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Remarks as Prepared

Thank you all for being here today.

It's an honor to speak to you all about the importance of biosimilars. Widespread access to biosimilars can significantly reduce health care costs and increase access to affordable treatments.

Treatments for patients suffering from diseases must be:

- discovered on the ground level through basic science;
- be developed into practical, usable, and marketable products; and
- be delivered to patients so the treatment may be effectively utilized.

There are roadblocks at each stage of the cycle, in large part because of an outdated regulatory structure. In general, this impacts medical device companies, physicians, clinicians, researchers – the list goes on and on. Ultimately, however, this negatively impacts patients.

Health care reforms need to be patient focused. The free market and competition are great tools for lowering costs for consumers. Health care is no different.

However, too often, the regulatory structure in place gets in the way of innovation. I held two roundtables in my District over the summer. The first featured patients and patient advocates. The second included health care providers:

- researchers;
- clinicians;
- diagnosticians; and
- representatives from medical device companies.

A common thread between all the participants is the overly burdensome regulatory structure which stifles innovation.

Alzheimer's patients struggle to gain access to a specialist because of regulations barring the widespread use of telehealth.

A mother whose three year old son suffers from Duchenne's cannot gain access to potentially life-improving treatments because of the risk-averse nature of the FDA.

The list goes on.

Another common theme that I heard, that's also applicable to biosimilars, is how Europe differs from the United States.

Europe approves medicines and medical devices years quicker than the US.

One participant mentioned overnight home dialysis for kidney patients – approved in Europe, but not here.

Biosimilars have had remarkable international success. However, the pathway forward is still not fully formed in the United States.

The Federal Trade Commission (FTC) released a report in 2009 that examines “the potential impact of follow-on biologics on the price of biologic drugs, and compares this with the impact of generic drugs on the chemical drug market.”

The Congressional Budget Office estimated the savings from generic drug use in 1994 was between \$8 billion and \$10 billion.

It stands to reason the same savings would occur through the use of biosimilars.

According to a study by Express Scripts, it's estimated that biosimilars have reduced treatment costs in Europe and Asia by 40%. That's a remarkable statistic.

It means real savings for thousands of patients. A number of studies have estimated that biosimilars can save billions of dollars over the next decade.

Competition lowers prices. It's the free market at work.

Biologic drugs are very complex, derived from living cells – as opposed to chemical reactions.

These drugs are used to treat diseases like psoriasis, or forms of arthritis, among many other conditions. However, biologic medications are traditionally extremely expensive.

Federal and state payers like Medicare and Medicaid, as well as individuals and businesses with private insurance, may have a hard time affording the cost of a biologic medication over a long period of time.

Biosimilars can dramatically bring down the costs for US patients – much like those in Europe and Asia.

Because the nature of biologic medications means they will be more expensive, there are significantly fewer manufacturers in the biosimilar space.

There are hundreds of companies that make traditional generics, using chemical reactions. To produce a biosimilar, a company would need more capital to invest into R&D; and have the scientific capabilities to properly build that infrastructure.

In so many industries, there are examples of regulations that are either overly burdensome or unclear, that kill innovation.

The final iteration of the regulatory structure of the biosimilar approval pathway cannot disincentivize the production of biosimilars. It would be a mistake, and a disservice to patients.

Since 2010, the FDA has been working on that pathway for the approval of biosimilar drugs, but the pathway has yet to be completed.

The Food and Drug Administration Safety and Innovation Act, better known as FDASIA, included the Biosimilar User Fee Agreement. Passed in 2012, it allows for user fees to be collected and for the FDA to hire new staff to approve biosimilars.

As we move forward, Congress will look to see how some of the potential hurdles are addressed. One big issue is the naming of biosimilars.

In the United States, on the chemical drug side, there are different brand names – for instance, Tylenol – but the same generic name.

This structure is used for small compound drugs and biosimilars in markets like Europe, Asia, and Australia.

For biosimilars in the US, the issue is still up for debate. However, applications are being submitted to the FDA and companies are developing biosimilar drugs.

It benefits the companies, the FDA, and most importantly, the patient, if FDA expediently provides clear guidance on this issue.

For biosimilars in Europe, extrapolation is assumed – the biosimilar can be used for all the same approved uses as the name brand biologic.

That is also the case in the United States with chemical drugs. However, guidance has not yet been issued by the FDA for biosimilars in the United States. Can a biosimilar that is approved be used to treat all of the same conditions as the name brand biologic? Can it be used to only treat the primary condition? Questions like these are the embodiment of regulatory uncertainty.

It is important to note that because they are made from living organisms, there will inherently be a small amount of variability from batch to batch.

From my perspective as a legislator, I want to work with the FDA and stakeholders, including patients, to ensure any approved biosimilars are statistically no different at treating the disease, and are both safe and effective.

Of course, intellectual property rights are important to include in this discussion.

If a company spends time, money, and effort to develop a biologic medication, that company should have exclusivity for that product.

Exclusivity incentivizes companies to invest in research and find the next breakthrough. We need to have an appropriate balance between allowing for that exclusivity and opening up a market to competition.

Free market principles can yield substantial savings. Alternatives are government-based price controls, which are not the solution.

Thank you for your time, and allowing me to speak today. This is part of a very important discussion.

Patient-centered health care reforms can increase access to affordable medications.

And that, ladies and gentlemen, is a laudable goal.

Thank you.