Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
Of
Subcommittee on Health Chairwoman Anna G. Eshoo

Hearing on "The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight"

March 17, 2022

Today, our Subcommittee examines 22 mostly bipartisan bills to speed the discovery of more cures, improve patient representation in clinical trials, and enhance the FDA's ability to fulfill its vital mission of ensuring the safety, efficacy, and quality of America's drug supply. This hearing is an enormous legislative undertaking and I appreciate the thoughtful work of our Subcommittee Members in putting these bills before us.

First, we're examining a bill I introduced, H.R. 5585, the *Advanced Research Project Agency for Health Act*. This legislation would establish ARPA-H as an independent agency within HHS with a presidentially appointed director who would have the authority to approve and terminate project funding, establish milestones, and coordinate with other health agencies, including NIH.

ARPA-H will embody the nimble spirit of the highly regarded and successful Defense Advanced Research Project Agency (DARPA) to pursue large-scale, high-risk projects. It will break the mold for federal research agencies by being uniquely focused on solving the "valley of death" to deliver transformational cures. ARPA-H will correct the gap that currently exists between the basic research pursued by the NIH and the development of commercial products by the private sector. With this mission, ARPA-H will drive scientific breakthroughs to improve our nation's health and help fulfill President Biden's promise to end cancer as we know it.

On Tuesday, the President signed into law the bipartisan Consolidated Appropriations Act of 2022 which provided $1 billion to establish an independent ARPA-H within HHS. This was a momentous first step in creating an agency that will be a beacon of hope to the American people, but our work is not yet done. Our Committee needs to pass the ARPA-H legislation to provide the agency with the full authorities it needs to be successful from Day One, including ensuring that it will be a nimble, dynamic, and independent agency.

Complementing ARPA-H is Reps. Upton and DeGette's Cures 2.0 legislation that they have worked on for three years. It ensures that our federal public health agencies are working seamlessly together to move new cures through the research stage all the way to FDA approval and Medicare coverage.

Next, we're considering three bills to improve the diversity of patients enrolling in clinical trials. All Americans should be confident that their treatments will work for them regardless of race, gender, or age. But FDA data shows that for the drugs approved in 2020, 75%

of clinical trial participants were white. Only 8% of trial participants were African American and 11% were Hispanic.

My legislation, the DEPICT Act, would have drug companies demonstrate how they will include diverse populations in their clinical trials by reporting to FDA a "diversity action plan" with targets by demographic subgroups. It would also give FDA the ability to ask for a postmarket study to gather more data if a sponsor does not meet the demographic targets it set for itself.

Representative Blunt-Rochester's *ENACT Act* and Representative Ruiz's *DIVERSE Trials Act* complement the *DEPICT Act* by addressing the barriers and burdens that often keep patients from being able to enroll in clinical trials.

Finally, Chairman Pallone and Ranking Member McMorris Rodgers have each proposed changes to the FDA's Accelerated Approval program, while several other Members have proposed bills to streamline the development and approval processes for drugs, especially for rare diseases and pediatric cancers.

We have a panel of industry and physician experts to advise us on these bills, as many of them previously did during our hearing on the FDA drug user fee agreements. I look forward to a highly instructive hearing on these important bills.