.

So, Madam Chair, I hope you can commit to continuing to work with me to ensure that pregnant and lactating people have better access to safe and effective therapies. I hope you can do that today. Yes?

Thank you very much. And with that assurance, I will yield back my time.

*Ms. Eshoo. I thank the gentlewoman. The -- yes, the ranking member of our full committee, Mrs. Rodgers, is recognized.

*Mrs. Rodgers. Thank you, Madam Chair. I would like to strike the last word.

Today's markup will be the fourth opportunity for the Health Subcommittee to consider the reauthorization of several key user fee programs, as well as other critically important policies related to drug discovery, clinical trial diversity, and securing our nation's health care supply

chains.

As we have seen throughout the pandemic, and as we have heard from FDA and industry, process improvements are needed to ensure essential health supplies and new cures are getting to the American people in a timely and dependable manner. A number of provisions included in this package today will do just that.

Policies led by Representatives Griffith, Hudson, Eshoo, and Welch will strengthen FDA's inspection capabilities, and provide a more level playing field for domestic and overseas drug manufacturers. The COVID-19 pandemic revealed gaps in our global supply chains, most notably America's over-reliance on China for certain critical medical supplies. A top lesson from the pandemic is that we can no longer remain dependent on nations that are not our allies to deliver essential medicines to Americans.

I am encouraged to see provisions of the bipartisan MADE in America Act led by Representatives Carter and Soto included in today's bill, which will incentivize domestic manufacturing of drugs and active pharmaceutical ingredients.

I am also proud to see our committee working in a bipartisan fashion to make sure patients in the United States continue to have the earliest access to the majority of new drugs in the world. The enhancements to FDA's accelerated approval pathway included in this package build upon this

needed pathway, while maintaining FDA's standards of safety and efficacy. I am hopeful that future innovation can treat diseases before clinical symptoms appear, but that innovation would need a pathway like accelerated approval to clear the FDA.

The FDA Act of 2022 also better prepares the agency for all the exciting advances in cell and gene therapy potentially coming over the next few years. Potential cures for diseases like sickle cell and rare childhood diseases. Mr. Crenshaw has repeatedly raised the need for more scientific exchange when it comes to cellular products, and I am glad that we were able to address that in the legislation.

The FDA Act of 2022 also pushes FDA to embrace change and use novel ways to develop drugs instead of animal models we have relied on for decades.

Clinical trials too can be modernized, and FDA should use Real-World Evidence often in its decision-making.

We often hear concerns about the growing resistance to antibiotics. This bill makes improvements to the pathway at FDA that incentivizes more research and development for those hard-to-develop products.

And Mr. Bilirakis's tireless leadership for those with rare diseases can be seen throughout this legislation. Republicans have said that we are ready to work with Democrats to lower the cost of prescription drugs, and this

bill does that. The provisions improving the generic drug and biosimilar pathways at FDA will make sure more of these lower-cost options are approved.

And we are just starting to see what biosimilars can do in the market, and there are some exciting ones on the horizon. This bill helps ensure FDA has staff and resources to meet timelines for review of biosimilars such as insulin.

In addition to the user fee agreements themselves, Mr. Carter and Mr. Hudson each have bipartisan proposals to help speed generic drug access and provide more transparency around competition in biologics.

And Mr. Guthrie's provision will make sure companies can tell insurance companies about what innovation is coming with the goal of helping to facilitate faster inclusion on formularies and, therefore, faster access for patients to new innovation.

I am pleased that we were able to continue the tradition of reauthorizing these critical user fee programs with bipartisan support. A big thank you again to Ranking Member Guthrie, Chair Eshoo, Chair Pallone for working together, all of us, to address these issues. And I know not everyone gets everything that they want in a package like this, but there is a lot of wins, and I am looking forward to supporting it and moving it to full committee.

Thank you, Madam Chair.

*Ms. Eshoo. Wonderful. Thank you, Mrs. McMorris Rodgers.

The chair is pleased to recognize the gentlewoman from Michigan, Mrs. Dingell.

*Mrs. Dingell. Thank you, Madam Chair. I move to strike the last word.

Thank you, Chairman Eshoo and Ranking Member Guthrie, for including user fee reauthorization package in today's markup. And I would like to thank Chairman Pallone and Ranking Member McMorris Rodgers for their, as well as the majority and minority committee staffs', tireless efforts to build consensus around these important policies.

This is especially notable because Congress received the user fee commitment letter relating to medical devices in late March, approximately two months after the statutory deadline. These agreements will give FDA the funding and expertise needed to appropriately evaluate the safety and efficacy of cutting-edge medical products and therapies. They will enable the agency to provide timely evaluations, and review drug and device applications to ensure that -- patient access for potentially lifesaving new treatments and cures.

Additionally, the package incorporates bipartisan policies championed by members of this committee to promote diversity in clinical trials, and improve FDA inspections of

foreign facilities, among other provisions, all of which will help the FDA meet its mission and remain the gold standard for safety and efficacy in its approvals.

So I do support this -- I will support this package, but it is important to highlight one area -- post-market review of FDA-cleared and approved medical devices -- which we can and should improve, moving forward.

FDA relies on a variety of databases and reporting mechanisms for post-market surveillance of medical devices. However, too often, delays in reporting, inaccuracies in data, and gaps in active surveillance fail to catch adverse events caused by malfunctioning or faulty medical devices, which can lead to tragic consequences for patients.

Additionally, while device manufacturers are required to assign unique device identifiers to medical devices, their use in uptake in existing health systems is generally lacking, which limits their usefulness in post-market surveillance.

FDA has a robust post-market monitoring for drugs, and it is my hope that we are able to make improvements to address these shortcomings for medical devices, as well, as we are moving forward.

I would like to ask unanimous consent to enter into the record this letter I have sent to the Government Accountability Office requesting an evaluation of current

post-market surveillance of medical devices.

And with that --

*Ms. Eshoo. So ordered.

*Mrs. Dingell. Thank you --

*Ms. Eshoo. So ordered.

*Mrs. Dingell. -- Madam Chair.

[The information follows:]

**********COMMITTEE INSERT**********

*Mrs. Dingell. And with that said, while this important work remains, this is a very strong consensus-based user fee package before us today which deserves our support. I urge my colleagues to support this legislation, and to continue to work on the post-market surveillance issue with me, moving forward.

Thank you, and I yield back, Madam Chair.

*Ms. Eshoo. The gentlewoman yields back. The chair is pleased to recognize one of the doctors from our subcommittee, Dr. Burgess, for your five minutes.

*Mr. Burgess. And I thank the chair. And it has been my privilege on this -- serving on this committee to have been through a number of these reauthorizations of the Food and Drug Administration.

It is -- oh, I beg your pardon, I wish to be heard on the underlying bill.

We have this unique opportunity every five years on this reauthorization. It is unlike other Federal agencies, where an authorization can slip and we can do an extension. This one has to be done because of the presence of the user fee agreements that began back in 1992. So every five years we get a good opportunity to have a hard look at what is going on at the FDA, and members of this committee are allowed to further their input into those policies, and see if there is any way forward to stimulate innovation and modernize and

rebuild the FDA.

With this legislation today we found common ground on many great policies. There is a lot more work that could have been done, and there will be work ahead of us in -- before the next reauthorization comes up. But I can't help but feel that there are lessons we could learn from the previous pandemic -- the country has been through an enormous amount of travail with the coronavirus -- and the opportunities that are in front of us that were perhaps showcased by Operation Warp Speed, and things that we could do to speed up the regular order at the Food and Drug Administration. The nation's coronavirus response can provide a direction and insight into new policies, and how we combat future pandemics, and how health emergencies are conducted and, indeed, just in everyday life.

I am pleased to see the provisions in the FDA bill that -- the Advancing Collection for Transformative Science, the so-called FACTS Act, included in this underlying bill. The provisions would call for the FDA to issue guidance addressing the use of Real-World Evidence and real world data, including data obtained from drugs and devices authorized for an Emergency Use Authorization during a public health emergency.

This is important, because, as we all learned going through the time of the coronavirus, it was not infrequent

that we were hearing data that was developed in Israel that had an impact on the direction of our policy here in this country. But we were never hearing from the FDA itself about what they were encountering during the time of the allowance of an Emergency Use Authorization. So the FACTS Act will allow the FDA and, in fact, require the FDA to include Real-World Evidence during their evaluation during an Emergency Use Authorization.

To be sure, there are ways that we can benefit from applying this Real-World Evidence during a public health emergency. And, as we have learned over the past two years, we need to do everything in our power to be making more informed decisions when it comes to public health. One of the big casualties of the pandemic has been the loss of public trust in our public health institutions. And my belief is that the FACTS Act will allow us to reclaim some of that loss of faith that the public has had.

In addition, there is the Protecting and Transforming Cyber Health Care Act, the so-called PATCH Act, that would implement cybersecurity protocols and procedures for medical devices moving through FDA approval. Our health care system is going to continue to advance and incorporate sophisticated and very interconnected technology. However, when we move towards interoperability, which I believe is a good thing, but as we move toward that interoperability we have to

prioritize patient safety and address the fact that our health care system is, in fact, critical infrastructure. We need to do everything we can to remain -- to ensure that it remains cyber-secure.

So certainly, I look forward to discussing the package in further detail. I want to thank all the members and the staff for the hard work that they have put forward in getting us to this point today.

And, Madam Chair, I am happy then to yield back to you.

*Ms. Eshoo. The gentleman yields back. The chair is now pleased to recognize the gentleman from North Carolina, Mr. Butterfield, for five minutes.

*Mr. Butterfield. Thank you very much, Madam Chair. I would like to strike the last word.

Madam Chair, I am very supportive of the underlying legislation, but I believe that it can be improved. I think it can be made even stronger between today's markup and the full committee markup.

And so, as the co-chair of the Childhood Cancer Caucus, I have spent the last 10 years or more focusing on laws to accelerate drug development for children with cancer and other life-threatening illnesses. During that time Congress has passed three laws which have provided hope to millions of families: the Creating Hope Act, the Race for Children Act, and the Childhood Cancer Star Act. I am proud of all

Congress has done, but there is more, much more, that we can do.

My fellow co-chair of the Childhood Cancer Caucus, Congressman Mike McCaul, and I have introduced H.R. 5416, the Give Kids a Chance Act, which will build on the progress that we have already made to spur innovation and create more cures for children with cancer. This bill is necessary, because cancer scientists tell us that adults and children with untreatable cancers need combinations of cancer drugs to be cured. Unfortunately, there are only a handful of these trials for children. The Give Kids a Chance Act would enable FDA to direct companies developing new combinations of cancer drugs for adults to study those combinations in children with cancers, as well.

While this bill has not been included in today's markup, I am encouraged by and thankful for the chair's and ranking member's commitment to continue working towards an agreement before full committee markup. I look forward to working with the committee, the FDA, and the industry on our shared goal of bringing hope, treatments, and cures to kids and families all across the country.

As I close, Madam Chair, let me also thank you for the inclusion of provisions of importance to rare disease patients and families. As the co-chair of the Rare Disease Caucus, this topic has long been of interest to me. This

Congress I am proud to be working with my good friend and caucus co-chair, Gus Bilirakis, on the STAT Act, which would enact a set of targeted reforms to advance development and approval of rare disease therapies.

In particular, I am pleased to see provisions in this legislation that recognize the important role that external, rare disease experts and patient communities play in the regulatory process. These provisions focus on the unique needs associated with regulatory science associated with very small populations, and facilitate an evaluation of our drug approval paradigm compared to that of the European Union.

I hope the Committee will consider additional rare disease provisions for inclusion in next week's full committee markup. And so I am hopeful that we will see continued development of FDA's rare disease capabilities and resources, so they can be applied consistently across centers. This will support the FDA's continued commitment to patient-focused drug development, something this committee has empowered in previous user fee agreements.

And so I thank you for the time, Madam Chair, I thank the committee in advance, and look forward to working with you as we go forward. I yield back the balance of my time.

*Ms. Eshoo. The gentleman yields back. And I would like to say to you that we are all indebted to you. We are all indebted to you, Mr. Butterfield, for your consistent and

persistent advocacy, especially on behalf of children and the issue of cancer.

Now, it is my understanding that the FDA -- we are working with the FDA. They have some additional technical adjustments, and I am giving you my full support. And I think Mr. Pallone and both sides of the aisle are willing to stand up and say that, that we get that particular bill taken up when we have the full committee markup.

So thank you. We hate to lose you, really. You have done beautiful work --

*Mr. Butterfield. And thank you --

*Ms. Eshoo. -- and continue.

*Mr. Butterfield. Thank you, Madam Chair.

*Ms. Eshoo. The chair now -- yes.

*Mr. Butterfield. Yes. On behalf of my co-chairs, we thank you.

*Ms. Eshoo. Sure. The chair now recognizes the gentleman from Virginia, Mr. Griffith.

*Mr. Griffith. Thank you very much, Madam Chair, speaking to the underlying bill.

But first, just a point of personal privilege, and I appreciate you saying we are going to miss Congressman Butterfield, a true gentleman. And I think we all should aspire to handle issues in a manner in which he handles them, even when we disagree.

But I will take this moment also to thank the committee staff for their efforts on PDUFA VII. They have worked hard on this. They have done an excellent job in helping address member concerns. And the user fee agreements are an important part of this committee's work, but we couldn't do it without committee staff.

I am particularly pleased to see the text of one of my bills, the Inspections Act, included here. It allows the FDA to recognize the work of other trusted countries who are conducting inspections. It requires FDA to consider an establishment's compliance history when determining how to prioritize risk-based inspections, and instructs the GAO to submit a report on FDA's foreign establishment inspections processes. This -- these measures will go a long way toward improving the current state of affairs in addressing backlogs at our inspections, particularly in -- around the world, as we have many of our medications made there.

There are still a couple of sections that I have some concerns about, and we are working through some questions to make sure we get the language right before the full committee markup. For example, at the very beginning of the text on pages four through eight, there is a section that changes the way allergenic extract products are treated. And I want to be sure it doesn't slow the process at bringing new allergy diagnostics to patients.

So one of my concerns, in particular, as you might imagine, is that currently we are doing the prick tests, where they just prick the skin to see if you have a reaction to various things. I want to make sure that we are not hampering the ability of our allergists to do those tests. If a new grass comes into the United States -- there are roughly 10,000 grasses known around the world, only 1,400 currently exist in the United States, but just about every year new species are being introduced accidentally -- sometimes on purpose, but new species are being introduced, and I wouldn't want to see our allergists not being able to add that to their list of things they test for.

Likewise, the Smithsonian estimates that we have about 70,000 insects that have not yet been identified. We don't know whether the insect feces or the insect may have some other effect on people who are susceptible to allergies. And I just want to make sure we are not slowing that down.

Now, in order to answer some of these questions -- because, unfortunately, I didn't read the underlying bill until Monday, I have to again compliment committee staff. Because Kristin Seum, who used to be a former staffer of mine, upon hearing my concerns, immediately got with the FDA, got them on the phone with me on the ride up here yesterday, and we were able to talk about it. I feel better, but I still want to take some time to reflect on it and make sure

that we are not causing a problem.

So I do appreciate everything the committee staff does to help us when we see something in the bill that we think might be a little hinky, and trying to answer those questions.

And I look forward to passing this bill out of subcommittee today, and continuing to work with all of you so that we can put out a solid, bipartisan product that we all are very proud of.

And I yield back, Madam Chair.

*Ms. Eshoo. Thank you. The gentleman yields back. The chair is pleased to recognize the gentleman from California, Dr. Ruiz.

*Mr. Ruiz. Thank you. I move to strike the last word.

As we all know, historically there have been a lack of diversity in clinical trials for vaccines, medications, diagnostics, and medical technology. This is problematic because gender, race, ethnicity, age, and lifestyle play important roles in how our bodies react to those products. So a lack of diversity in trials leads to a huge disparity in our health care system.

What is more, even if a trial sponsor wants to expand their trial to a more diverse population, there are barriers that stand in the way of them doing so.

My bill, H.R. 5030, the Diverse Clinical Trials Act,

which I introduced with my friend, Dr. Bucshon, addresses some of those barriers.

One of the barriers that we are seeking to address is the need to go to the physical location of the trial. Decentralizing trials by removing this barrier and allowing engagement in additional locations, or even in the home, will increase and diversify patient participation. My bill does this by requiring the FDA to issue guidance on decentralized clinical trials for trial sponsors.

So I want to thank the committee for including this provision in the Food and Drug Amendments Act being marked up today.

Additionally, my bill would allow trial sponsors to pay for some of the non-medical ancillary costs to trials participation like transportation, meals, and technology. With these provisions, we will break down the barriers that keep many individuals who may be willing to participate, but cannot afford to do so, out of this critical process.

So I urge the committee to move this provision in a future markup, as it is vital to ensuring that clinical trials participation is not solely available to people with means, and I look forward to continuing our work on this.

And I thank the chairwoman for her own work to address this critical issue.

Thank you, I yield back.

*Ms. Eshoo. The gentleman yields back.

The chair is pleased to recognize the gentleman from Florida, Mr. Bilirakis, for your five minutes.

*Mr. Bilirakis. Thank you, Madam Chair. I move to strike the last word.

Madam Chair, I want to thank you again. I want to speak in support of the underlying FDA user fee package, and thank the, of course, the chair and the ranking member and the staff for their tireless efforts to negotiate it and bring it together. It is a real win. We have got to get it across the finish line, of course.

Ultimately, I believe the package will keep encouraging innovation for potential breakthrough treatments and lower drug costs for our constituents. The package includes two bills I have co-authored to reauthorize the successful programs within the FDA.

The first is my bill with Representative Butterfield, my good friend, to reauthorize the Orphan Drug Grant Program, which funds studies that address knowledge gaps, supports clinical trials, and advances rare disease medical product development. I am grateful to have included -- I am grateful that the language was included, the language that I authored to expand on this orphan drug program to include new methods, and developing regulatory science of individualized therapies for those with rare diseases and conditions.

The second is a bill I was glad to co-lead with Representative Fletcher to reauthorize FDA's pediatric medical device programs, the Pediatric Device Consortia Grant Program, and the humanitarian device exemption pathway. Both of these efforts go a long way ensuring our children have access to the same innovative devices as many adults do. And I am glad to see them in this package, and I appreciate it very much.

However, I would be remiss if I also did not express my sincere disappointment that, despite being a part of the process during our legislative hearing, and having strong bipartisan support in this committee, this package does not include my bill along with Representative Butterfield -- and he mentioned this during his comments -- H.R. 1730, the Speeding Therapies Access Today, or the STAT Act.

