

Opening Statement for the Honorable Brett Guthrie
“Subcommittee Markup of 6 Bills”
May 11, 2022
As Prepared for Delivery

Thank you, Madam Chair.

Today we are marking up legislation to increase innovation and continue fighting the rise of mental illness and substance use disorder that is taking thousands of lives in the United States.

H.R. 7667, the FDA Act of 2022, introduced by Chair Eshoo and I, along with the leaders of the full committee, will reauthorize the user fee program at the Food and Drug Administration through 2027. The legislation will specifically promote lower drug costs while incentivizing biopharmaceutical innovation and protecting access to potentially life-saving therapies.

This legislative package also includes policies that promote the use of real-world evidence, protect access to the 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 dependence 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.

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 payors. 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 year-over-year rise in drug overdoses in our nation's history, a majority of which involved illicit fentanyl.

That is why H.R. 7666, the 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 struggling with mental health crises.

The package includes my legislation, the Substance Use Prevention, Treatment and Recovery Support Services Reauthorization Act.

I thank Representatives Tonko, McKinley, and Wild for their work on reauthorizing this critical program. 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. Should the temporary scheduling expire, it will be more challenging to prosecute the criminals running these drug enterprises both domestically and abroad. 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 local level with a 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 we are, yet 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 Restoring Hope for Mental Health and Well-being Act. This legislation will ensure individuals seeking help overcoming substance use disorder or those battling mental health issues can receive needed care as quickly as possible.

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