Statement of Congresswoman Anna G. Eshoo
House Committee on the Judiciary
Subcommittee on Courts and Competition Policy
Hearing on "Biologics and Biosimilars: Balancing Incentives for Innovation
July 14, 2009

Thank you Mr. Chairman. I'm pleased to be here today to discuss this important issue – developing a regulatory pathway for biosimilars that protects patients while balancing incentives for innovation.

The field of biotechnology is the future of medicine – we're just beginning to scratch the surface of the potential to harness the extraordinary power of biology and the astounding natural processes which occur in the human body, in animals, and in other living organisms to advance breakthrough medical discoveries and treatments.

This vital future must advance, but the costs of biologic treatments are very high and I believe the time has come to develop a pathway for biosimilar products in our country.

What, exactly, do I mean when I say "develop a pathway" for biosimilars?

In 1984 the *Drug Price Competition and Patent Term Restoration Act*, otherwise known as 'Hatch-Waxman,' ushered in a new era of competition and cheaper drugs for traditional pharmaceuticals – compounds.

It's now appropriate to create a pathway for follow-on versions of biologics. However, biologics and traditional drugs are fundamentally different and require different legal and scientific frameworks.

First, we need to understand the differences between biologics and traditional drugs.

Many of us take a prescription or over-the-counter drug frequently. Each time we reach for a pill, we expect the same safety and effectiveness, whether using a brand name or generic drug.

Small-molecule chemical compounds of traditional drugs are ideal for replication as generics. These products have well-defined structures that can be thoroughly characterized and copied, and generic drugs are chemically identical to the reference products they copy. Doctors and patients can expect that generics will have the same properties, the same efficacy, and the same safety characteristics as the innovative product they copy.

Biological products are fundamentally different. A biologic is a large, complex molecule, which is 'grown' in living systems such as a microorganism, a plant or animal cell. The resulting protein is unique to the cell lines and the specific process used to produce it, and even slight differences in the manufacturing of a biologic can alter its nature. As a result,

biologics are difficult, sometimes impossible to characterize, and laboratory analysis of the finished product is insufficient to ensure its safety and efficacy. *[SEE DISPLAY]*

Even if a biosimilar is proven to be safe and effective, it will likely still have different properties than the original innovative product. There may be differences in dosing, different side effects or safety profiles, and differences in effectiveness for certain diseases or patient groups.

Biologics are expensive and risky to develop. A recently released study sponsored by the National Venture Capital Association analyzed the relative costs for investors in biotechnology and found that the 'cost of capital' for start-up biotech companies is more than double the costs that other companies must pay. These costs stem from long developmental timelines of typically 10 years or more, extraordinary levels of risk (fewer than 1% of biologics make it to market), and the large amounts of capital required to support development.

To preserve existing incentives for investment and innovation the *Pathway for Biosimilars Act* provides a data exclusivity period equivalent to patent protections for small molecules. The Congressional Budget Office has determined that 11.5 years is the average length of time that drugs are marketed under patent. In other words, innovative drugs and biologics typically stay on the market for about 12 years before facing competition. My legislation maintains this level of protection for biologics.

Today innovators are assured that the costly clinical trial results and data that they develop during their approval process cannot be used by competitors to secure approval and enter the market, even if their patents do not prevent entry. In effect innovators now have 'infinite' data protection, which allows for competition but doesn't permit 'free riding' on their data.

I'm proposing to allow competitors access to their data and a shortcut into the market, but also preserving the existing incentives for innovators by maintaining a 12-year period of concurrent data protection as a 'backstop' to existing patent protections.

In order to protect the rights of all parties and ensure that all patent disputes involving a biosimilar are resolved before the expiration of the data exclusivity period, H.R. 1548 also establishes a simple, streamlined patent resolution process.

This process would take place within a short window of time – roughly 6-8 months after the biosimilar application has been filed with the FDA. It will help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large.

Unlike any other proposal, our legislation also preserves the ability of third-party patent holders such as universities and medical centers to defend their patents.

Once a biosimilar application is accepted by the FDA, the agency will publish a notice identifying the reference product and a designated agent for the biosimilar applicant. After an exchange of information to identify the relevant patents at issue, the applicant can decide to challenge any patent's validity or applicability. All information exchanged as part of this procedure must be maintained in strict confidence and used solely for the purpose of identifying patents relevant to the biosimilar product.

The patent owner will then have two months to decide whether to enforce the patent. If the patent owner's case is successful in court, the final approval of the application will be deferred until the patent expires.

The *Pathway for Biosimilars Act* sets forth a straightforward, scientifically based process for expedited approval of new biologics based on innovative products already on the market. This new biosimilars approval pathway will promote competition and lower prices, but also ensure that patients are given safe and effective treatments that have been subjected to thorough scrutiny and testing by the FDA.

I'm pleased that Congressmen Inslee, Barton and I have been joined by a diverse group of 125 bipartisan cosponsors in the House.

I also want to note that my bill is the only legislation endorsed by the Association of American Universities, the National Venture Capital Association, the Biotechnology Industry Organization, the governors of 4 states, and a wide array of patient and industry groups.

This broad support is extremely encouraging, and I look forward to working finally addressing this critical issue in the 111th Congress.

Thank you again for inviting me to testify today.