As co-chair of the Rare Disease Caucus, I know the FDA must do better to facilitate the development of rare disease therapies through better coordination and fewer bureaucratic hurdles. There are more than 7,000 rare diseases, as the panel knows, and almost 95 percent are without an FDA approval therapy.

My bipartisan legislation seeks to build upon the success of the Center of Excellence model, ironically embraced by the FDA in the oncology space. It would complement and build upon the existing cross-agency work

focused on rare disease, and provide a stronger FDA organization for rare disease activities.

Despite the precedents set for oncology -- very successful, again -- the FDA provided technical assistance raising concerns that the Center of Excellence would be duplicative of existing efforts within the agency. I respectfully disagree with their assessment, and instead reiterate our intent has been to strengthen and build upon the existing infrastructure, rather than replace or duplicate it.

And my proposed reforms, along with Representative Butterfield's -- we worked real hard on this -- the reforms would do just that by incorporating all aspects of the FDA's internal expertise, and organizing it to advance policies in the regulatory process. It would also focus on addressing the current regulatory and policy challenges faced by very small patient populations -- again, ultra rare diseases.

The time is now for FDA to convene a conversation about defining and addressing the distinct needs of this ultra-rare population, leveraging internal expertise across centers, and involving rare disease stakeholders and experts in this process.

And I know I don't have much time, Madam Chair, so, instead of finishing up, I am going to yield back the rest of my time. Thank you.

*Ms. Eshoo. Well, we thank you for your beautiful statement, Mr. Bilirakis.

Now the Chair is pleased to recognize the gentlewoman from Minnesota, Ms. Craig, for your five minutes.

*Ms. Craig. Thank you so much, Madam Chair, and I move to strike the last word. Today I speak in support of H.R. 7667, the Food and Drug Amendments of 2022, a carefully crafted bipartisan agreement to make sure that FDA can fulfill its critical mission.

As a Member of Congress, one of my top priorities has been to lower the cost of health care for my constituents, and increasing generic drug competition is a critical component of lowering costs for patients and the health care system overall. I am pleased that title 6 of the bill includes a provision I cosponsored with Mr. Carter to expedite the generic drug approval process.

The provision allows a generic drug to be approved, even if the brand manufacturer makes changes to the label during the approval process, a tactic used by pharmaceutical companies to delay the market entry of lower-cost generic alternatives.

I also applaud the inclusion of cybersecurity requirements for medical devices under title 8, an issue I worked on with my colleague, Dr. Burgess.

Over the past few years I have seen an alarming uptick

in cyber attacks that threaten patient safety and our national security. These provisions would require manufacturers to have a plan in place for addressing cybersecurity vulnerabilities, and help protect American patients from ransomware attacks. I urge my colleagues to support this vital legislation.

Thank you, Madam Chair, and I yield back.

*Ms. Eshoo. The gentlewoman yields back.

The Chair is pleased to recognize another one of the fine doctors on our committee, Dr. Bucshon, for your five minutes.

*Mr. Bucshon. Thank you. I move to strike the last word on the underlying bill.

I want to thank the chair and the ranking member and the staff for their hard work in delivering a bipartisan FDA user fee agreement. This is an important reauthorization that is necessary to help drive innovation and make sure patients have continued access to critical treatments and cures.

I am pleased to see the continued focus on innovation in this agreement, as well as policy I helped author to promote diverse participation in clinical trials. More can be done, however, to protect patients, one example being diagnostic testing. Specifically, lab-developed tests.

For well over five years I have been working with my good friend and colleague, Representative DeGette, on the

VALID act, H.R. 4128, which establishes a risk-based regulatory framework for diagnostic and laboratory-developed tests. This legislation allows for leading-edge development and innovation to thrive, while assuring doctors and patients have the certainty that their test results are analytically and clinically valid.

The sponsors put in the time, and worked tirelessly over the last five years with stakeholders and the FDA to get the policy right and address the issue in a fair and balanced approach that prioritizes innovation. It is disappointing that, even after all the requests to hold hearings on this critical legislation, here we are today with a package that doesn't address the issue.

The Senate is collaborating in a bipartisan manner to tackle issues like the issue addressed by the VALID act. It is time to answer the call and address the pitfalls that exist in the current regulatory framework surrounding laboratory-developed tests.

Switching gears to accelerated approval, section 804 includes new labeling requirements for products approved under the pathway. I am a staunch supporter of the accelerated approval pathway. However, my concern with how it is drafted in this bill is over how the FDA would implement these new requirements for an application for accelerated approval that has already been submitted and

pending based on current labeling requirements. I believe there needs to be clarity on the implementation of this section, so that the FDA isn't left changing the rules in the middle of the game.

In addition, this could be an unnecessary drain on FDA resources, result in -- and result in review delays that impact FDA's performance under PDUFA commitments.

I would like the chair and ranking member to work with me as we head to full committee to address the implementation of the new accelerated approval provisions to ensure there is clarity for sponsors of pending applications. Thank you, I look forward to continuing to work with the chair and the ranking member to pass this important legislation to ensure patients have access to innovative cures and treatments.

I yield back.

*Ms. Eshoo. The gentleman yields back. The chair is pleased to recognize the gentlewoman from Washington State, another one of the terrific doctors we have on our subcommittee, Dr. Schrier.

*Ms. Schrier. Thank you, Madam Chair, and I move to strike the last word and speak on the underlying bill.

First and foremost, I want to thank you, Chairwoman Eshoo. I want to thank Chairman Pallone, ranking members, and all committee members and staff for the work that went into crafting this really remarkable, monumental bipartisan

reauthorization package.

I also want to thank you for including my bill on diagnostic devices.

When considering new diagnostic tests, perspectives about real-world issues and benefits is really critical, grounds us. So bringing together industry and public health experts and the FDA every year to discuss pandemic preparedness and the use of in vitro diagnostic medical devices like home antigen tests, for example, will help us stay ahead of crises and future pandemics. And frankly, this sort of annual meeting will provide the transparency needed to rebuild trust within the medical community and trust by the public at large. So I want to thank you for including this important priority.

On a separate theme, I have been tracking the development of the type one diabetes moonshot, islet cell transplants, for decades. Yes, researchers were pursuing this 37 years ago, in 1985, when I was diagnosed with type one diabetes. But the thing is that, last year, researchers actually succeeded. And a person with type one diabetes, for the first time ever, may have been cured by this technology.

And as you know, type one diabetes is a lifelong disease that requires careful management of insulin and blood sugars to avoid devastating short and long-term consequences. And technology has made this management easier, but we really

need a cure. And for families with young children with this disease, a cure would bring a peace of mind that they will otherwise never know.

So I, for one, am frustrated that this islet cell study has been put on hold. And evidently, the pause in this research and in others in cell and gene research has been because of staff shortages, not safety or technical concerns. And so I just want to say that I sure hope that the staffing increases and more in-person meetings in this bill will allow this research to quickly resume. And I will be working with the chair and the ranking member to make sure that is the case, because a lot of people are waiting, and a lot of families are hoping.

Finally, I just want to mention one piece of legislation that was not included in this bill, but is important to businesses in my district, manufacturers, patients, and providers. And this bill involves the remanufacturing of medical devices like MRI machines or ultrasound equipment, for example, because we count on those to work as developed and as they came out of the factory. And right now there are parts used in repairs that are of quality comparable to the original parts, and they cross the line into remanufacturing.

We just need the FDA to clarify these activities, so that patients and doctors can feel confident that the CT, MRI, or ultrasound study that they are getting is the quality

that they expect, because substandard parts slapped together in China might appear to work fine, but they [inaudible] compromise patient safety.

*Ms. Eshoo. Would the gentleman -- would the gentlewoman yield on this point?

*Ms. Schrier. I --

*Ms. Eshoo. On the --

*Ms. Schrier. Yes.

*Ms. Eshoo. On the remanufacturing. I want to thank you for co-leading the legislation that you have with Representatives Peters and Joyce.

These are important comments, colleagues, because there is confusion about what remanufacturing entails, and the effects for patient safety.

What this issue is about is that the FDA has said that the line between servicing and remanufacturing needs to be clear, because what has actually caused or contributed to these adverse events that the gentlewoman is speaking to is remanufacturing. That is under FDA regulation, but servicing -- and it is not servicing, which is not under FDA regulation. Dr. Shuren, during the hearing that we had, our subcommittee, said that legislation would help clarify device remanufacturing.

So we need Mr. Pallone to cooperate with us, and -- so that there is consensus legislative language that includes

the FDA's input on how to best define remanufacturing before the bill comes to the full committee.

So we need your help, Mr. Chairman.

*The Chairman. Would the gentlewoman yield?

*Ms. Eshoo. I would be glad to. It is not my time, though.

We are out of time.

*Ms. Schrier. I would be glad to.

*The Chairman. Oh, she is out of time?

*Ms. Eshoo. Yes.

*The Chairman. Or I could ask for my own time.

*Ms. Eshoo. Yes.

*Voice. So I think now we are onto Mr. Hudson.

*Ms. Eshoo. Yes, we will go to Mr. Hudson, and then we will come to you, Mr. Chairman.

*The Chairman. Sure.

*Ms. Eshoo. I know you are king of the committee, but we have got to stick with our order here, okay?

Yes, and we want to hear from you.

The chair is pleased to recognize the gentleman from North Carolina, Mr. Hudson, for your five minutes.

*Mr. Hudson. I thank the chair, and I move to strike the last word.

I would like to first acknowledge the tremendous effort of yourself and other members of this committee, our staff,

the FDA, and, very importantly, the stakeholders on the bipartisan work over the past several months and, indeed, years to reach this comprehensive agreement.

During the -- ensuring the FDA is best equipped to support future innovation is a top priority of mine. And these user fees are what ensure that continued success.

There are many important policies and bills included in this agreement, and I am proud to have two pieces of legislation among them. One is H.R. 6980, or section 725 in the base text, the unannounced foreign drug facility inspections pilot program which I was pleased to work on with Chair Eshoo.

It has been devastating to witness the delay and backlog in foreign inspections for both medical devices and drugs over the course of this pandemic. This is a serious patient safety and access issue, and has led to increasing build-up of overdue approvals that could be saving lives. For example, between March 2020 and October 2020, the FDA only conducted three foreign inspections. In comparison, the FDA conducted more than 600 foreign inspections over the same time period in each of the 2 prior years.

While the FDA has worked to improve between October 2020 and April 2021 -- excuse me -- inspections increased to 18. We still need to ensure the FDA is using every tool at its disposal to complete drug approvals. While I am pleased the

FDA finally resumed in-person domestic inspections in February, we must continue to do more abroad.

This bill will help address this issue by establishing an unannounced inspection pilot program for foreign drug facilities, such as those in adversarial countries like China and Russia. This program would increase the number of inspections at foreign facilities, and require a report to evaluate any differences between unannounced and announced inspections, as well as any recognized barriers and challenges.

This is a well documented issue. In fact, the Government Accounting Office report recently called on the FDA to strengthen its foreign inspections program, urging the agency to implement a pilot program such as exactly what our bill would require.

We must ensure the FDA has all necessary tools and information to move quickly and efficiently on these inspections and pending approvals, which is why I am so pleased to see this bill included in the package today.

I am also pleased that H.R. 7035, the Biologics Marketing Transparency Act, or section 7025 of the underlying bill, has been included. I led this bill with Congresswoman Kathy Manning to require prompt reports in the changes and availability for both biologics and biosimilars. By requiring transparency for both FDA and stakeholders as to

which biologics are on the market and when, we can ensure continued patient access to and education on essential medicines.

Finally, we support policies under section 721 to allow for the remote records assessment of medical devices in advance of or in lieu of formal inspection. We have seen the proven success of this additional authority throughout the COVID-19 pandemic, and this provision would make this current pilot program permanent. This provision would modernize medical device inspections, while still ensuring the FDA has the necessary tools and information it needs.

I am proud of the work we have done on these policies, and I would urge my fellow committee members to consider favorably and adopt H.R. 7667.

And with that, Madam Chair, I will yield back.

*Ms. Eshoo. The gentleman yields back. The chair is pleased to recognize chairman of the full committee, Mr. Pallone.

*The Chairman. Thank you, Chairwoman Eshoo. Let me just talk briefly about this effort to define remanufacturing.

The problem we face -- and I have to, you know, reiterate this to everyone -- is I am taking a great deal of pride in the fact that we are able to move this bill today and to full committee next week, and that we have a

consensus, a bipartisan consensus. I said to Chairwoman Eshoo yesterday I don't remember -- you know, I have been here 34 years -- I don't remember any time when we were trying to, you know, reauthorize user fees that we actually were able to move so quickly.

And the reason we want to move quickly is because we don't want a situation where the FDA has to set out these pink slips, which they have done before. And so the problem is that we have members of the committee on both sides of this issue with concerns about competition, access to repair services, patient safety.

And so, as introduced, I just don't think that the policy on remanufacturing has reached a level of consensus, and it is not going to reach a level of consensus by next week. So if we tried to define remanufacturing, we would probably delay this bill weeks, if not months. And then you run into the same thing with the pink slip.

So in all fairness, I just have to be honest, we are not going to be able to do this in order to go to a full committee markup next week. I mean, we can, obviously, continue to talk about it, but there is such a --

*Ms. Eshoo. Would the gentleman -- yes.

*The Chairman. There is such a battle here on -- and it is not a partisan battle -- with members defining this that I am -- I just can't commit to saying that we would do this by

the full --

*Ms. Eshoo. Would the chairman yield?

*The Chairman. -- committee markup.

Yes, sure, of course.

*Ms. Eshoo. Would the chairman yield?

*The Chairman. I yield back.

*Ms. Eshoo. I appreciate --

*The Chairman. I mean I yield to the gentlewoman.

*Ms. Eshoo. -- everything that you are saying. We always have to develop consensus. And that is the imprimatur of today's entire effort: there has been consensus.

Let me make a suggestion. It was Dr. Shuren that said to me that FDA needs clarity, it would be helpful for FDA to have clarity. Why don't we go to FDA, see if they can give us language that might be consensus?

Now, if it doesn't work, I am not the one that is going to throw sand in the gears to have FDA issue pink slips. I mean, that is not -- you know, that is not responsible. But why don't we try?

*The Chairman. Well, let me just say this --

*Ms. Eshoo. Why don't we try?

*Ms. Eshoo. We have already done that, as you know, as I spoke to you about this last week, or a couple of days ago. We went back to Dr. Shuren, and he made it quite clear that he wants this bill to move, and doesn't want to send out the

pink slips.

We will do what you said, Chairwoman Eshoo. But I am trying to -- I am really, in all honesty, I am telling you it is probably not going to happen by next week. And I don't want to delay the bill because of that.

*Ms. Eshoo. No, I --

*The Chairman. And it is not important enough for him to delay the bill.

So certainly, we are going to do that, and we will try. But I just -- I want the members to know that we have worked very hard on trying to do this, and there is not a consensus, and I don't believe we can accomplish it by next week. But certainly, we will continue to work towards that, absolutely, Chairwoman Eshoo.

*Ms. Eshoo. Okay. Well, I am the eternal optimist. You have expressed your pessimism.

[Laughter.]

*Ms. Eshoo. Let's get some language from FDA and maybe, just maybe, we can all win. But thank you, Mr. Chairman.

Okay, who else would like to speak on -- Mr. Carter of Georgia is recognized for five minutes.

*Mr. Carter. I move to strike the last word.

Madam Chair, I want to thank the chairwoman and the ranking member for holding this markup of this crucial package that will lower drug costs, spur more lifesaving

innovation, secure America's supply chains, protect access to breakthrough drugs and therapies, and ultimately improve lives.

As you know, I have dedicated much of my time on the Energy and Commerce Committee to finding solutions that lower prescription drug costs for patients. Increasing access to generic drugs and promoting competition is a critical tool to ensuring patients can afford their medicines at the pharmacy counter. So I am thankful to the committee for including my legislation, H.R. 6973, the Expanding Access to Affordable Medicines Act, in the user fee reauthorization agreement we are discussing today.

This streamlined process will improve efficiency at the FDA, and get affordable drugs into patients' hands faster. I look forward to working with the committee to make sure this common-sense legislation is signed into law.

As everyone here is aware, shortages of generic drugs and other medical products continue to create public health challenges in the U.S. The surge in demand for these products during the COVID-19 pandemic demonstrated not only how vulnerable our supply chain is, but also the need to prevent such shortages in the future by improving our regulatory system, and creating a more modern, domestic manufacturing sector. That is why I am thrilled and deeply grateful to this committee for including provisions from my

bill, the MADE in America Act.

This bipartisan bill, which I introduced with my colleague, Representative Darren Soto, would empower the FDA to prevent and mitigate drug shortages by enforcing our stringent safety measures abroad, and encouraging the adoption of new manufacturing platforms and technologies here at home.

While no one policy can solve the drug shortage problem, I am confident that these policies, taken together and working in concert with many other provisions in this bill, will have a significant impact in ensuring that our nation's hospitals, physicians, pharmacies, and patients have access to the drugs they need.

I also want to thank the chairwoman and the ranking member for including the FDA Modernization Act in this package. I was an early supporter of the provision on the committee to allow the United States to do a reset on the animal testing mandate and Federal law for our drug development protocols.

As a pharmacist, I know we can do better on drug pricing, delivery times to patients, while improving -- by improving both safety and effectiveness, as well. And I also know we can do better when it comes to pre-clinical test methods, and apply 21st century strategies that rely on human biology, not so much on beagles.

This crucial package will lower drug costs, spur more lifesaving innovation, secure America's supply chains, protect access to breakthrough drugs and therapies, and ultimately improve lives. I call for my colleagues to support this package.

And I yield back.

*Ms. Eshoo. The gentleman yields back. The chair is pleased to recognize gentlewoman from New Hampshire, Ms. Kuster, for five minutes.

*Ms. Kuster. Thank you, Madam Chair. I move to strike the last word.

A picture is worth a thousand words. And the photographs I have recently seen of medical device alterations that cross the line into remanufacturing give me cause for concern.

When a medical device is remanufactured, the device has been significantly changed from what it was intended to do. In comparison, when a device is simply serviced, it remains in its FDA-approved and intended condition. The confusion that currently exists between what constitutes servicing a medical device and remanufacturing a device which the FDA already has the statutory authority to regulate (sic). This lack of a clear definition of what constitutes remanufacturing creates unnecessary risk for patients and health care providers.

The FDA has been working to clarify the difference between servicing and remanufacturing in the form of public meetings, white papers, and agency guidance. I commend the FDA for their work to date, but I also believe that congressional action is needed to codify more clarity in statute between the difference between these two technical yet distinct activities.

