Opening Statement for the Honorable Brett Guthrie
"The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight"
March 17, 2022
As Prepared for Delivery

Thank you to my friend, Chair Eshoo, for holding this important legislative hearing today.

We're here today to discuss proposals designed to increase American biopharmaceutical innovation, a goal that I think we can confidently all say we share. Over the past decade, more novel therapies have been approved in the United States than in any other country.

The United States is home to the world's leading biopharmaceutical industry with the Food and Drug Administration approving 50 new therapies in 2021. 27 of the approved therapies were first in class drugs and 26 were to treat rare diseases. Of these 50 newly approved drugs, 76 percent were approved in the United States before any other country.

One of the most publicly reported approvals was Biogen's Aduhelm through the Accelerated Approval pathway. This was the first FDA-approved drug to treat Alzheimer's disease since 2003. It is estimated this historic approval would benefit nearly one million out of six million Americans living with early onset Alzheimer's, which now have some hope of treatment against this vicious disease.

Approval of this new Alzheimer's treatment through the Accelerated Approval pathway could lead to other potential benefits, including the development of more effective treatments and encouraging investments in finding a cure for this terrible disease. Despite its real promise, the Centers for Medicare and Medicaid Services is now attempting to only allow access to the approved drug to a very limited patient population. If CMS moves forward with this plan, access to Aduhelm and future FDA-approved Alzheimer's treatments would be restricted for Americans with intellectual disabilities, such as Down Syndrome, and patients with other neurological conditions. This could have a chilling effect on investments in Alzheimer's research moving forward.

Not only is CMS undermining the Accelerated Approval pathway, but we also have a bill before us today that calls for further restricting the Accelerated Approval pathway. Instead of adding more red tape, we should be focused on developing policy solutions that are intended to break down regulatory barriers and promote more collaboration between the regulatory community and private-sector partners. That is why I am thankful to my colleagues for including my legislation and several other bipartisan bills in this hearing.

My legislation, H.R. 7008, the Pre-Approval Information Exchange Act, would help address what's known as the "Valley of Death," or the time between when a drug or a device is approved by the FDA and when it is covered by a payor.

The bill would specifically allow drug and device sponsors to share key health care economic information, including pre-clinical trial results and other important information, with health insurers and other payors before a drug or device is approved by the FDA.

This would help patients gain access to potentially life-saving treatments, such as Aduhelm, more quickly by giving the marketplace a chance to price-in therapies working towards FDA approval. In fact, the FDA even acknowledged the potential impact these communications could have by releasing guidance in 2018 allowing for these communications to occur. Codifying this guidance would instill further confidence in the marketplace and provide needed regulatory certainty to the companies and payors already engaging in these information exchanges. I encourage my colleagues to support to support H.R. 7008, which also has broad industry support.

Additionally, in the case of Aduhelm, we should also be promoting policies that will help to ensure patients are receiving timely access to breakthrough therapies without significantly increasing the cost of care for our health care system. For example, Representatives Schrader, Mullin and I have been working on a bipartisan proposal that would permit state Medicaid programs to enter into value-based purchasing arrangements that link reimbursement to clinical outcomes.

These payment models could have dual benefits. This could promote greater access to some of the most expensive treatments on the market for lower income populations, while also helping shield state budgets against having to pay for a drug if it fails to meet its clinical endpoints. This latter point is especially important when we're talking about Accelerated Approvals. If clinical benefits are in doubt, let's focus on reforming our laws so that we only have to pay for a drug if it actually works, as opposed to stymieing access to potentially lifesaving treatments.

I look forward to continuing to work with my bipartisan colleagues in advancing this important measure. I also look forward to finding ways to advance the many proposals we're discussing today. Thank you, and I yield back.