Opening Statement
Rep. Gene Green
Health Subcommittee Hearing: Examining Implementation of the Biologics Price Competition and Innovation Act
February 4, 2016

Good morning and thank you all for being here.

Today's hearing is the first we have had in the House of Representatives on biosimilars since passage of the Biologics Price Competition and Innovation Act (BPCIA) as part of the Affordable Care Act in 2010.

It is particularly timely because the FDA is both developing the standards for approval of biosimilars and reviewing and acting on an increasing number of applications.

At the same time, CMS recently released the final Physician Fee Schedule (PFS) rule, which detailed the Medicare Part B payment methodology for biosimilars.

Determinations on how biosimilars are approved, regulated and reimbursed at all critical to the success of this new, emerging market, and must be in alignment to facilitate a robust, safe, and competitive marketplace.

As we know, biologics play an important and growing role in our health care system.

Arguably, they represent the future of therapeutics and hold immense promise to further transform the way we treat and prevent disease.

According to the RAND Corporation, worldwide sales of biologics were $46 billion in 2002, representing 11 percent of the global pharmaceutical market.

Experts are predicting that by 2017, sales of biologics are expected to grow to between $205-235 billion, representing approximately 20 percent of the global pharmaceutical marketplace.

Recognizing the need for non-innovator biologics analogous to the generic drug market facilitated by Hatch-Waxman, I worked with then Representative Tammy Baldwin and former Representative Jay Inslee years ago to introduce a bill proposing a pathway for the approval of biosimilars.

Not long after, the BPCIA became law, paving the way for the injection of competition into the biologics space.

I know we all agree that competition is good for patient safety and consumer choice, and drives savings for consumers and the health care system at large.

There are a number of outstanding issues on how biosimilars will be evaluated and treated by the FDA, including naming, interchangeability, labeling and extrapolation.

The complexity of these issues is difficult to overstate, and I thank FDA for their ongoing efforts to develop policies on these questions.

However, decisions on these major issues should not be made on a case-by-case basis, and it is time for FDA to articulate clear guardrails and principles to industry and the public so that the rules of the road are established and understood.

Public and provider trust in the safety of biosimilars is vital to the success of this market.

Acceptance of generics did not happen overnight - only through public, transparent processes of developing guidances and rulemaking will the public trust be earned.

I look forward to hearing from FDA on the status of these policies and how the agency is moving these efforts forward.

Recently, CMS detailed how biosimilars will be treated under Medicare Part B and I have serious concerns with the final rule. While I appreciate the agency's desire to control costs, I fear that in this instance, it could undermine this infant market and create a race to the bottom.

If all biosimilars are in the same blended code, we actually disincentive companies from investing in further trials for additional indications, and will drive folks away from this market we are trying to foster.

Robust competition will ultimately realize the most sustainable, significant savings for the program and new options for patients.

This rule seems in conflict with the efforts of FDA to foster the biosimilars marketplace, and I look forward to hearing from

CMS about how this determination was made and responses to concerns about the potential undermining of the biosimilars market.

Thank you all for being here today and I yield back the balance of my time.