I am pleased that my colleagues, Dr. Schrier, Mr. Peters, and Mr. Joyce have introduced H.R. 7253, the Clarifying Remanufacturing to Protect Patient Safety Act. This bipartisan legislation will not only help bring clarity to the issue, it will also help raise awareness of the current ambiguity between remanufacturing and servicing that will help to educate the broader medical device community.

I was pleased that, at a recent subcommittee hearing, the director of FDA's Center for Devices and Radiology Health, Dr. Jeff Shuren, committed to working with this committee on the issue. And I was pleased to receive a letter today from more than 25 patient organizations expressing their support for passage of H.R. 7253.

Madam Chair, H.R. 7253 is a technical fix that will strengthen patient safety protections. The patient community supports it, and I encourage this committee to work to incorporate this bill in the user fee reauthorization bill.

And I yield back.

*Ms. Eshoo. The gentlewoman has completed her statement, and we have -- the chair will now recognize another one of our doctors on our subcommittee, Dr. Dunn of Florida, for your five minutes of questions.

*Mr. Dunn. Thank you, Madam Chair. I move to strike the last word.

I am concerned about this proposal that is working its way through the committee, specifically H.R. 7253, which is the remanufacturing versus servicing bill that we are -- have been speaking about. And I would like to associate myself with the comments of Chairman Pallone.

H.R. 7253, as written, is problematic. I acknowledge and understand the intentions and the good intentions of the Doctors Schrier and Joyce in trying to define the exact difference between true servicing and remanufacturing of medical devices. But I would like to lend my experience to this conversation surrounding the issue.

I think there is a lot of work to be done on H.R. 7253, and I would like to work with the sponsors and the OEMs and the third-party servicers and, frankly, the end users. And that is people like me, all right?

You know, it is people like me that buy these tools and use these tools. I have literally spent tens and tens and tens of millions of dollars on CT scans, pet scanners, MRI, linear accelerators, lithotripters, and even cyclotrons. I

have run a practice that has all of those things in it, and I am a happy customer. I like my OEMs. I get along with them, these are great treatments.

But no one would ever buy one of these pieces of equipment unless they knew beforehand that they had reliable, prompt servicing available for that equipment. It has to be prompt. High -- and this is not a complaint about the equipment, it is just high technology, it needs a lot of engineering TLC.

I want to give you an example. It is Friday. Your linear accelerator broke down. You are treating people with radiation therapy for cancer. The literature is replete with stories that show that, if you delay -- onset, starting the treatment back -- more than three days, that you have a much higher failure rate of that therapy. That is to say the cancer comes back and the patient dies.

So I am here to tell you that slow service on these tools, these piece of complex machinery, kills patients. And that applies just exactly as much to diagnostic therapies as it does therapeutic.

I never would have bought the machines I bought unless I had a cadre of reliable, prompt servicing people available to me.

Now, why isn't it available to me? Well, if you live in New York City, Atlanta, Miami, Chicago, you probably have a

Siemens, GE, Varian rep in your city ready to come to your side when you need them. But if you live in north Florida, that is just not true. I have to wait for somebody to fly in from one of those cities.

And I want you to know this is -- we are not talking about Broken Arrow, Arizona here, out in the hinterlands. We are talking about cities like Pensacola, Panama City, Tallahassee, Jacksonville, Daytona, Tampa, Clearwater, Naples. These are pretty big cities. They do not have OEM reps, servicing reps, in those cities. They never have, they never have shown any interest in that. And those things are simply not available. This decreases access to care.

I want to make one more point. This subject was probably born in a C-suite someplace, where they are saying, "We are leaving 30 percent on the table. We should service our own equipment.'' I love these machines. I love -- I paid lots of money for them. But I think the C-suite is wrong in this case. They think they want this bill. I think they are wrong. And this is why. Their universe of people to buy these machines shrinks if they put these servicers out of business. I just don't buy the machines. So all of a sudden you have got fewer machines up for sale.

I think that they are -- have not thought this through. So what I would like to do is work with the OEMs. I want to work with the sponsors of the bill. I want to be sure that

we have a clear definition for servicing.

And I have seen all the iterations of this definition that have been coming out through the OEMs and the third-party servicers. Nobody has made it clear yet, I promise you that.

So I will work with you, and I will work with you any hour of the day or night. But, you know, trust me, you know, I love these machines, but I can't get behind this bill. So I appreciate your understanding, and I hope that you all will work --

*Mr. Upton. Will the gentleman yield?

*Mr. Dunn. Thank you.

*Mr. Upton. Will the gentleman yield for two seconds?

*Mr. Dunn. Yes.

*Mr. Upton. I would just like to point out for Mr. Mullin that Broken Arrow is in Oklahoma, not Arizona.

[Laughter.]

*Mr. Dunn. I missed that.

*Ms. Eshoo. Okay, the -- do you want to repeat it, Fred?

*Mr. Guthrie. What was it?

*Ms. Eshoo. What was it?

*Mr. Upton. The gentleman said that having a technician go to Broken Arrow, Arizona. But Broken Arrow is actually in Oklahoma.

*Mr. Guthrie. Oh.

*Mr. Dunn. A suburb of Tulsa.

*Voice. [Inaudible.]

[Laughter.]

*Ms. Eshoo. That is the easy way to do it, right?

Okay, the gentleman yields back.

Just for the interest of members, we don't have any other Democrats that wish to speak. We have two Republicans, and then we can move on to amendment.

So I will now recognize the gentleman from Texas, Mr. Crenshaw, for your five minutes of questions.

*Mr. Crenshaw. Thank you, Madam Chairwoman. I would like to strike the last word.

A few years ago I was introduced to the concept of stem cell therapies by a small biotech firm in Houston. They were having trouble with the FDA because the way they extracted stem cells from fat tissue, or adipose tissue, did not meet the narrow guidelines allowed by the FDA. In fact, you can't use stem cells at all from adipose tissue.

And it is not just an issue faced by one company in Houston, either. We have talked with dozens of companies, universities, and stakeholders who have the same complaints, that the FDA regulates adult stem cell therapies like transplants. And that regulation was drafted in 1997, which does not reflect the advancements made in stem cell therapies

since then.

The FDA has pushed back against stem cell therapies as a whole, citing two very specific, isolated incidents in which patients were harmed by unsafe practices that accompanied stem cell therapies. Rather than shutting out innovative adult stem cell therapies, we should focus on building a regulatory framework that allows our biotech industry to develop safe and innovative stem cell therapies. My bill, that I introduced with Dr. Burgess, would take the first step in this process. It requires the FDA to convene a public workshop on best practices on how to generate the scientific data needed to better evaluate these stem cell therapies.

I am glad to see that this provision has been included in this package of bills as section 707, and I want to say a very special thank you to my friend, and the chair of the subcommittee, Anna Eshoo, for working with me so diligently on making sure this piece of legislation was included in the bill.

I would also like to thank our Republican leader, Cathy McMorris Rodgers, and her team, Grace and Kristin, for all your work on this provision, and for your hard work in putting together this package of bills.

I yield back.

*Ms. Eshoo. I thank the gentleman for his very kind remarks. It is a pleasure working with you.

The Chair now is pleased to recognize another one of our wonderful doctors on the committee, Dr. Joyce of Pennsylvania, for your five minutes.

*Mr. Joyce. Madam Chair, I wish to strike the last word.

*Ms. Eshoo. So ordered.

*Mr. Joyce. Thank you, Madam Chair. I wish to address two critical issues on this bill.

First, I would like to thank Representative Matsui and Representative Griffith for working with me to introduce H.R. 7649, which will require the FDA to open a public docket on which factors should be taken into consideration when they review proposed changes to a third-party vendor, aiding in the implementation of existing Risk Evaluation and Mitigation Strategy, or what is known as the REMS, for a particular drug. This is specifically important to address the issue of vendor switches, because in the past we have seen instances where patient data does not transfer from vendor to vendor, creating a myriad of problems for the doctor and for the patient.

While we are very pleased to see this specific bill included in this agreement, this is only the first step in addressing problems that many of us have heard with the REMS process, and making sure patient and provider input is heard so that continued access to medications is not interrupted.

All too frequently I hear from doctors being locked out from their specific REMS websites, which prevents patients from being prescribed lifesaving and life-altering medication. Then, when the doctors go to the FDA about these concerns, unfortunately, they have been ignored. This cannot be allowed to continue. And I look forward to working with everyone here to fix these problems once and for all.

On another important issue that we are discussing today regarding patient safety, I would like to echo comments made by my colleague, Chair Eshoo, Representative Peters, and Representative Dr. Schrier regarding remanufacturing of medical devices.

Further, I would like to commit to building a consensus around this issue, so that we can address all concerns and, ultimately, that all patients are protected. This is a complex problem, and we have to be able to address the serious patient consequences if equipment is improperly repaired.

While the FDA justifiably regulates the use of these devices, and provides for their approval, I have seen evidence from hospitals in Pennsylvania and around the nation that some who are repairing these medical devices are crossing a line, and inadvertently changing how a device functions.

One very important example that I would like to

highlight is involving infusion pumps. Infusion pumps deliver millions of infusions every day in the United States, and are a highly complex device that can endanger patients if not functioning properly. Case in point: a company, not an original manufacturer, took a key part of an infusion pump, and had it copied and mass produced in China, and installed in thousands of pumps here in the United States. And unfortunately, that after-market part began to fail, often resulting in unregulated flow of a drug to a patient. And as a result, three patients died. There were dozens of adverse events, and ultimately thousands of these pumps had to be recalled.

And this incident isn't alone. In fact, in a 2018 report from the FDA it was noted that many adverse medical device events attributed to servicing were actually remanufacturing.

To clarify this ambiguity, my colleagues and I have introduced H.R. 7253, the Clarifying Remanufacturing to Protect Patient Safety Act. This legislation, supported by members of both sides of the aisle, is a common-sense measure that will serve to raise awareness of what remanufacturing is and what it isn't.

While a statutory definition of remanufacturing like this legislative process may seem a small measure, it will go a long way not only to provide clarity to those who work on

these devices, but ultimately protecting patients.

We also stand ready to work with colleagues to make sure standard, routine servicing and repair is excluded from this definition.

And for these reasons, Madam Chair, I wish to voice my strong support for H.R. 7253, and advocate for its inclusion in the final medical device user fee agreement.

This is an ability to advocate for patient safety. I ask my colleagues to consider this, and I look for the clarification necessary to get this to the final markup.

Thank you, Madam Chair, and I yield.

*Ms. Eshoo. The gentleman yields back. I see no other members seeking to speak on the underlying bill, and the chair now recognizes herself to offer an amendment in the nature of a substitute, which is at the desk. So the clerk will report the amendment, please.

*The Clerk. Amendment in the nature of a substitute to H.R. 7667, offered by Ms. Eshoo of California. Strike all after the enacting clause, and insert the following: Section 1 --

*Ms. Eshoo. Without objection, the reading of the amendment will be dispensed with.

[The amendment of Ms. Eshoo follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. And the chair recognizes herself for five minutes.

I have already spoken, colleagues, at length to the many beneficial provisions of this user fee bill. This amendment in the nature of a substitute -- excuse me -- makes several technical corrections based on feedback from the FDA and tailors some provisions of the bill for more clarity.

For example, the amendment clarifies the scope of the report on rare diseases under section 703. It also better describes the congressional intent behind its request for FDA to hold a public meeting on stem cell therapies, an issue, as we have heard several times, championed by Congressman Crenshaw.

Throughout this process, we have worked closely with FDA, with industry, with patients to ensure that each provision is technically workable and would not have unintended consequences.

One issue is missing from this amended bill. I support providing FDA authority to require notification of critical device shortage outside of a public health emergency. I think that that should be around the clock, day in, day out, year in, year out. And thanks to our bipartisan work in the CARES Act, the FDA has been able to use device shortage reporting to prevent or mitigate shortages for PPE, test supplies, and ventilators. This authority saved lives during

the pandemic. Device shortages will continue outside of the COVID-19 public health emergency: weather events, factory closures, shipping delays. These can all cause shortages that require the FDA to be alert and proactive to mitigate the impact.

I urge members to speak to local hospitals about device shortages. My local children's hospital, Lucile Packard Children's Hospital, which is part of Stanford Health Care, is currently dealing with a shortage of syringes for heparin, which the FDA has been helping to address. A few years ago, many hospitals, tragically, didn't have pediatric breathing tubes because of a shortage.

The legislation should not require piles of paper or lengthy reports, as Dr. Shuren said at our hearing, that the agency doesn't want to sort through that, either. So no one wants that. But a targeted, clear authority on what specifically needs to be reported for critical devices that may go into shortage is important to protect patients and health care workers both during and outside of a public health emergency.

So with compromise from private industry, FDA, the members of this subcommittee, we can reach a suitably tailored solution to include this important authority in next week's full committee markup. And I ask members to give a thought to this, because this, as I said just now -- and I am

going to repeat myself -- this will be dealt with, whether there is a pandemic or not. So we need to address it. And I think we can address it without it really impairing or being a burden to industry or to the FDA.

So meanwhile, this amendment in the nature of a substitute continues our technical work to improve the bill, and I urge the members of the subcommittee to support it.

Okay. Are there any members seeking to be recognized on the --

*The Chairman. Madam Chair?

*Ms. Eshoo. -- on the amendment?

Chairman Pallone.

*The Chairman. Oh, is there Republicans?

*Ms. Eshoo. Are there any Republicans first that would like to speak?

All right, then we will go to Mr. Pallone.

*The Chairman. Thank you.

*Ms. Eshoo. You are recognized.

*The Chairman. I just wanted to speak in favor of the amendment in the nature of a substitute, and also the underlying bill.

The FDA -- well, the Food and Drug Amendments of 2022 represents a clear bipartisan statement of support for strengthening our public health system, and ensuring we have a strong FDA. It is, obviously, a critical asset in our

nation's fight against COVID-19, and the staff worked very hard every day to ensure our medical products are safe, and we certainly appreciate everything the FDA does.

The user fee package will fund FDA's review programs and post-market safety initiatives, and will carry FDA into the future by significantly increasing the agency's capacity to facilitate the development of novel medical devices and therapies, including cell and gene therapies for rare diseases. And the reauthorization of these user fees will keep FDA at the forefront of science, and it is critically important that we advance them today.

In addition to reauthorizing user fees, I am proud that we have been able to come together across the aisle to include so many members' priorities in the FDA 2022 package. I do not have time to go over every program that we were able to include, but I want to highlight a few.

First, this bill includes important provisions from my bill to build greater program integrity into the accelerated approval pathway at FDA. Under accelerated approval, certain drugs that are proven safe may be approved more quickly, based on a surrogate endpoint, if FDA believes that it is reasonably likely that the endpoint will demonstrate a clinical benefit. As part of that program, drug sponsors are required to conduct an adequate and well-controlled phase 4 study after approval to confirm the clinical benefit of the

drug. And if such study does not pan out, the drug should come off the market.

Unfortunately, however, we have heard from FDA officials that some drugs take years just to begin their post-approval studies. And if the study does not show a clinical benefit, current processes for removing the drug's approval may take the agency years to implement.

So FDA 2022 fixes these issues by allowing the agency to require sponsors to begin their phase 4 studies before the approval is granted, and streamlines the process of withdrawing a drug if no clinical benefit is found, or if the sponsor fails to complete a study with due diligence, as FDA requires.

So the bill also requires more frequent reporting from drug sponsors on the progress they are making towards their post-approval studies, and builds transparency into a drug's label about its approval status.

New to this version of the bill are provisions that would codify FDA's rare disease endpoint advancement pilot, which will help sponsors of drugs for rare diseases identify clinical endpoints to increase discussion with FDA, and a clarification of FDA's existing ability to allow Real-World Evidence to augment or support post-approval studies that, by regulation, are required to be well controlled.

So overall, I am pleased that the bill before us will

help ensure that patients have access to the drugs they need, while providing them with the assurance that they are safe and effective. And I am glad we have come to a bipartisan agreement on that today.

Additionally, this bill will take great strides towards ensuring that clinical trials for new drugs and medical devices are inclusive and representative of the patients that sponsors intend to serve with their products. Drawing from the DEPICT Act introduced by Chairwoman Eshoo and Representative Kelly, the bill requires sponsors to submit Diversity Action Plans as part of their applications, and requires FDA and stakeholders to examine how we can increase the enrollment of historically under-represented populations in clinical studies.

Additionally, the bill draws from the Diverse Trials Act sponsored by Representatives Ruiz and Dr. Bucshon, and the Cures 2.0 Act, sponsored by DeGette and Upton. I mentioned that before. That requires the FDA to issue new guidance on decentralized clinical trials, which can encourage increased diversity and participation.

The bill also continues this committee's efforts to bring down drug costs by increasing competition from generic drugs. The ranking member mentioned that. Just last year generic competition saved the American health system $338 billion, and the bill stands to increase those savings by

facilitating better communications between FDA and generic drug sponsors about regulatory requirements, speeding their development time, and it will ensure that last-minute changes by brand manufacturers won't interfere with a generic drug coming to market.

Last, but certainly not least, I am pleased that the bill bolsters FDA's inspection authority -- several members mentioned that -- which are vital to ensure that the drug supply remains safe for all Americans.

So all the members can be proud of the product we are advancing through the subcommittee today, and I look forward to working with my colleagues to improve it as it moves through the full committee. We expect that markup next week, and then to the House floor. And obviously, we have to get the Senate to act, and the President will then sign it.

So thank you again, Chairwoman Eshoo, and all the committee members, for their work on this legislation. And I yield back, Chairwoman Eshoo.

*Ms. Eshoo. The gentleman yields back. Thank you, Mr. Chairman.

Now, are there any members who seek recognition to offer an amendment to the amendment in the nature of a substitute?

For what purpose does the gentleman from Florida seek recognition for?

I am sorry, Georgia.

*Mr. Carter. The other great state.

*Ms. Eshoo. The great state? Okay, I will amend my words. From -- the gentleman from the great state of Georgia.

*Mr. Carter. Madam Chair, I have an amendment at the desk.

*Ms. Eshoo. What is your amendment labeled? Do you have it?

*Mr. Carter. Section 601 of --

*Ms. Eshoo. All right, the clerk will report the amendment.

*The Clerk. Is it CartGA_079?

*Mr. Carter. Sorry.

*The Clerk. Okay, I have the amendment.

Amendment to the amendment in the nature of a substitute to H.R. 7667, offered by Mr. Carter --

*Ms. Eshoo. Okay. Without objection, the reading of the amendment will be dispensed with.

[The amendment of Mr. Carter follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. The gentleman is recognized for five minutes to speak to his amendment.

*Mr. Carter. Thank you, Madam Chair.

Madam Chair, this amendment would do two things. Rather than providing specific information about the brands -- the brand drug's formulation, it would allow FDA to provide directional assistance to the generic drug maker to identify what additional changes are needed to ensure the generic drug is the same as the brand.

It would also clarify the scope of what types of drugs FDA can provide information about.

I share Ms. Kuster's goal of getting more generics to market as soon as possible, but believe we must do so in a way that protects the sensitive commercial information of brand drugs to preserve incentives to bring new, innovative products to market.

Additionally, this amendment would clarify that FDA is permitted to provide this information only for drugs that FDA regulations specify must be qualitatively and quantitatively the same as the brand drug with respect to inactive ingredients. I believe this language appropriately clarifies the intent of Ms. Kuster's bill, which is to allow FDA to provide certain information to generic drug makers when the drug is not qualitatively and quantitatively the same as the brand.

Madam Chair, I feel strongly that these issues be resolved as we work towards final passage of the user fee bill. We would like to ask for your commitment to work with me to address these concerns before full committee markup.

*The Chairman. Will the gentleman yield?

*Mr. Carter. I yield.

*The Chairman. Oh, I forgot to say the gentleman from the great state of Georgia.

*Mr. Carter. He will yield, too.

*The Chairman. And I do love Georgia, from Atlanta to Savannah, and particularly the Sea Isles (sic). It is all wonderful. It really is.

I wanted to say that I appreciate that Mr. Carter is seeking to fulfill the intent of the bill. As you know, this provision in the legislation was agreed to by sponsors on both sides of the aisle before being included in the bill because we feel it is important to facilitate the development of new generic drugs and bring about more competition.

Rather than requiring sponsors to play a guessing game to know if drugs are meeting quantitative and qualitative benchmarks for approval, the bill allows the FDA to communicate the degree to which a generic drug sponsor's application is off in these regards, and that makes it easier for sponsors to get their drugs approved and come to market and compete.

So if the gentleman would agree to withdraw his amendment, we will review his proposal in detail to determine whether it still meets these goals, and we will discuss it with him and Representative Kuster, what options we have between now and the full committee markup.

And I would yield back to the gentleman.

*Mr. Upton. Will the gentleman yield -- Mr. Carter, will the gentleman from the great state of Georgia yield to the better state of Michigan for --

*Mr. Carter. I yield. Well, I am sorry --

*Mr. Upton. Thank you, thank you --

*Mr. Carter. What was that?

[Laughter.]

*Mr. Upton. First I want to thank the chair for the markup, and the words from Mr. -- from the chairman, Mr. Pallone, as well. This is an important markup.

While I certainly support the bulk of this bill, there is this one section 601, which the gentleman from the wonderful state of Georgia has referenced, that I would think would have a detrimental impact on the innovation in the drug sector. It is the section that would require the FDA to provide generic drug sponsors, upon request, the information regarding any difference in ingredients between their generic and the referenced listed drug to which they are compared to facilitate generic drug development and review.

While it sounds good on its face, I think it might be unnecessary, and would disrupt the Hatch-Waxman balance, which we have had for a good number of years, undermining incentives for innovation, and perhaps even raise constitutional issues.

So the section would mark a fundamental shift in the careful balance that we have had between encouraging innovation and facilitating access to generic drugs. The Hatch-Waxman contemplates that a generic sponsor may provide resource-intensive clinical trials by relying on the approval of the innovator's drug without having access to the underlying data, not the FDA, which would disclose the innovator's trade secrets, such as proprietary inactive ingredient information to the generic sponsor, as well.

So I would hope that we might be able to get this thing worked out before we go to full committee. And again, I encourage my good friend, Mr. Carter, to insist that we might be able to modify this to make it acceptable to all.

And with that I yield back to my friend from Georgia --

*Mr. Griffith. Mr. Chairman?

*Ms. Eshoo. The --

*Mr. Griffith. Ms. Chairman, would the -- or Madam Chairman, would the gentleman yield?

*Mr. Carter. I yield.

*Mr. Griffith. I would just say I weigh in on this with

Buddy, Mr. Carter, on this issue, but I hope we can work the language out as we move forward. I yield back.

*Ms. Eshoo. The gentleman yields back.

*Mr. Carter. Madam Chair, I appreciate the chair's comments. And with that, Madam Chair, I will withdraw my amendment and yield back with the anticipation and hope that we will work on this in full committee.

*Ms. Eshoo. All right. The gentleman yields back and withdraws his amendment.

At this time, no further debate. We will proceed to a vote.

*Voice. No, no, no --

*Ms. Eshoo. No? Not yet? Oh, you withdrew it.

*Voice. So now Ms. Matsui --

*Ms. Eshoo. Oh, I am sorry. I didn't realize that Ms. Matsui wanted to speak.

The chair -- or pleased to recognize the gentlewoman from California, Ms. Matsui, for five minutes.

*Ms. Matsui. Thank you very much, Madam Chair. I have an amendment at the desk.

*Ms. Eshoo. The gentlewoman has an amendment at the desk.

What is the -- do you -- the clerk will -- do you know -- what is your amendment labeled?

*Ms. Matsui. It looks like it is Matsui01.

*Ms. Eshoo. Okay, the clerk will report the amendment.

*The Clerk. Amendment to the amendment in the nature of a substitute to H.R. 7667, offered by Ms. Matsui of California. Page 182 --

*Ms. Eshoo. Without objection, the reading of the amendment will be dispensed with.

[The amendment of Ms. Matsui follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. And the chair recognizes the gentlewoman for five minutes to speak to her amendment.

*Ms. Matsui. Thank you very much, Madam Chair, and I want to thank FDA, the industry, this committee, and other stakeholders for coming together to reauthorize these critical user fee agreements.

Advancing this legislation will provide FDA with the resources it needs to continue making sure that drugs are safe and effective. However, I am disheartened that this latest authorization omits any efforts to further the use of patient-focused drug development. That is why I am offering this amendment based on the BENEFIT Act, legislation that I co-authored with my colleague on the Ways and Means Committee, Representative Wenstrup, and my bipartisan Senate colleagues, Senators Wicker and Klobuchar.

This amendment revises the BENEFIT act to reflect technical feedback from the FDA. The bill seeks to elevate the patient voice in the drug development process as clear -- and as a clear next step to build upon the work that we have done in previous versions of PDUFA and 21st Century Cures.

Thanks to that work, the FDA now has a framework for collecting patient experience data, and indicating whether a sponsor submitted patient experience data in a new drug application. However, the process currently stops there. Sponsors are not required to submit patient experience data,

nor is the FDA required to indicate whether or how the data affected a review. The BENEFIT Act would require FDA to take the next step.

However, I want to make this point clear: the BENEFIT Act does not require FDA to create a direct relationship to obtain the patient experience data review and the final result of the application. It simply requires FDA to provide additional information on how the agency used patient experience data in its overall analysis.

Patients need to know that their voices don't just go into a black box, that when they take the time to collect and contribute data it has some level of impact.

Madam Chair, I am withdrawing this amendment at this House committee markup, but I appreciate the opportunity to continue to work with you to address any concerns with this legislation. It is vital that we build upon the great work of this committee, and ensure that the patient voice is not left out of this round of PDUFA.

Thank you, and I yield back.

*Ms. Eshoo. Would the gentlewoman yield?

*Ms. Matsui. Yes, I yield.

*Ms. Eshoo. Well, I appreciate your clarification that we are not -- you are not proposing to require FDA to describe whether the patient experience data impacted a specific regulatory outcome. It is -- instead, it is about

how any patient experience information was viewed during a given review. And I don't think that is really asking for too much.

I think that there is a real opportunity to get this straightened out and work with the FDA, because I do think that there is a shared goal of consistent and deeper utilization of patient experience data. So I hope we can work with the FDA to do that before next week's full committee markup.

And thank you for your work, and I yield --

*Mr. Guthrie. Would the gentlelady yield to me, just for --

*Ms. Eshoo. It is the --

*Mr. Guthrie. I know it is Ms. Matsui --

*Ms. Eshoo. -- Matsui's time.

*Mr. Guthrie. I just -- I didn't want to have to strike the last word and go through that.

But I just received a letter from AHIP, which is American Health Insurance Plans, that support the PIE Act, which is in this bill. And so I just wanted to offer that for the record.

And I yield back to the lady from California -- well, both of you are from California -- the lady from Sacramento, California.

*Ms. Matsui. Exactly. Well, thank you very much to

both of you, and I yield back.

*Ms. Eshoo. The gentlewoman yields back.

Is there -- are there any other -- well, no, that amendment has been withdrawn.

So are there any members who seek recognition to offer an amendment to the amendment in the nature of a substitute?

*Mr. Curtis. Madam Chair, this is Representative Curtis --

*Ms. Eshoo. Where is he?

*Voice. He is online.

*Ms. Eshoo. Oh, I am sorry. The gentleman from --

*Voice. Utah.

*Mr. Curtis. Utah.

*Ms. Eshoo. -- Utah, Mr. Curtis, is recognized for five minutes.

*Mr. Curtis. Thank you, Madam Chair. I have an amendment --

*Ms. Eshoo. To offer your amendment, I am sorry.

*Mr. Curtis. Yes, thank you. I have an amendment at the desk, section 814, therapeutic equivalence determination.

*Ms. Eshoo. Okay. The clerk will report the amendment, please.

*The Clerk. Amendment to the amendment in the nature of a substitute to H.R. 7667 --

*Ms. Eshoo. All right.

*The Clerk. -- offered --

*Ms. Eshoo. Without objection, the reading of the amendment will be dispensed with.

[The amendment of Mr. Curtis follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. The gentleman is recognized for five minutes to speak to his amendment.

*Mr. Curtis. Thank you, Madam Chair and Ranking Member Guthrie, for holding this important hearing. I just wish I could be with you today.

I do plan to withdraw my amendment, but I would like to highlight an issue that I have been working on, and that I hope we can consider during this process.

My amendment would modernize the therapeutic equivalence, TE, rate determination. This legislation would help lower the out-of-pocket costs for Utahans and all Americans by speeding up the development and access to lower-cost generics. By leveraging certain data from already-approved drugs, we can safely make the approval process of these drugs more efficient. Requiring FDA to assign a therapeutic equivalence rating for 505(b)(2) applications will level the playing field for these products to come with brand -- to compete with brand-name drugs, lowering the cost of drugs for consumers.

With that, Madam Chair, I withdraw my amendment.

*Ms. Eshoo. The gentleman yields back. If there is no further discussion or amendments, we can now proceed to a vote on the amendment in the nature of a substitute.

All those in favor of the amendment in the nature of a substitute to H.R. 7667 will signify by saying aye.

All those opposed will signify by saying no.

In the opinion of the chair, the ayes clearly have it.

Okay, moving on, moving forward --

*Mr. Griffith. Madam Chair?

*Ms. Eshoo. Yes?

*Mr. Griffith. Was that on the adoption or forwarding it to the full committee?

*Ms. Eshoo. That is a --

*Mr. Griffith. That was just the adoption of the --

*Ms. Eshoo. Of the amendment.

*Mr. Griffith. Thank you.

*Ms. Eshoo. Of the AINS, yes.

We are now going to --

*Voice. Now we are going to voice on the forwarding.

*Ms. Eshoo. Okay, the question now occurs on favorably forwarding H.R. 7667 to the full committee.

All those in favor of forwarding H.R. 7667, as amended, to the full committee --

*Voice. Asked for a roll call.

*Ms. Eshoo. -- and the ranking member requests a roll call vote. A recorded vote is ordered. Those in favor of forwarding 7667, as amended, to the full committee will say aye, and those opposed will say no.

The clerk shall call the roll.

*The Clerk. Mr. Butterfield?

[No response.]

*The Clerk. Ms. Matsui?

[No response.]

*The Clerk. Ms. Matsui?

*Ms. Matsui. Aye.

*The Clerk. Ms. Matsui votes aye.

Ms. Castor?

*Ms. Castor. Aye.

*The Clerk. Ms. Castor votes aye.

Mr. Sarbanes?

*Mr. Sarbanes. Aye.

*The Clerk. Mr. Sarbanes votes aye.

Mr. Welch?

[No response.]

*The Clerk. Mr. Schrader?

*Mr. Schrader. Aye.

*The Clerk. Mr. Schrader votes aye.

Mr. Cardenas?

*The Clerk. Mr. Cardenas votes aye.

Mr. Ruiz?

[No response.]

*Voice. You guys --

*The Clerk. Mrs. Dingell?

*Mrs. Dingell. [Inaudible.]

*The Clerk. Mrs. Dingell votes aye.

Ms. Kuster?

*Ms. Kuster. Ms. Kuster votes aye.

*The Clerk. Ms. Kuster votes aye.

Ms. Kelly?

[No response.]

*The Clerk. Ms. Barragan?

*Ms. Barragan. Barragan votes aye.

*The Clerk. Ms. Barragan votes aye.

Ms. Blunt Rochester?

*Ms. Blunt Rochester. Ms. Blunt Rochester votes aye.

*The Clerk. Ms. Blunt Rochester votes aye.

Ms. Craig?

[No response.]

*The Clerk. Ms. Schrier?

*Ms. Schrier. Schrier votes aye.

*The Clerk. Ms. Schrier votes aye.

Mrs. Trahan?

*Mrs. Trahan. Trahan votes aye.

*The Clerk. Mrs. Trahan votes aye.

Mrs. Fletcher?

*Mrs. Fletcher. Fletcher votes aye.

*The Clerk. Mrs. Fletcher votes aye.

Mr. Pallone?

*The Chairman. Votes aye.

*The Clerk. Mr. Pallone votes aye.

Mr. Guthrie?

*Mr. Guthrie. Aye.

*The Clerk. Mr. Guthrie votes aye.

Mr. Upton?

*Mr. Upton. Votes aye.

*The Clerk. Mr. Upton votes aye.

Mr. Burgess?

*Mr. Burgess. Votes aye.

*The Clerk. Mr. Burgess votes aye.

Mr. Griffith?

*Mr. Griffith. Aye.

*The Clerk. Mr. Griffith votes aye.

Mr. Bilirakis?

*Mr. Bilirakis. Aye.

*The Clerk. Mr. Bilirakis votes aye.

Mr. Long?

*Mr. Long. Aye.

*The Clerk. Mr. Long votes aye.

Mr. Bucshon?

*Mr. Bucshon. Aye.

*The Clerk. Mr. Bucshon votes aye.

Mr. Mullin?

*Mr. Mullin. Mullin votes aye.

*The Clerk. Mr. Mullin votes aye.

Mr. Hudson?

*Mr. Hudson. Aye.

*The Clerk. Mr. Hudson votes aye.

Mr. Carter?

[No response.]

*The Clerk. Mr. Dunn?

*Mr. Dunn. Aye.

*The Clerk. Mr. Dunn votes aye.

Mr. Curtis?

*Mr. Curtis. Curtis votes aye.

*The Clerk. Mr. Curtis votes aye.

Mr. Crenshaw?

*Mr. Crenshaw. Crenshaw votes aye.

*The Clerk. Mr. Crenshaw votes aye.

Mr. Joyce?

*Mr. Joyce. Joyce votes aye.

*The Clerk. Mr. Joyce votes aye.

Mrs. Rodgers?

*Mrs. Rodgers. Aye.

*The Clerk. Mrs. Rodgers votes aye.

Chairwoman Eshoo?

*Ms. Eshoo. Votes aye.

*The Clerk. Chairwoman Eshoo votes aye.

*Ms. Eshoo. Madam Clerk, who is not recorded?

*The Clerk. Mr. Butterfield?

[No response.]

*The Clerk. Mr. Welch?

[No response.]

*The Clerk. Mr. Ruiz?

*Mr. Ruiz. Mr. Ruiz votes aye.

*The Clerk. Mr. Ruiz votes aye.

Ms. Kelly is not recorded. Ms. Craig is not recorded, and --

*Ms. Craig. Ms. Craig votes aye.

*The Clerk. Ms. Craig votes aye.

And Mr. Carter is not recorded.

*Ms. Eshoo. And he was -- been here all morning, too. And so have some of the other members -- at least spent time here.

All right, does any member wish to change his or her vote?

If not, is it -- our side tried to -- we are not -- they are not coming? Okay. All right, well, I am sorry that they are not.

If not, then the clerk will report the tally, please.

*The Clerk. On that vote, Madam Chairwoman, the yeas were 30 and the nays were 0.

*Ms. Eshoo. Wonderful, thank you. Good work, members.

Oh, dear, you missed it. We just finished H.R. 7667. Put your beautiful statement into the record, Peter. Dress it up. Sorry.

All right, H.R. 7667, as amended, is now forwarded to the full committee. We are now going to move to the chair calling up H.R. 7666, the Restoring Hope for Mental Health and Well-Being Act of 2022.

The clerk will report the bill.

*The Clerk. H.R. 7666, a bill to amend the Public Health Service Act to reauthorize certain programs relating to mental health and substance use disorders, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America and Congress assembled, section 1 short title table of Contents. Short title, "This Act may be cited as the Restoring Hope for Mental Health and Well-Being Act'' --

*Ms. Eshoo. Without objection, the first reading of the bill will be dispensed with, and the bill is now considered as read and open for amendment at any point.

[The bill follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. Are there any members seeking recognition to speak on H.R. 7666?

The chair --

*Voice. Madam Chair?

*Ms. Eshoo. The chair recognizes Mr. Guthrie, our ranking member, to speak on the bill.

*Mr. Guthrie. Thank you. Thank you, Madam Chair.

I just want to first say that I know we have had a lot of issues with COVID lockdowns, and children and -- particularly, have been alone, and not been able to socialize, and be -- and have had negative effects. And I just -- you know, hopefully, as we move forward, as we continue to work on mental health and substance abuse issues, we look at that.

Also, illicit fentanyl that we know is coming across the borders not permanently scheduled, if we can move into that area, looking at that area as well.

And also, as we were discussing amongst ourselves on the Republican side about some of the authorization levels as we see in the bill moving forward, and as we started looking at them, some of the authorization levels agreed upon by all of us were because the appropriations levels have increased. And I know that is kind of an age-old issue here in Congress, those who authorize and those who appropriate. But it would be helpful if our appropriators would follow our

authorizations as we move forward. But I do know that, if we -- if they are appropriating to a certain level and we don't authorize that level, it gives a lot more discretion. So I think that is appropriate that we do.

And then I just want to touch that I am proud to say that the Restoring Hope for Mental Health and Well-Being Act is included in this legislation. Also, the Substance Abuse Prevention and Treatment Act Recovery Services Block Grant of 2022. And this would provide continuing and sustainable support for substance abuse disorder, prevention, treatment, and recovery services administered through 2027 to the states.

So the legislation would help to continue to deliver a more coordinated substance use disorder care, as well as explicitly authorize the use of funding for recovery support services, which would include workforce training and peer support services.

These workers are wanted. I know a lot of times people have come out of recovery -- into recovery, and sometimes because of their addiction have had run-ins with the law and records. And I will tell you that I know in my area people were willing to give them a chance because they are wanted, and they are needed. And so this is an opportunity for people to get the training they need to plug in, to find a place, a sense of place. And so I am just glad this is

moving forward.

And I urge my colleagues to vote yes on Restoring Hope for Mental Health and Well-Being, and I yield back.

*Ms. Eshoo. The gentleman yields back. The chair recognizes the chairman of the full committee, Mr. Pallone, for your five minutes of -- for a statement.

*The Chairman. Thank you, Chairwoman Eshoo. The nation, and particularly children and young people, face a growing mental health and substance use crisis, experiencing increasing challenges and barriers to care and services. And I am proud that today we are taking action to help address these challenges by considering this bipartisan package of reforms that Ranking Member Rodgers and I worked on together.

I want to thank the ranking member and her staff for all of their work on this bill. Neither of us got exactly what we wanted, but it represents a compromise, a balanced one that incorporates both Democratic and Republican priorities. And the final product recognizes the need to limit new spending and avoid creating new initiatives that merely duplicate existing programs, but it is a package that represents a shared recognition that we must rise to the moment and provide support and resources for our communities who are suffering. So the bill will bring meaningful support to millions of Americans suffering from mental health and substance use disorders. And I am proud of our bipartisan

effort.

So the bill encompasses the five-year reauthorizations of critical SAMHSA and HRSA public health programs and key additional activities to address this crisis through efforts to support mental health and well-being, prevent suicide, and support substance use disorder, prevention, treatment, and recovery support services.

The Act supports the continued investment and flexibility of the Community Health -- Mental Health Services Block Grant and the Substance Use Prevention, Treatment, and Recovery Service Block Grant. It extends the Maternal Mental Health Screening and Treatment Grant program to enhance maternal mental health and substance use disorder treatment, and reauthorizes grants to support American Indian and Alaska Native communities with mental health and substance use disorder, prevention, treatment, and recovery services.

H.R. 7666 also meets the youth mental health crisis head on through a range of programs, including reauthorizing the comprehensive Community Mental Health Services for Children with Serious Emotional Disturbances program and the Youth and Family Tree Treatment and Recovery Service programs.

The bill also expands access to treatment for opioid use disorders by directing SAMHSA to access flexibility provided to opioid treatment programs during the COVID-19 public health emergency, and reducing unnecessary and arbitrary

barriers to care.

Further, the bill expands the integration of behavioral and physical health care through the reauthorization of the Pediatric Mental Health Care Services Access Grant program to improve the integration of pediatric primary care providers with behavioral health providers via telehealth.

H.R. 7666 improves the integration of evidence-based behavioral health care into primary care settings for the treatment of mental health and substance use disorders.

Particularly timely, in light of the 988 National Suicide Prevention Lifeline dialing code, which was -- which will be launched in July, the bill also establishes a behavioral health crisis coordinating office within SAMHSA.

And lastly, this bill addresses a barrier that, for far too long, has hindered frontline workers' access to mental health services by closing a loophole in current law that allows self-funded state and local government health insurance plans to opt out of mental health parity.

There are, however, several pieces of legislation not included in this package that we are continuing to work on, and I hope we can consider these bills at the full committee markup. I mentioned the MAT Act and the MADE Act, for instance, that would provide critical tools to address the devastating opioid and substance use crisis by removing barriers to medication-assisted treatment, and providing

practitioners with important training and education to better recognize and treat substance use disorder.

So I look forward to moving this legislation forward, and supporting the mental health and well-being of all Americans. And hopefully, we can get these additional items included and have a consensus by the time we come to full committee next week.

So thank you again, Chairwoman Eshoo, and I yield back.

*Ms. Eshoo. The gentleman yields back. The chair is pleased to recognize the ranking member of the full committee, Mrs. Rodgers, for your statement.

*Mrs. Rodgers. Thank you, Madam Chair. I would like to strike the last word.

Our children are in crisis. Last year there was a two-and-a-half-fold increase in emergency department visits for suicidal ideation and self-harm among children under the age of 18. Over the past two years, pandemic fear has dominated our lives and shut us down. And the fear has been forced on our children. Fear, pushed by government arrogance and overreach, kept schools closed and made the crisis worse.

Our kids are hurt by -- the most by the collateral damage of more stress, anxiety, and depression. Youth suicide is the second-leading cause of death in the United States for children aged 10 to 14. This is unimaginable. But every pediatrician, parent, teacher, and mental health

professional I have spoken to raises the alarm.

I think back to a mom who told me in February of 2021, when schools and extracurricular activities were shut down, children feel neglected, ignored, and told they aren't important. That was the wrong message to send children who deserve bright futures. Our message to them is that they matter. They are loved.

I have been saying since I think our first meeting this Congress that we need to tackle and address the mental health issues and the overdoses. And I am encouraged today that we are taking action. This legislation is the most comprehensive effort to date to revive hope and healing since COVID-19 and government COVID-19 policies and school shutdowns worsened a mental health crisis and an overdose crisis in America.

We have been examining several existing SAMHSA and HRSA programs to ensure that they are working and coordinated to help states and community partners make a difference in children's mental health. And I am proud to be leading with Congresswomen Trahan, Kim, and Axne to reauthorize the Garrett Lee Smith Memorial Act. This has helped bring additional mental health resources to places like Washington State University.

I remember the devastation the WSU community felt when they tragically lost the football's quarterback, the football

team's quarterback, to suicide in 2018. This program helped the faculty and students begin the healing process and work to overcome the trauma of losing their classmate.

Another initiative, the Pediatric Mental Health Care Access Program, is a necessary approach to improving access to children's mental health services. This program integrates behavioral health services with pediatric primary care through telehealth, making it easier for providers to coordinate and improve health outcomes. I am glad Dr. Mariannette Miller-Meeks led this important program to make sure it is available in all states.

This committee has done a lot of work looking at maternal mortality in the United States. And I am glad that we were able to build on that, including the Into the Light for Maternal Health Care Act, led by Dr. Burgess and Representative Herrera Beutler.

Adult suicide rates are also alarmingly high. I am encouraged that the mental health package includes provisions from the Reaching Improved Mental Health Outcomes for Patients Act, led by Mr. Griffith and Ms. Tenney, which will improve crisis response care and adult suicide prevention initiatives.

Mr. Crenshaw and Mr. Garcia led on provisions to reauthorize the primary source of funding for states to address mental health, the Community and Mental Health

Services Block Grant.

Clinicians and researchers alike have consistently told us that early intervention is key to helping children and adults experiencing substance use disorder, which is why I am glad we included the language from Dr. Bucshon's legislation, the Timely Treatment for Opioid Use Disorder Act, which removes the one-year wait requirement for a person to enter an opioid treatment program.

We are also reauthorizing SAMHSA's Youth and Family Tree Program, led by Dr. Joyce, which provides comprehensive treatment, early intervention, and recovery support services for youth and their families with substance use disorders.

There are many more examples, and I am proud that we were able to include many bipartisan member priorities in this legislation, and build on the foundation of the programs that exist today. Thank you for that commitment.

I am pleased to be supporting this legislation moving to the full committee, and I urge my colleagues to support it.

I yield back.

*Ms. Eshoo. The gentlewoman yields back. Are there any other members seeking recognition to speak on the underlying bill?

Oh, I am sorry --

*Mr. Guthrie. Do you have any more on your side?

*Voice. We have more people.

*Mr. Guthrie. Okay, okay.

*Ms. Eshoo. We do? Who is next on our side?

*Mr. Guthrie. We have Burgess --

*Ms. Eshoo. The gentlewoman from California is recognized, Ms. Matsui, for five minutes.

*Ms. Matsui. Thank you, Madam Chair. I move to strike the last word.

We are here today to respond to the mental health crisis facing our nation, and it is important that the 29 million Americans who struggle with an eating disorder are included in this conversation.

Since the onset of the pandemic, eating disorder diagnoses have increased 25 percent for kids between 12 and 18 years old. Medical admissions for adolescents with eating disorders more than doubled in 2020. Many primary care physicians, especially pediatricians, have found themselves on the front lines of caring for youth mental health, yet most primary care physicians lack training in eating disorders.

Only 20 percent of medical schools offer elective trainings on eating disorders, and a mere 6 percent require it. And that is why I introduced the Anna Westin Legacy Act legislation that authorizes a center of excellence for eating disorders to continue training health care professionals to screen, intervene, and refer individuals to treatment for

eating disorders. I am pleased to see this bipartisan bill included in this package, and thank my colleagues for your support on this important legislation.

Eating disorders take an enormous toll on a person's mental and physical health. The expert support provided by the center is key to breaking down systemic barriers that historically made it difficult for people, especially children, to get the effective, professional help that they need.

I urge my colleagues to support this bill and reauthorize this important program in a timely manner.

Thank you, Madam Chair, and I yield back.

*Ms. Eshoo. The gentlewoman yields back. The chair is pleased to recognize Dr. Burgess for five minutes.

*Mr. Burgess. Thank you, and I would like to be heard on the bill. This is important work that we are undertaking today.

I would just remind this committee that two Congresses ago President Trump declared a public health emergency because of drug overdose deaths. This committee responded, we did an open Member Day. We heard from, I think, 55 Members of not just the committee, but Members of Congress in general. And under the leadership of -- and Chairman Walden came up with the SUPPORT Act.

The SUPPORT Act took about a year to come through this

committee's process, but in October of 2018 was signed into law. And the effect of the SUPPORT Act was there was a brief but perceptible reduction in overdose deaths in this country, and that is incredibly important.

Now, the pandemic did intervene. A number of other situations were having to be dealt with, and overdose deaths now have begun to increase, and they have increased year over year by an alarming amount.

But here is the bottom line. We can talk about what public health measures we might have to deal with substance use disorder. But if we do not deal with the complete breakdown in security in the southern border of this country -- predominantly my state, but it is also California, Arizona, and New Mexico -- the amount of fentanyl produced in Chinese labs that is being trafficked across the southern border is responsible for those 107,000 deaths that the CDC now records for the last calendar year.

If the Administration was serious about this, it would be serious about protection on the southern border, and recognize that that illicitly-produced fentanyl, which is coming from other countries and then being trafficked across our border, is, in fact, a crisis.

If this were a chemical weapon that had struck down 100,000 of our young people last year, this country would respond, and respond in a significant way. Well, I would

just simply ask, where is the response? Where is the response from our border czar? Where is the response?

Secretary Mayorkas testified to another committee that there was operational control of the southern border. Mr. Secretary, I beg to differ. There is not operational control. There is operational chaos on our southern border, and we have lost 100,000 citizens in the last year because of that inability to respond.

This committee has a history of having responded to this problem in the past, and done so in a way that positively affected the number of overdose deaths. Let's get busy and do that again. Our country is waiting for us.

Thank you, Madam Chair. I yield back.

*Ms. Eshoo. The gentleman yields back.

I think another layer of tragedy is that the United States of America is a demand market. It is a demand market for these horrible drugs. If there wasn't demand in the country, there wouldn't be, you know, the economic impetus of these evildoers trying to get it and successfully getting it into the country online and all of that.

All right. Now, who would like to speak to this on the Democratic side? Do we have any members that wish to speak?

All right, the chair recognizes the gentleman from Maryland, Mr. Sarbanes, for five minutes.

[Pause.]

*Voice. Sorry, it is Cardenas.

*Ms. Eshoo. All right. The chair is pleased to recognize the gentleman from California, Mr. Cardenas, for five minutes.

*Mr. Cardenas. Thank you, Madam Chairwoman. I appreciate this opportunity for us to come together on this -- these important issues.

Mental health has, in fact, affected way too many Americans, and this pandemic has only exacerbated the situation across the country in every neighborhood, in every community, and too many households.

Also, what -- I would like to remind everybody that, as you are all well aware, 988 will go live in July of this year. This three-digit calling code will be a lifeline for those in mental health distress. Given the proximity of the 988 rollout, which is just in two short months, in July of this year, the 988 and Parity Assistance Act in the mental health package that we are deliberating today is also part of this package.

I am very proud of that fact, that we are working together to bring it across -- through the committee and to the floor, and eventually to the President's desk. But I also want to take this moment to make it clear just how far we have to go to make sure that 988 lives up to its promise.

For example, in Ohio, where demand for behavioral health

resources jumped nearly 350 percent, only 8 percent of the chats and texts where people reached out were answered. In New Mexico, a state that saw 128 increase in the calls to National Suicide Prevention Lifeline, only 65 percent of those calls from people in crisis, those calls, were answered. And in South Carolina, without additional funds and staff, it is estimated that, when 988 goes live in just 2 short months, 8 out of 10 calls will not be answered by someone on the other line in that state. We cannot be satisfied with this possibility.

I urge my colleagues to support 988 provisions in this bill. We simply cannot afford to fumble our way through this opportunity. And I think it is very important for us to understand that we in the United States of America have gotten so accustomed to taking for granted 911, we are blessed to take 911 for granted. That means that, across America, when somebody dials 911, they know their call is going to be answered. They know that that urgent moment is going to be met with someone literally coming out to their home, or to the scene of that physical health issue.

But the problem is this: we are not prepared, nor have we been handling ourselves as a country, when it comes to mental health crisis moments. And this is an opportunity for us to assist local governments in making sure that they are ready for the 988 calls that are going to come in, so that

they are able to save lives, so they are able to respond.

But until we do our part at the Federal level to support communities across America, we are going to find ourselves in a situation, as I pointed out earlier, that in South Carolina they already know that they are not going to be able to handle the calls. So it is really important that we do what we can at the Federal level. This is a local government issue, 911 is handled by local law enforcement, it is handled by local firefighters and local paramedics and local hospitals.

And thank God we have a system that we -- it is so robust that we can actually take it for granted. We need to get to the point where 988 is a household-understood reality, that when you call 988, and somebody is having a mental health crisis, or they are contemplating suicide, or there is a drug addiction moment going on in a household or a family in a neighborhood, that somebody is going to come out there, where there is someone to call, and that is 988. Someone will come, and there will be somewhere to go. We are not there yet, ladies and gentleman.

So once again, I urge us to please support the bill on 988 that is before us today, and also that we have much, much more work to do, and hopefully we will continue to work together to make it happen.

So with that, Madam Chairwoman, I yield back.

*Ms. Eshoo. The gentleman yields back.

The chair recognizes the gentleman from Florida, Mr. Bilirakis, for your five minutes.

*Mr. Bilirakis. Thank you, Madam Chair. I move to strike the last word.

I strongly support this amendment and the underlying bill, the Restoring Hope for Mental Health and Well-Being Act.

I want to dedicate my vote today to the great Naomi Judd, who lost her battle with depression, and she lost her battle with mental illness. She made such an impact. She made such an impact on others to seek treatment. And she really did, because she spoke out publicly about this issue. And again, I appreciate her, and she is still making a difference after life.

So the Restoring Hope for Mental Health and Well-Being Act, which authorizes the key SAMHSA block grant programs for mental health and substance use disorder, prevention, and treatment services, it contains a bill from Leader Rodgers that I was proud to cosponsor, which reauthorizes the Garrett Smith Memorial Act Suicide Prevention Program, which will provide resources to states and campuses to prevent suicide in youth.

It is clear that these bipartisan solutions are needed now more than ever before, since we are sadly in the midst of

a mental health crisis in our nation. And it has been accelerated by the COVID pandemic.

Emergency departments' boarding and wait times for placement for teens and children with serious emergency emotional disturbance and other mental health conditions are highly -- again, more than ever they go to the emergency rooms. Just this past weekend the New York Times published a piece discussing a surge in mental health issues among teens, resulting in hundreds of instances of teens at risk of suicide boarding and sleeping in emergency rooms for days or even weeks at a time.

I would like to insert the article -- and I know you alluded to it, Madam Chair -- into the record, please, the New York Times article.

*Ms. Eshoo. So ordered.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Bilirakis. Thank you. The New York Times piece mentions that, despite residential treatment facilities being a much better place for these teens to stay as a calmer, more stabilizing setting, they, sadly, have long waits, an average of 10 days. Some cannot wait that long.

The number of treatment programs for teens under age -- under the age of 18 has fallen by over 30 percent in the past decade, meaning emergency rooms have had to pick up the slack, a problem that has worsened since the pandemic. Experts have called this a national crisis, and it is, and I believe we must be doing more on every level of continuum care.

I am grateful we worked to address this earlier in Congress when we passed my bill, the Effective Suicide Screening and Assessment in the Emergency Department Act, to improve hospital capacity and training to identify risk of suicide, and better connect them with mental health resources.

In addition to this SAMHSA package, I hope we can get both bills to the President's desk as soon as possible. I urge the Senate to pass this bill immediately.

This can also be addressed at the residential level, where there are programs with trauma-informed treatment models that address the mental health and behavioral health needs of children, such as foster youth who put -- who can't

always get full access to Medicaid, due to IMB exclusion -- I do have some time. Unfortunately, this potential solution has not been addressed in today's bills, in neither this package nor the Medicaid bill.

I understand my colleague, Dr. Burgess, will also be addressing this issue later on, and I fully support him and these efforts.

My bipartisan bill that I lead with Representative Castor, and cosponsored by many bipartisan members of this committee, would restore access to qualified residential treatment programs, which should play a role in the continuum of care.

I am disappointed, Mr. Chairman, that we haven't actually addressed this bill, as chairman of the full committee. This issue -- I hope that we address this issue as soon as possible, because we can't have these arbitrary barriers to care, particularly for our children.

We can't afford to wait any longer to address the mental health crisis. This comprehensive SAMHSA mental health package presents much-needed solutions that will give hope to patients, and improve access to mental health care. And I am proud to support it.

But it doesn't mean we should stop here, and I know we won't. We must work together to address suicide and mental health across the nation.

*Voice. And thanks for doing this --

*Mr. Bilirakis. Thank you so very much, I appreciate it.

*Voice. -- need to be --

*Mr. Bilirakis. And I yield back, Madam Chair.

*Voice. That's the [inaudible] people.

*Ms. Eshoo. I am sorry, Mr. Bilirakis. Did you finish?

*Mr. Bilirakis. Yes.

*Ms. Eshoo. Thank you. Thank you for your statement. Thank you for your work. The gentleman yields back.

The chair is pleased to recognize the gentlewoman from Michigan, Mrs. Dingell, for five minutes.

*Mrs. Dingell. Thank you, Madam Chair. I move to strike the last word.

Thank you, Chairwoman Eshoo and Ranking Member Guthrie, again for your work on this mental health legislation, which contains a variety of provisions to reauthorize and improve programs to meet the mental and behavioral health needs of all Americans.

And again, I want to recognize the outstanding efforts of our full committee chairman and ranking member, as well as both the Democratic and Republican Committee staffs for the long hours spent in building consensus and putting together this package.

The Restoring Hope for Mental Health and Well-Being Act

will reauthorize and strengthen critical mental and behavioral health programs, including those that serve at-risk Americans as well as children in rural and under-served communities, those that have been hit hardest by behavioral, mental health, and substance disorders.

I also want to thank you for the inclusion of a provision my colleague, Congresswoman Katie Porter, and I led as part of the Mental Health Justice and Parity Act of 2022. This provision closes a critical gap in health care coverage for mental health and substance abuse treatment for frontline workers who are covered by the approximately 180 state and local government plans that have opted out of these mental health and substance use disorder parity protections.

Fixing this coverage gap will allow thousands of first responders, public school teachers, and other city and state workers to receive the care that they need. An independent estimate showed this fix is likely to be cost neutral, or potentially even save on overall health care costs.

Inclusion of this provision shows the bipartisan willingness of committee leadership and my colleagues to strengthen mental and behavioral health coverage. These benefits are critical to the health and well-being of our frontline workers.

I have been -- yesterday I met with a group of nurses from the University of Michigan who talked about how -- the

mental health state of so many of their workers as they are getting ready for another surge. I have been holding town hall meetings with these nurses --

[Audio malfunction.]

*Mrs. Dingell. -- scared. I have met with the family of a nurse who committed suicide in Wyandotte, Michigan just a few weeks ago. And it is over and over and over. We have to do something.

And I know all of my colleagues -- this bill is a beginning. But as my colleagues are saying on both sides of the aisle, many of us have lived it ourselves. You don't know the desperation, the hope that people need. And especially for our young people, they don't have it. There are no beds, there are no providers. There is no one to take care of so many of these young people.

In my own family, a cousin was looking for help, couldn't find it. Her daughter went to a gun store, bought a gun, learned how to use it, came home, and shot herself to death in the bathtub. And we are luckier than 99 and 9/10 of the people in this country. We have a crisis. We can't stop.

Finally, I would also like to mention the issue of co-prescribing, a proven intervention that reduces overdoses and saves lives. My colleague, Congressman French Hill, and I have legislation, the Preventing Overdoses and Saving Lives

Act 2.0, whose inclusion would further strengthen the legislation before us today. As the package advances, I would like to continue to explore ways with committee leadership and my colleagues to include these important bipartisan provisions.

With that being said, this is a strong package that deserves our support. I just hope all of us won't stop. We will keep fighting, because there are too many people that need help right now.

Thank you, Madam Chair, and I yield back.

*Ms. Eshoo. The gentlewoman yields back. The chair is pleased to recognize the gentleman from Utah, Mr. Curtis, for your five minutes.

*Mr. Curtis. Thank you, Madam Chair. I move to strike the last word.

I would like to thank the chair and the ranking member for including my legislation, the Helping Enable Access to Lifesaving Services, or the HEALS Act, in the mental health package today. This bill will help address the workforce shortages we are facing that have been talked about in this hearing today in the mental health behavioral health space.

And with that, Madam Chair, I yield my time back.

*Ms. Eshoo. Wow. That is --

*Mr. Curtis. That is how you do it.

*Ms. Eshoo. -- extraordinary. That is the way. Now

you are talking.

Okay, now the chair now recognizes the gentlewoman from Delaware, Ms. Blunt Rochester, for your five minutes.

*Ms. Blunt Rochester. Thank you, Madam Chair, and I move to strike the last word.

[Pause.]

*Voice. She is recognized.

*Ms. Eshoo. You are recognized.

*Ms. Blunt Rochester. Thank you so much. Thank you for the recognition, and especially thank you for your leadership.

From news reports, current research, and from our very own constituents we have all heard about the significant mental health challenges that young people in this country are facing. Last year the U.S. Surgeon General issued a youth mental health crisis advisory, and leading youth mental health stakeholders declared a national state of emergency in children's mental health.

Investing in services and supports that promote timely access to pediatric mental health care could not be more urgent. That is why I am disappointed that we were not able to come to an agreement on the legislation -- my legislation, Helping Kids Cope Act, or Chairwoman Eshoo's Strengthening Kids Mental Health Act Now. These bipartisan bills were designed to address the fragmented pediatric mental health

care system we have today.

I have heard some of my colleagues talk about the fact that there are the New York Times stories, 60 Minutes, we are hearing it from our constituents, but that they believe this legislation is duplicative of existing programs. But if existing programs alone are meeting the needs of our nation's youth and children, why are we facing such a severe youth mental health crisis now?

Why is it that, even before the pandemic, rates of depression, anxiety, and suicidal thoughts among young people were trending up? Nearly 80 percent of American youth with mental health problems do not receive treatment from a specialized mental health care provider. And to me, that indicates that the system is not working.

I am grateful that we are reauthorizing very important mental health programs in this bipartisan package. Many of these programs have demonstrated the value of investing in and implementing systems of care and supports, particularly for youth with the most serious mental health illnesses. But we should not stop there. We should build on those successes, take the lessons learned, and apply them to all children.

The majority of children who face mental health challenges do not experience the most serious mental health illnesses, but they are still deserving of our support. We

must invest in the entire spectrum of care, from primary care to inpatient care, through enhancements to existing programs and also new initiatives.

I urge my colleagues to join me in creating a system where all children, all youth, can live their healthiest and most fulfilling lives.

Thank you, Madam Chair, and I yield back.

*Ms. Eshoo. We thank the gentlewoman for her beautiful statement.

The chair is now pleased to recognize the gentleman from Texas, Mr. Crenshaw, for your five minutes.

*Mr. Crenshaw. Thank you, Madam Chair. I move to strike the last word.

A few years ago I was introduced -- I am sorry, wrong one.

It has been said already, but I know everyone on this committee is alarmed by the escalating rates of suicide, depression, and anxiety in our districts and states, and I am particularly concerned for our teenagers, who, on top of longstanding challenges related to just being a teen, have also had to deal with drastic changes to their normal life because of pandemic lockdowns and school closures and, of course, social media that is actively changing the way their brains process information and emotions.

We have talked with pediatricians, counselors,

psychiatrists, schools, and hospitals in Houston, and they are all struggling with this new mental health crisis. And frankly, we are still trying to figure out how exactly to reach our young people with the treatments that actually work for them.

I am glad we have put together this package of bills, and I am glad to work with people on the committee who are equally concerned about our mental health. I am grateful to the chair and ranking member for including my bill, the Community Mental Health Services Block Grant Reauthorization, in this package.

Many of you know this is a block grant to states empowering them to establish new pilot projects. This bill will help them find new ways of treating mental health in hard-to-treat populations like teenagers. And it will also help them maintain successful ongoing programs like the Texas Child Mental Health Care Consortium.

I am grateful to my friends, Representatives Butterfield, Garcia, and Luria, for introducing this bipartisan bill with me, and I yield back.

*Ms. Eshoo. The gentleman yields back.

The chair now recognizes the gentlewoman from Minnesota, Ms. Craig, for your five minutes.

*Ms. Craig. Thank you. Thank you so much, Madam Chair. I would like to speak today in support of H.R. 7666, the

Restoring Hope for Mental Health and Well-Being Act, which will provide desperately-needed mental health resources to our communities and to those in crisis.

I am particularly pleased that title C consists of the mental health services bill I introduced with Mr. Griffith, Reaching Improved Mental Health Outcomes for Patients.

As my colleagues have noted today, we are dealing with a mental health crisis in this country, especially among our youth. It is hard to overstate the devastating mental health impact of this pandemic, which, of course, makes the need to reauthorize these SAMHSA programs all the more critical.

Today's bill would reauthorize seven existing programs to address our community's mental health needs and suicide prevention. These programs include the Mental Health Awareness and Training Grant, which helps first responders, law enforcement, and school personnel recognize the signs of serious mental illness, and employ de-escalation techniques.

The training grants also help build connections between school and community-based mental health agencies so individuals in crisis can be referred to the appropriate services. For the rural communities in my district, these types of programs provide a lifeline to the community and those in crisis. For example, the Northfield Healthy Community Initiative is using the grant they received to provide evidence-based crisis prevention trainings to over

3,000 school personnel, law enforcement, first responders, health care providers, high school students, and veterans.

I urge my colleagues to support this vital legislation.

Thank you, Madam Chair, and I yield back.

*Ms. Eshoo. The gentlewoman yields back.

I understand there aren't any other Republicans to speak, so I will go to Dr. Schrier of Washington State for your five minutes.

[Pause.]

*Ms. Eshoo. All right. We will go to the gentlewoman from Texas, Mrs. Fletcher, for your five minutes.

*Mrs. Fletcher. Thank you, Madam Chairman. I am thrilled to have my legislation, H.R. 5218, the Collaborate in an Orderly and Cohesive Manner bill, included in H.R. 7666, the Restoring Hope for Mental Health and Well-Being Act of 2022.

The collaborative care model is a measurement-based model that integrates behavioral health within the primary care setting, and features a primary care physician, a psychiatric consultant, and care manager, all working in tandem to provide care and ensure patients are improving.

And we know that it works. There are more than 90 published trials demonstrating its efficacy in different settings for both adults and children. Most recently, a study found that the collaborative care model was associated

with reductions in racial disparities in mental health screening among pregnant and postpartum women, an issue that I know is particularly important to members of our committee. And additional studies have shown that the model lowers total cost of care, reduces stigma related to mental health, and improves health equity.

It is also a workforce multiplier. An analysis by the Meadows Institute found that the collaborative care model can leverage psychiatrist time three-and-a-half times over. Extending the reach of our psychiatrists is imperative, as we work to address demand in the face of workforce shortages.

The collaborative care model is covered by Medicare, most private insurers, and many state Medicaid programs. This alleviates the huge financial burden that can often be associated with accessing mental health care.

Despite its proven effectiveness, implementation of the collaborative care model remains low because of the upfront costs. My bill addresses this roadblock by providing grant funding for primary care physicians and practices looking to adopt the model.

I urge my colleagues to pass this important piece of legislation to address the mental health crisis that we are facing in the United States, and I thank you, and yield back.

*Ms. Eshoo. The gentlewoman yields back.

Colleagues, it is my understanding that votes are going

to be called. It is going to be, what, quite a series of -- 2:00, about 2:00? So let's see if we can't wrap all of this up, because members are really not going to want to come back to finish out two smaller parts of -- well, I shouldn't say small, everyone feels -- very, very important last two parts of this bill.

*Mr. Long. Second [inaudible].

*Ms. Eshoo. Pardon me?

*Mr. Long. [Inaudible.]

[Laughter.]

*Ms. Eshoo. Okay, thank you. So we are going to finish now with statements from members with Dr. Schrier.

You are recognized for five minutes.

*Ms. Schrier. Thank you, Madam Chair. I move to strike the last word, and speak on the underlying bill.

First and foremost, again, I want to thank you, Chairman Pallone, all the committee staff that went -- that worked hard to get this package through on mental and behavioral health.

These reauthorizations really meet the moment that we are in, because the moment is dire. Rates of depression, anxiety, eating disorders, self-harm, suicidality have all been on the rise in kids since 2007. And this was then exacerbated further by all of the various stressors relating to the pandemic. So now we are in a pediatric mental health

crisis, and our kids really need us to step up.

But one big problem is that we are seriously lacking in behavioral health specialists, particularly in rural areas. And anything we can do to extend the reach of the specialists we do have helps kids. That is why I am happy that my bill, the Supporting Children's Mental Health Care Access Act, is included in today's markup.

These provisions reauthorize vital HRSA and SAMHSA programs for kids. And section 402 of this bill authorizes the Infant and Early Childhood Mental Health Grant program under SAMHSA, which funds mental health interventions for children birth to 12.

Section 401 of this bill authorizes the Pediatric Mental Health Care Access Program, and these programs give pediatricians quick access to mental and behavioral health specialists for right-there, on-the-spot consultation and guidance. And I can't tell you how important this has been to me.

An example of this is the Partnership Access Line, or PAL, a resource I used as a practicing pediatrician, because pediatricians do treat psychiatric conditions, lots of them. But every now and then a case will arise when we really need to consult with a specialist. And that is where PAL comes in. One on-call psychiatrist can advise hundreds of pediatricians, really leveraging that expertise and reaching

far more kids than he or she ever could in their own practice. It is just one way to allow the limited workforce we do have to stretch a little further while we find ways to train up more mental health care specialists.

Right now, emergency departments, as you know, are overflowing with children who are thinking about hurting themselves, who can't go home. These children need social workers, psychologists, counselors, psychiatrists. Last month Seattle Children's kept 72 patients in the ER for over 16 hours, just waiting for care. We need more pediatric specialists. For now let's stretch them with programs like PAL.

And I look forward to working with this committee to shore up the pediatric mental health workforce.

Thank you, and I yield back.

*Ms. Eshoo. The gentlewoman yields back.

Now it is my understanding that everyone that wished to speak has spoken, and that a recorded vote is ordered.

Those in favor of forwarding H.R. 7666 to the full committee will say aye; those opposed will say no.

And the clerk shall call the roll. My understanding that -- we want a roll call vote, yes? Okay.

So, Madam Clerk, please proceed.

*The Clerk. Mr. Butterfield?

[No response.]

*The Clerk. Ms. Matsui?

*Ms. Matsui. Aye.

*The Clerk. Ms. Matsui votes aye.

Ms. Castor?

[No response.]

*The Clerk. Mr. Sarbanes?

*Mr. Sarbanes. Aye.

*The Clerk. Mr. Sarbanes votes aye.

Mr. Welch?

*Mr. Welch. Aye.

*The Clerk. Mr. Welch votes aye.

Mr. Schrader?

*Mr. Schrader. [Inaudible.]

*The Clerk. Mr. Schrader votes aye.

Mr. Cardenas?

[No response.]

*The Clerk. Mr. Cardenas?

[No response.]

*The Clerk. Mr. Ruiz?

*Mr. Ruiz. Aye.

*The Clerk. Mr. Ruiz votes aye.

Mrs. Dingell?

*Mrs. Dingell. Aye.

*The Clerk. Mrs. Dingell votes aye.

Ms. Kuster?

*Ms. Kuster. Aye.

*The Clerk. Ms. Kuster votes aye.

Ms. Kelly?

[No response.]

*The Clerk. Ms. Barragan?

[No response.]

*The Clerk. Ms. Blunt Rochester?

*Ms. Blunt Rochester. Blunt Rochester votes aye.

*The Clerk. Ms. Blunt Rochester votes --

*Mr. Cardenas. Cardenas votes aye.

*The Clerk. -- aye.

Ms. Craig?

*Ms. Craig. Ms. Craig votes aye.

*The Clerk. Ms. Craig votes aye.

Ms. Schrier?

*Ms. Schrier. Schrier votes aye.

*The Clerk. Ms. Schrier votes aye.

Mrs. Trahan?

*Ms. Eshoo. Is that Mr. Cardenas that said he voted aye?

*Mr. Cardenas. Cardenas, aye.

*Ms. Eshoo. Mr. Cardenas, was that you?

[No response.]

*The Clerk. Mr. Cardenas votes aye.

*Ms. Barragan. Is Ms. Barragan recorded?

*The Clerk. No, you are not.

*Ms. Barragan. Barragan votes aye.

*The Clerk. Ms. Barragan votes aye.

Mrs. Trahan?

[No response.]

*The Clerk. Mrs. Fletcher?

*Mrs. Fletcher. Fletcher votes aye.

*The Clerk. Mrs. Fletcher votes aye.

Mr. Pallone?

*The Chairman. Pallone votes aye.

*The Clerk. Mr. Pallone votes aye.

Mr. Guthrie?

*Mr. Guthrie. Aye.

*The Clerk. Mr. Guthrie votes aye.

Mr. Upton?

*Mr. Upton. Votes aye.

*The Clerk. Mr. Upton votes aye.

Mr. Burgess?

*Mr. Burgess. Votes aye.

*The Clerk. Mr. Burgess votes aye.

Mr. Griffith?

*Mr. Griffith. Aye.

*The Clerk. Mr. Griffith votes aye.

Mr. Bilirakis?

*Mr. Bilirakis. Aye.

*The Clerk. Mr. Bilirakis votes aye.

Mr. Long?

*Mr. Long. Aye.

*The Clerk. Mr. Long votes aye.

Mr. Bucshon?

*Mr. Bucshon. Aye.

*The Clerk. Mr. Bucshon votes aye.

Mr. Mullin?

*Mr. Mullin. Aye.

*The Clerk. Mr. Mullin votes aye.

Mr. Hudson?

*Mr. Hudson. Aye.

*The Clerk. Mr. Hudson votes aye.

Mr. Carter?

*Mr. Carter. Aye.

*The Clerk. Mr. Carter votes aye.

Mr. Dunn?

*Mr. Dunn. Aye.

*The Clerk. Mr. Dunn votes aye.

Mr. Curtis?

*Mr. Curtis. Curtis votes aye.

*The Clerk. Mr. Curtis votes aye.

Mr. Crenshaw?

*Mr. Crenshaw. Crenshaw votes aye.

*The Clerk. Mr. Crenshaw votes aye.

Mr. Joyce?

*Mr. Joyce. Joyce votes aye.

*The Clerk. Mr. Joyce votes aye.

Mrs. Rodgers?

[No response.]

*The Clerk. Chairwoman Eshoo?

*Ms. Eshoo. Votes aye.

*The Clerk. Chairwoman Eshoo votes aye.

*Mr. Bucshon. May I ask how I am recorded?

*Ms. Eshoo. Certainly. How is Dr. Bucshon --

*The Clerk. Mr. Bucshon votes aye.

*Voice. Mrs. Rodgers.

*Ms. Eshoo. Mrs. Rodgers?

*Voice. Mrs. Rodgers.

*Ms. Eshoo. Mrs. Rodgers?

*Mrs. Rodgers. Rodgers votes aye.

*Ms. Eshoo. There she is.

*The Clerk. Mrs. Rodgers votes aye.

*Ms. Castor. Madam Chair?

*Ms. Eshoo. Yes, the gentlewoman from Florida.

*Ms. Castor. Votes aye.

*The Clerk. Ms. Castor votes aye.

*Ms. Eshoo. Who is not recorded?

*The Clerk. Mr. Butterfield?

[No response.]

*The Clerk. Ms. Kelly?

[No response.]

*The Clerk. And --

*Ms. Eshoo. Anyone wish to change --

*The Clerk. And Mrs. Trahan.

*Ms. Eshoo. -- his or her vote?

*Voice. Mrs. Trahan is supposed to be on the way.

*Ms. Eshoo. On the way? We need to take up the rest of the bills, so --

*Voice. They say she's two seconds away.

*Ms. Eshoo. Two seconds?

There you are. How does Mrs. Trahan from Massachusetts vote?

*Mrs. Trahan. Aye.

*The Clerk. Mrs. Trahan votes aye.

*Ms. Eshoo. Okay. All right. The clerk will report the tally, please.

*The Clerk. On that vote, Madam Chairwoman, the yeas were 32 and the nays were 0.

*Ms. Eshoo. Wonderful. All right. H.R. 7666 is forwarded to the full committee.

All right. Now the chair now calls up H.R. 7233, the Keeping Incarceration Discharges Streamlined for Children and Accommodating Resources in Education Act, or called the KIDS CARES Act.

The clerk will report the title of the bill.

*The Clerk. H.R. 7233, a bill to amend title 19 of the Social Security Act to provide --

*Ms. Eshoo. Without objection, the first reading of the bill will be dispensed with. The bill is now considered as read.

[The bill follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. Without objection, the bill is considered as read and open for amendment at any point.

Are there any members seeking recognition to speak on H.R. 7233?

The chair --

*Mr. Hudson. Would this be an appropriate --

*Ms. Eshoo. Yes, yes, I am.

*Mr. Hudson. -- time to introduce an AINS?

*Ms. Eshoo. Yes. The chair recognizes the gentleman from North Carolina, Mr. Hudson.

*Mr. Hudson. I thank the chairwoman. I would like to offer an amendment in the nature of a substitute on H.R. 7233, the KIDS CARE Act.

I am proud to lead H.R. 7233, along with Representative Kuster --

*Ms. Eshoo. Just a minute, Mr. Hudson.

*Mr. Hudson. Yes, ma'am.

*Ms. Eshoo. The clerk needs to report the bill.

*The Clerk. Amendment in the nature of a substitute to H.R. 7233, offered by Mr. Hudson of North Carolina.

Strike all after the enacting clause, and insert the following: section 1 --

*Ms. Eshoo. All right. Without objection, the reading of the amendment will be dispensed with.

[The amendment of Mr. Hudson follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. And Mr. Hudson is recognized for five minutes.

*Mr. Hudson. I thank the chairwoman. The KIDS CARE Act would support kids as they transition out of incarceration by having state Medicaid programs establish a plan to conduct physical, mental, and behavioral health screenings for eligible children prior to release from prison.

After the screenings, these children would then be offered a referral service to seek additional help, support, and services based on their own specific needs.

This bill also aims to improve school-based health services. Currently, elementary and high schools have the ability to provide and receive reimbursement for certain health services carried out within the school system. However, we have heard from school administrators that this submission and claims process is burdensome, disjointed, and confusing, essentially making it unworkable.

Our bill would direct the Centers for Medicare and Medicaid Services to update its school-based claims guide, including providing best practices for schools and school health centers. This would help schools cut red tape, decrease administrative burdens, and increase the availability of already existing services. This is especially important for small and rural school districts like those in my community, which are more likely unable to

manage the bureaucratic burdens.

Taken together, the common-sense solutions in this bill will go a long way towards reducing recidivism in our youth population. In talking to our own North Carolina department of health and human services and department of juvenile justice and delinquency prevention, we received much support and very helpful feedback on this legislation. Experts not only agree that not only will the screenings and referral process help establish a landing spot for these recently released, but they will improve coordination of services and greatly improve the overall well-being of our vulnerable kids.

I would encourage other members of the committee to talk to your own state agencies on the impact this bill will bring to your states.

Along these lines, the AINS I am offering today would incorporate some technical assistance, as well as some of the feedback we received directly from our state partners. The AINS would add a case management transition service for the 30 days post-release to help coordinate the necessary referrals and next steps upon reentry to society.

I am proud of the work we have done on this bill. I want to again thank Representative Kuster for working with me, and I urge my fellow committee members to consider favorably and adopt the AINS.

And with that, Madam Chair, I will yield back.

*Ms. Eshoo. All right, the gentleman yields back.

Is there anyone on our side that wishes to speak on the amendment?

If not, we will go to ranking member the full committee, Mrs. Rodgers.

*Mrs. Rodgers. Thank you, Madam Chair. I would like to strike the last word. I would like to thank Mr. Hudson and Ms. Hinson for their important work on the KIDS CARE Act. This is a targeted approach to supporting kids in need that have -- that will have an important impact.

We know that children in Medicaid and children in the criminal justice system are disproportionately likely to have mental health or behavioral health needs. That is why it is so important that we are improving access to care for these kids wherever possible. The KIDS CARE Act will make improvements to the Medicaid program by requiring screenings and case management for children living in incarceration, and by improving the ability for schools to reimburse for Medicaid services, a place where a majority of children who need mental and behavioral health care services have reported receiving such care.

I do want to make one note regarding the spending in this markup. Many of the bills in the markup authorize discretionary spending, and often at the currently

appropriated levels, meaning that our committee has authorized the appropriators and the Federal agencies certain parameters and limits for the eventual appropriation and usage of taxpayer dollars. Those dollar amounts are ultimately set every year in our annual appropriations bill.

A few provisions and bills that we have entered -- included in this package will have mandatory spending implications. I want to -- I would -- I want to commit to colleagues that when the mental health package from Energy and Commerce is on the floor, that any mandatory spending will be fully offset. That -- this has been the case for a number of bipartisan bills with mandatory spending that have moved through this committee in the past, including the SUPPORT Act. So I would like to ask the Chairman if he would be willing to work with me on the mandatory spending in the mental health package before consideration on the floor.

*Ms. Eshoo. Is the gentlelady yielding?

*Mrs. Rodgers. I yield, yes.

*The Chairman. The packages will be offset, of course, if that is what you are asking. We will do that.

*Mrs. Rodgers. Okay, that would be great.

*The Chairman. Before we go to floor.

*Mrs. Rodgers. Okay. I look forward to supporting this legislation in the full committee and on the floor, and I urge my colleagues to join me.

Thank you, I yield back.

*Ms. Eshoo. All right. We don't have any other speakers on our side on this amendment. Any on the Republican side?

*Mr. Guthrie. We are done. Yes, we are done.

*Ms. Eshoo. All right. The chair now recognizes herself with an amendment at the desk.

The clerk will report the amendment, please.

*The Clerk. Amendment to the amendment in the nature of a substitute to H.R. 7233, offered by Ms. Eshoo of California.

At the end --

*Ms. Eshoo. Without objection, the reading of the amendment will be dispensed with.

[The amendment of Ms. Eshoo follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. And the chair recognizes herself.

Colleagues, in the interest of time I am not going to -- I am going to put my full statement in the record and just say that this amendment directs CMS to provide very important Medicaid guidance documents to the states about how to better provide support for mental health services. We are all on this issue of mental health services, a need for integration so that everyone that needs the help that is -- has risen to a crisis level in our country will be able to get it.

So I just -- this is a shorthand on what the amendment is. I know you have all prepared for the hearing, and you have read about it, so I will put the rest of my -- I will put a full statement in the record.

Is there anyone that would like to speak on this amendment?

All right. Not seeing or hearing anyone, the -- let's see. We are going to go to a vote here. Wonderful to skip pages in this binder.

If there is no further debate, we are going to proceed to a vote on the two amendments.

*Voice. No, just --

*Ms. Eshoo. No? On mine first, yes?

*Voice. Yes, just on -- no, no, no. We have to vote on hers before we go to another one.

*Ms. Eshoo. All right, all right. So all those in

favor of the amendment will signify by saying aye.

Those opposed?

In the opinion of the chair the ayes have it. The amendment is agreed to.

Are -- and -- well, we have a further amendment, correct? And how do want -- do a -- a voice vote, or to --

*Voice. No, no, go backwards.

*Ms. Eshoo. Oh, there are other amendments. I am sorry.

All right, then, we will go now to -- the chair will recognize Mr. Burgess. For what purpose does the -- is he here?

*Voice. Yes, he is there.

*Ms. Eshoo. Oh, I don't see him. Okay. For what purpose does the member seek recognition?

*Mr. Burgess. I do have an amendment at the desk.

*Voice. You ask him which one, because he has two.

*Ms. Eshoo. Yes, would the -- would you signify which amendment --

*Mr. Burgess. The IMD exclusion Burgess amendment.

*The Clerk. What is the file name of your amendment?

*Mr. Burgess. One forty.

*Ms. Eshoo. Turn your microphone on. I don't think she can hear you.

*Voice. I think it's Burgess140.

*Ms. Eshoo. Burgess140? Okay.

*The Clerk. I have the amendment.

*Ms. Eshoo. All right.

*The Clerk. Amendment to H.R. 7233, offered by Mr. Burgess of Texas.

At the end, the following: section blank. Lifting --

*Mr. Burgess. I ask unanimous consent the amendment be --

*Ms. Eshoo. Without objection, the reading of the amendment will be dispensed with.

[The amendment of Mr. Burgess follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. And the member is -- Dr. Burgess is recognized to speak on his amendment.

*Mr. Burgess. I thank the chair. This amendment would further lift the Institute for Mental Disease exclusion by allowing for a state plan amendment an option to provide treatment for individuals with serious mental illness and substance use disorder in an institute for mental disease.

Specifically, this amendment would codify and expand SMI18-011, which was included in the SUPPORT Act, lifting the IMD exclusion for substance use disorder under a state 1115 waiver.

Additionally, this amendment would increase the average length of stay permitted in an institute for mental disease for serious mental illness and substance use disorder from 30 days to 45 days.

Through reasonable at the time of its creation, the IMD exclusion was initially enacted in 1965 as a way to ensure that state and -- the community responsibility for mental health treatment, and avoiding unnecessary institutionalization. However, it is important for our laws to evolve with the progress of medicine and science. Thankfully, the way mental illness is understood and treated has greatly evolved since 1965. Yet the IMD exclusion has served as significant -- as a significant barrier for individuals seeking inpatient behavioral health care.

This law deserves modernization, as it limits the number of beds available, the days in which an individual can receive care, and disproportionately it affects Medicaid beneficiaries who are often those with the greatest need for these services. Access to inpatient behavioral health care is of essence right now, and the Institute for Mental Disease exclusion is one of the great inhibitors of progress.

Our nation was already facing the opioid epidemic and the mental health crisis prior to the pandemic, and now we are witnessing the crisis worsening. This targeted approach would enable states the flexibility to increase access to inpatient care for those who truly need it.

Now, I understand there is additional work that is going to be done on this between now and the time of the full committee markup, and for that I am very grateful to the chairman of the full committee for that consideration. So at present, while I have submitted the amendment, I would ask unanimous consent to withdraw it, and we will await further activity at the time of full committee markup.

*Ms. Eshoo. All right, the gentleman is withdrawing his amendment.

Are there any members who seek recognition to offer an amendment in the nature of a --

*Ms. Blunt Rochester. Madam Chair?

*Ms. Eshoo. -- substitute.

*Ms. Blunt Rochester. Madam Chair, I have an amendment at the desk.

*Ms. Eshoo. All right, the -- for what purpose does the member seek recognition?

*Ms. Blunt Rochester. Madam Chair, thank you so much for the recognition.

[Inaudible] I am offering today is based on the bipartisan telehealth [inaudible] --

*Ms. Eshoo. Just a minute. Just a minute.

*Ms. Blunt Rochester. [Inaudible.]

*Ms. Eshoo. What is your amendment labeled, first?

*Ms. Blunt Rochester. Okay, it --

*Ms. Eshoo. And then the clerk needs to report the amendment.

*Ms. Blunt Rochester. It is H7233 --

*Ms. Eshoo. All right.

*Ms. Blunt Rochester. -- [inaudible].

*Ms. Eshoo. All right, the clerk will report the amendment, please.

*The Clerk. Amendment to the amendment in the nature of a substitute to H.R. 7233, offered by Ms. Blunt Rochester of Delaware.

At the end, the following --

*Ms. Eshoo. All right. Without objection, the reading of the amendment will be dispensed with.

[The amendment of Ms. Blunt Rochester follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. The gentlewoman is recognized for five minutes -- or less, if you can -- so please proceed.

*Ms. Blunt Rochester. Thank you, Madam Chairwoman. The amendment I am offering today is based on the bipartisan Telehealth Improvement for Kids' Essential Services, or TIKES Act, which helps states better understand how to increase access to telehealth under Medicaid and CHIP.

And although telehealth services have been available in many [inaudible], telehealth usage has increased significantly during the pandemic and is now an important modality addressing mental, emotional, and behavioral health issues.

In April 2020 the Centers for Medicare and Medicaid Services issued a state Medicaid and CHIP Telehealth Toolkit, which was meant to assist states in expanding the use of telehealth services. They have since updated the toolkit with important policy [inaudible] considerations related to COVID-19.

This amendment will require HHS to regularly update the guidance to clarify strategies to overcome existing barriers, and to ultimately increase access to telehealth under Medicaid and CHIP. The guidance will give great examples to people of the best practices and the types of things that are covered, including billing codes and just how to simplify the work that they do to align with licensing and enrollment, and

the integration of telehealth into value-based care models.

We look forward to supporting this, and I especially want to thank my colleague, Mr. Burgess, for working with me on this important bipartisan policy.

Again, I am pleased that we are considering mental health legislation today, and I encourage my colleagues to support the amendment and the underlying bill.

Thank you, and I yield back.

*Mr. Burgess. With the gentlelady yield?

*Ms. Blunt Rochester. Yes, I will yield to the gentleman.

*Mr. Burgess. I thank the gentlelady for yielding. And I -- you know, I have had a lot of discussions throughout this pandemic for doctors and patients, all of whom have sung the praises of telehealth.

And look, let's be honest, we are not going back to the status quo, where we were before the pandemic. This technology was helpful in keeping people out of waiting rooms and out of the doctors' offices during the pandemic, but it also contains much promise for the future of health care. And we certainly cannot forget the children as we craft these telehealth policies.

So this amendment will improve telehealth usage in Medicaid programs, and would require updates to the Trump Administration's guidance to issue best practices to states

how to enhance telehealth in Medicaid.

I urge everyone to support this amendment. It is a great amendment. I thank my colleague, Blunt Rochester, for bringing it forward.

And I will yield back.

*Ms. Blunt Rochester. Thank you, sir, and I yield back, Madam Chair.

*Ms. Eshoo. The gentlewoman yields back.

We thank the members for the work that they have done on this. Is there any other member that seeks recognition to speak to the amendment?

All right. If not, then we will move on.

All those in favor of the amendment will signify by saying aye.

All those opposed will signify by saying no.

In the opinion of the chair, the ayes have it. The amendment is agreed to.

Are there any further amendments to the amendment in the nature of a substitute?

All right. The chair recognizes Dr. Burgess for five minutes.

*Voice. Offer the amendment.

*Ms. Eshoo. To offer the amendment, yes.

And then the clerk needs to take it from there.

*The Clerk. Amendment to H.R. 7233, offered by Mr.

Burgess of Texas. At the end, the following: section blank, removal of inmate limitation on benefits for Medicaid --

*Ms. Eshoo. Without objection, the reading of the amendment has been stated, and will be dispensed with.

[The amendment of Mr. Burgess follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. Mr. Burgess, you are recognized to speak on your amendment.

*Mr. Burgess. Thank you. Currently, the Medicaid inmate exclusion policy denies Federal benefits to individuals who are incarcerated. The exclusion applies to both those who have been found guilty of a crime and those held pending adjudication who are still presumed innocent because they have not been proven guilty. This denial of Federal benefits shifts the full financial burden of health care of inmates to local jails and local taxpayers.

The bill amends the Medicaid inmate exclusion policy to ensure that states have the option to provide Medicaid coverage for pre-trial detainees. Additionally, the bill provides grant dollars for the Department of Health and Human Services to award to states for implementing this policy and improving the quality of care provided in jails by enhancing the network of providers available to treat this population.

So once again, though, I recognize that there is going to be additional work done between now and the time of the markup of the full committee. So, Madam Chair, I would ask unanimous consent to withdraw the amendment at this time, and look forward to working with the chairman as we work toward full committee.

*The Chairman. Mr. -- Dr. Burgess, would you yield for a minute?

*Mr. Burgess. Yes, I would be happy to yield to the chairman.

*The Chairman. I just wanted -- before -- I know you are going to withdraw it, but I did want to express my support for this important policy. And I hope we can continue to work on this bill in a bipartisan fashion, so we can ultimately pass it out of the House.

The -- your amendment is based on or similar to legislation by Representative Trone, which would ensure that individuals being held in pre-trial detention don't lose Medicaid.

And as you said, this -- you know, when an individual is incarcerated, the state cannot receive Federal Medicaid funds. However, withholding these funds for individuals pre-trial, when they have the presumption of innocence, seems fundamentally unfair. So this provision has strong bipartisan support, and I hope we can continue to work on it to ensure continuity of access to care for individuals on Medicaid.

I just wanted to say that I do support it, and we will work on it. Thank you.

I yield back.

*Mr. Burgess. Thank you. I yield back.

*Ms. Eshoo. The gentleman yields back. Are there any other members that wish to speak on this?

Seeing and hearing none, we will move to a recorded vote. Those in favor --

*Voice. On the AINS.

*Ms. Eshoo. On the AINS, yes. I am sorry. Right, right, right, right. We will --

*Voice. A voice on the AINS --

*Mr. Guthrie. We don't want a recorded --

*Ms. Eshoo. All right.

All those in favor of the amendment in the nature of a substitute to H.R. 7233, as amended, will signify by saying aye.

All those opposed will signify by saying no.

In the opinion of the chair, the ayes have it.

Okay, now -- a recorded --

*Mr. Guthrie. We want a recorded --

*Voice. Keep on going --

*Ms. Eshoo. A recorded vote is ordered.

Those in favor of the --

*Voice. You have got two more -- one more.

*Ms. Eshoo. Oh, we have to vote on this whole thing?

*Voice. Yes.

*Ms. Eshoo. Those in favor of forwarding H.R. 7233, as amended, to the full committee will say aye.

Those opposed?

*Mr. Guthrie. We want a recorded.

*Ms. Eshoo. You want it recorded?

*Mr. Guthrie. We would.

*Ms. Eshoo. Okay. All right, then we will -- Madam Clerk, we will go to you to call the roll.

*The Clerk. Mr. Butterfield?

[No response.]

*The Clerk. Ms. Matsui?

*Ms. Matsui. Aye.

*The Clerk. Ms. Matsui votes aye.

Ms. Castor?

*Ms. Castor. Aye.

*The Clerk. Ms. Castor votes aye.

Mr. Sarbanes?

*Mr. Sarbanes. Aye.

*The Clerk. Mr. Sarbanes votes aye.

Mr. Welch?

[No response.]

*The Clerk. Mr. Welch?

[No response.]

*The Clerk. Mr. Schrader?

[No response.]

*The Clerk. Mr. Cardenas?

*Mr. Cardenas. Cardenas, aye.

*The Clerk. Mr. Cardenas votes aye.

Mr. Ruiz?

*Mr. Ruiz. Ruiz votes aye.

*The Clerk. Mr. Ruiz votes aye.

Mrs. Dingell?

*Mrs. Dingell. Aye.

*The Clerk. Mrs. Dingell votes aye.

Ms. Kuster?

*Ms. Kuster. Aye.

*The Clerk. Ms. Kuster votes aye.

Ms. Kelly?

[No response.]

*The Clerk. Ms. Barragan?

[No response.]

*The Clerk. Ms. Blunt Rochester?

*Ms. Blunt Rochester. Blunt Rochester votes aye.

*The Clerk. Ms. Blunt Rochester votes aye.

Ms. Craig?

*Ms. Craig. Ms. Craig of Minnesota votes aye.

*The Clerk. Ms. Craig votes aye.

Ms. Schrier?

*Ms. Schrier. Schrier votes aye.

*The Clerk. Ms. Schrier votes aye.

Mrs. Trahan?

*Mrs. Trahan. Trahan votes aye.

*The Clerk. Mrs. Trahan votes aye.

Mrs. Fletcher?

*Mrs. Fletcher. Fletcher votes aye.

*The Clerk. Mrs. Fletcher votes aye.

Mr. Pallone?

*The Chairman. Pallone votes aye.

*The Clerk. Mr. Pallone votes aye.

Mr. Guthrie?

*Mr. Guthrie. Aye.

*The Clerk. Mr. Guthrie votes aye.

Mr. Upton?

*Mr. Upton. Votes aye.

*The Clerk. Mr. Upton votes aye.

Mr. Burgess?

*Mr. Burgess. Aye.

*The Clerk. Mr. Burgess votes aye.

Mr. Griffith?

*Mr. Griffith. Aye.

*The Clerk. Mr. Griffith votes aye.

Mr. Bilirakis?

[No response.]

*The Clerk. Mr. Long?

[No response.]

*The Clerk. Mr. Bucshon?

*Mr. Bucshon. Aye.

*The Clerk. Mr. Bucshon votes aye.

Mr. Mullin?

*Mr. Mullin. Aye.

[Pause.]

*Mr. Mullin. Aye.

*The Clerk. Mr. Mullin votes aye.

Mr. Hudson?

*Mr. Hudson. Aye.

*The Clerk. Mr. Hudson votes aye.

Mr. Carter?

*Mr. Carter. Aye.

*The Clerk. Mr. Carter votes aye.

Mr. Dunn?

*Mr. Dunn. Aye.

*The Clerk. Mr. Dunn votes aye.

Mr. Curtis?

*Mr. Curtis. Curtis votes aye.

*The Clerk. Mr. Curtis votes aye.

Mr. Crenshaw?

*Mr. Crenshaw. Crenshaw votes aye.

*The Clerk. Mr. Crenshaw votes aye.

Mr. Joyce?

*Mr. Joyce. Joyce votes aye.

*The Clerk. Mr. Joyce votes aye.

Mrs. Rodgers?

*Mrs. Rodgers. Aye.

*The Clerk. Mrs. Rodgers votes aye.

Chairwoman Eshoo?

*Ms. Eshoo. Aye.

*The Clerk. Chairwoman Eshoo votes aye.

*Ms. Eshoo. All right. Madam Clerk, who is not recorded?

*The Clerk. Mr. Butterfield is not recorded. Mr. Welch is not recorded. Mr. Schrader is not recorded.

*Mr. Schrader. Schrader votes aye.

*The Clerk. Mr. Schrader votes aye.

*Ms. Eshoo. Mr. -- how is Mr. Long recorded?

*The Clerk. Mr. Long is not recorded.

*Ms. Eshoo. Mr. --

*Mr. Long. Aye.

*The Clerk. Mr. Long votes aye.

*Ms. Eshoo. Mr. Welch?

*Ms. Barragan. Ms. Barragan? How is Barragan recorded?

*The Clerk. Ms. Barragan is not recorded.

*Ms. Barragan. Barragan votes aye.

*The Clerk. Ms. Barragan votes aye.

*Mr. Welch. This is Mr. Welch. How am I recorded?

*The Clerk. Mr. Welch is not recorded.

*Mr. Welch. Welch votes aye.

*The Clerk. Mr. Welch votes aye.

*Ms. Eshoo. Mrs. Rodgers?

*Mrs. Rodgers. Madam Chairman, how am I recorded?

*The Clerk. Mrs. Rodgers is recorded as aye.

*Mr. Guthrie. How am I recorded?

*The Clerk. Mr. Guthrie is aye.

*Ms. Eshoo. Dr. Bucshon?

*Mr. Guthrie. There he is.

*The Clerk. Mr. Bucshon is --

*Ms. Eshoo. There he is.

*Mr. Bucshon. [Inaudible.]

*The Clerk. -- votes aye.

*Ms. Eshoo. All right. How is Mr. Bilirakis recorded?

*The Clerk. Mr. Bilirakis is not recorded.

*Ms. Eshoo. Mr. Bilirakis --

*Mr. Bilirakis. [Inaudible.]

*Ms. Eshoo. -- aye.

*The Clerk. Mr. Bilirakis votes aye.

*Ms. Eshoo. All right. Are there any other members who are not recorded?

*The Clerk. Mr. Butterfield and Ms. Kelly.

*Ms. Eshoo. All right. Well, it doesn't --

*Voice. We are not going to wait.

*Ms. Eshoo. We are not going to wait. Does any member wish to change his or her vote?

All right, hearing none, the clerk -- we ask the clerk to report the tally.

*The Clerk. On that vote, Madam Chairwoman, the yeas

were 32 and the nays were 0.

*Ms. Eshoo. All right, the vote is 32 to 0.

*Mr. Guthrie. This is our last one.

*Ms. Eshoo. Yes, and H.R. 7233, as amended, is forwarded to the full committee.

All right, let's move on these. The chair now calls up H.R. 623, the Gabriella Miller Kids First Research Act 2.0, and the clerk will report the bill.

*The Clerk. H.R. 623, a bill to require certain civil penalties to be transferred to a fund through which amounts --

*Ms. Eshoo. Without objection, the first reading of the bill will be dispensed with, and the bill is now considered as read.

Without objection, the bill is considered as read and open for amendment at any point.

[The bill follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. Are there any members seeking recognition to speak to H.R. 623?

*Ms. Castor. Madam Chair, I --

*Ms. Eshoo. I already --

*Ms. Castor. -- have an amendment at the desk.

*Ms. Eshoo. Yes, I already made my comments in my opening statement this morning, so I am not going to add to that. Place that in the record.

Does the gentlewoman from Florida seek to be recognized?

You are for five minutes -- or less.

*Ms. Castor. I have an amendment at the desk, it is --

*Ms. Eshoo. All right.

*Ms. Castor. -- AINSH623, SCD, AINS1.

*Ms. Eshoo. Clerk will report the amendment, please.

*The Clerk. Amendment in the nature of a substitute to H.R. 623, offered by Ms. Castor of Florida.

Strike all after the enacting clause, and insert the following. Section 1 --

*Ms. Eshoo. Without objection, the reading of the amendment will be dispensed with.

[The amendment of Ms. Castor follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. And Ms. Castor is recognized for five minutes.

*Ms. Castor. Thank you, Madam Chair.

The Gabriella Miller Kids First Program first became law in 2014, after we learned about the brave and tragic story of Gabriella Miller. Gabriella was diagnosed with a terminal form of brain cancer at the age of nine. During her treatment Gabriella raised thousands of dollars for charity, and launched a foundation to bring awareness to pediatric brain cancer.

Sadly, we lost Gabriella in 2013 at the age of 10. Her last directive to elected officials was clear: start -- stop talking and start doing.

Well, we are doing. As the co-chair of the Children's Health Care Caucus, I am proud to introduce this amendment to reauthorize the Gabriella Miller Kids First Research Program at the National Institutes of Health for an additional five years. It increases the funding authorization to $25 million per fiscal year. The Kids First Program at NIH funds important research into pediatric cancer and birth defects, and administers a database that researchers and pediatricians can access to review thousands of patient cases.

The reauthorization provided in this amendment allows for stability and reliability, and may someday lead to a game-changing breakthrough in treating pediatric cancer.

I would like to extend a warm thank you to Ellen and Mark Miller, Gabriella's parents, for their continued advocacy and coordination, and especially Representative Wexton, who has been the leader, and really introduced this legislation this Congress. She has made it possible. This would not have been possible without their advocacy.

I would also like to thank my Florida friend and colleague, Representative Bilirakis, for co-introducing this amendment with me today.

And I urge everyone to support the amendment.

Thank you, and I yield back.

*Ms. Eshoo. The gentlewoman yields back. I think we can all be proud that the pledge we made to Ellen when she testified, were are -- this subcommittee is keeping its promise.

Are there any other members that wish to speak on this?

All right --

*Mr. Guthrie. Gus does.

*Ms. Eshoo. Gus does?

*Mr. Bilirakis. Thank you very much, I appreciate it very much.

*Ms. Eshoo. Well, bravo to the work that you have all done together.

All right, the -- there are no other amendments, so we can keep moving on. We can keep going as I get to the right

page here.

All right, the -- going to do a recorded vote.

Okay, no further discussion or amendments. We will proceed to a vote on the amendment in the nature of a substitute.

All those in favor of the amendment in the nature of a substitute to H.R. 623, as amended -- no, it is not amended -- will signify by saying aye.

All those opposed?

All right. In the opinion of the chair, the ayes have it.

A recorded vote -- is we don't need a recorded vote? All right.

The amendment in the nature of a substitute to H.R. 623 is agreed to.

The question now occurs on favorably forwarding H.R. 623, as amended, to the full committee.

You want to do a voice vote? Okay, you are good? All right.

All those in favor of forwarding H.R. 623, as amended, to the full committee will signify by saying aye.

All those opposed signify by saying no.

In the opinion of the chair, the ayes have it.

Okay. Here? No, no, no. All right. The -- H.R. 623 is forwarded to the full committee. Okay.

The chair now calls up H.R. 3771, the South Asian Heart Health Awareness Act of 2021.

And the clerk will report the bill.

*The Clerk. H.R. 3771, a bill to amend the Public Health Service Act --

*Ms. Eshoo. All right, without objection, the first reading of the bill will be dispensed with. The bill is now considered as read.

And without objection, the bill is considered as read and open for any amendment at any point now.

[The bill follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. Are there any members seeking recognition to speak on H.R. 3771?

Mr. Pallone?

*The Chairman. Yes. I have an amendment. Is that in order at this time, Madam Chair?

*Ms. Eshoo. As long as there aren't any members that want to speak to the bill, yes.

*The Chairman. Okay.

*Ms. Eshoo. You are recognized.

*The Chairman. I have an amendment at the desk. Thank you.

*Ms. Eshoo. The clerk will report the amendment, please.

*The Clerk. Amendment to H.R. 3771, offered by Mr. Pallone of New Jersey.

*Ms. Eshoo. All right. Without objection, the reading of the amendment will be dispensed with.

[The amendment of The Chairman follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. And Mr. Pallone, you are now recognized for five minutes, or less, to speak in support of the amendment.

*The Chairman. Thank you, Madam Chair. And I am going to ask that my full statement be introduced in the record.

*Ms. Eshoo. So ordered.

[The information follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. And just try to summarize, because I want to -- we all need to go to the floor.

So the South Asian Heart Health Awareness and Research Act of 2021 was introduced by Representative Jayapal and Mr. Wilson of South Carolina, and it shines a light on the serious issue of cardiovascular health in communities disproportionately affected by heart disease.

And I just wanted to mention that this bill is not new. Our committee considered this legislation, the 116th Congress, and it was passed in the full House but, of course, didn't pass the Senate. And it basically provides grants to support cardiovascular health promotion and heart health research among the South Asian community, but also for other groups. It mentions the South Asian community specifically because their risk of cardiovascular disease is four times higher than the general population.

And as I said, I am -- the amendment only makes clarifying changes to the underlying legislation by providing more targeted research and updating the authorization period. It is just technical.

So I would just urge my colleagues to support this amendment and underlying bill. Again, we have already voted to support this in the past. I would like to see it done again, and show the committee's support for communities disproportionately affected by heart disease.

And I yield back --

*Mr. Guthrie. Would the gentleman yield for just a second?

*The Chairman. Yes, sure.

*Mr. Guthrie. I just wanted to note there are some concerns on our side with the bill.

I know there is already identity gaps for disproportionately impacted communities in CDC, and I know they have some concerns about data.

While I know this is going to move forward on a voice, I just want to make sure, as we go to full committee, there -- we all know there are concerns on the bill for the record.

Thank you. I yield back to you, Mr. Chair.

*The Chairman. Thank you, and I appreciate that.

Thank you, Madam Chair.

*Ms. Eshoo. The gentleman yields back. Are there any members that wish to speak to the amendment?

If not, then the -- if there is no further debate, we will proceed to a vote on the amendment.

All those in favor of the amendment will signify by saying aye.

All those opposed, signify by saying no.

In the opinion of the chair, the ayes have it. The amendment is agreed to.

Are there any other amendments to this legislation?

There are not. All right. So we will -- the question now occurs on favorably forwarding 3771, as amended, to the full committee.

All those in favor of forwarding H.R. 3771, as amended, to the full committee signify by saying aye.

All those opposed, signify by saying no.

In the opinion of the chair, the ayes have it.

Now we will forward this to the full committee. You want a recorded vote?

*Mr. Guthrie. I do not.

*Ms. Eshoo. Okay. All right. Then all those in favor of favorably forwarding H.R. 3771 to the full committee, signify by saying aye.

All those opposed?

*Ms. Eshoo. H.R. 3771, as amended, is forwarded to the full committee.

Okay, we are moving right on here. This is the last one.

The chair now calls up H.R. 5585, the Advanced Research Project Agency Health Act, or ARPA-H. And I certainly don't mind being last, because every single one of the parts of what we have done today have been all important.

We need the clerk to read the first reading the bill.

*The Clerk. H.R. 5585, a bill to establish the Advanced Research --

*Ms. Eshoo. Without objection, the first reading of the bill will be dispensed with. The bill is now considered as read.

And without objection, the bill is considered as read and open for amendment at any point.

[The bill follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. The chair recognizes herself to strike the last word and speak on behalf of ARPA-H.

My colleagues, this subcommittee has heard me speak many, many, many times about this legislation. It would create, as you all know, an independent agency within HHS with a presidentially-appointed director who would have the authority to approve and end project funding, establish milestones, and coordinate with other agencies.

I want to skip over most of my remarks in the interest of time, and place my full statement in the record.

[The information follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. Suffice it to say this has a very broad vision that is so exciting about what we can accomplish in the future. You all know and respect the DARPA model, and ARPA is modeled off of that highly successful model.

This new enterprise will be outside of NIH, and will embody the nimble spirit of the highly regarded DARPA model to pursue large-scale and very purposefully high-risk projects. If there is anyone that would like to speak to this -- I really want to move on in the interest of time so that this can be part of the overall legislation.

Let me thank the chairman of the full committee for his cooperation to put this in this large bill; for the ranking member of the full committee's cooperation; for, you know, Mr. Upton's cooperation; and Dr. Burgess; and there are others. Mr. Hudson has asked excellent questions, and added to this.

So if there is anyone else that would like to speak to it -- yes. Mr. Upton?

*Mr. Upton. Thank you, Madam Chair.

*Ms. Eshoo. I yield.

*Mr. Upton. I had a -- strike the last word. And I will only take 30 seconds here. So I am going to put my statement into the record. I had a great statement praising you and the need to do this, and I will save it, a lot of it, I guess, for full committee. But I just -- I appreciate your

leadership. I appreciate all the Republicans and Democrats willing to make this a success.

And, you know, we have had some hearings on it. We have had a lot of discussions. It needs to be part of the process that moves forward because it will, in fact, at the end of the day, really bring some breakthrough drugs to the marketplace to solve the diseases that all of us want to see happen. So let's do it the right way.

I appreciate your leadership. And with that, I yield back.

*Ms. Eshoo. Dr. Burgess, did you -- I would be happy to --

*Mr. Burgess. Yes, I --

*Ms. Eshoo. -- yield time to you.

*Mr. Burgess. I support what you are doing. Like you, I was a little concerned when Secretary Becerra talked about collocating this on the campus of NIH. I hope we can address that before we get to full committee. But I am supportive of what you are trying to do, and I yield back.

*Ms. Eshoo. Well, the legislation contains language that the -- this enterprise will be outside of Washington, D.C. We already have -- and your home state has stepped out, and I think there is going to be healthy competition for where this is located, again, outside of Washington, D.C.

Is there anyone else that would like to speak to this?

If not, we will proceed to a vote. We will proceed to a vote. Let me get the right language here.

All right, the question now occurs on favorably forwarding 5585 to the full committee.

All those in favor of forwarding 5585 to the full committee will signify by saying aye.

All those opposed will signify -- thank you for all the ayes; we hear you -- all those opposed will signify by saying no.

In the opinion of the chair, the ayes have it.

Let's see. We are going to go with a -- that is it, right?

*Voice. It is just forwarded.

*Ms. Eshoo. Yes. I am very happy to say H.R. 5585 is forwarded to the full committee.

All right. Now, the last -- without objection, the staff is authorized to make technical and conforming changes to the bills consistent with the actions taken by the subcommittee today.

We have a unanimous consent request to enter the --

*Mr. Guthrie. No objection.

*Ms. Eshoo. No objection, the following documents into the record.

Without objection, they will be.

And I want to thank all the members of this wonderful

subcommittee for the hard work that members have done. I think that I can say that every single subcommittee member worked to bring this product forward today, and we are so proud to forward it to the full committee.

With that, bless all of you. The subcommittee now stands adjourned.

[Whereupon, at 2:13 p.m., the subcommittee was adjourned.]