

## H.R. 1548 better than alternatives on new drug class

The Hill

H.R. 1548 better than alternatives on new drug class

By Rep. Anna Eshoo (D-Calif.)

Posted: 07/08/09 12:06 PM [ET]

The field of biotechnology is the future of medicine. Today we're just scratching the surface of the potential for biology-driven breakthroughs that hold the promise of treating cancer, diabetes, arthritis, Alzheimer's and other deadly and debilitating diseases. The innovation and discovery in this vital field will transform medicine in the coming decades, but these biologic treatments are expensive. To meet our national priority of improving health while reducing costs, we must look for ways to deliver safe and effective, lower-price alternatives.

Comprehensive healthcare reform offers a timely and appropriate vehicle in which to accomplish this.

One successful model for reform was the 1984 Hatch-Waxman Act. Introducing small-molecule generic drugs ushered in a new era of competition and helped consumers afford innovative pharmaceuticals. The same concept inspires us to create a marketplace for follow-on versions of biotechnology products. Our challenge is to replicate the success of the generic drugs marketplace, while developing a legal and scientific framework that addresses the complex research, efficacy and patient safety variables that make biologics fundamentally different.

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. The 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.

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.

The fundamental uniqueness and complexity of biologics demands more rigorous regulation than what exists today for generic small molecule drugs, and new legal considerations.

I have introduced legislation, H.R. 1548, the Pathway for Biosimilars Act, which is based on sound science and does more than any other proposal to protect patient safety. Under my bill the FDA retains ultimate authority to make critical determinations related to testing and interchangeability, but the agency must solicit views and information from experts and stakeholders before waiving key patient safeguards. My legislation ensures that physicians make critical decisions about appropriate treatments — not insurance companies, pharmacy benefit managers, or pharmacists. These standards are consistent with recommendations made by the FDA's Chief Scientist.

#### Biologics

are expensive and risky to develop. A soon-to-be-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 percent 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.

Small-molecule drug manufacturers rely on patent protection to recoup the hundreds of millions of dollars it takes to bring a drug to market. Valid patents are very effective in preventing generic patent infringement because generic drugs are required by law to be chemically identical to innovative products. However, biosimilars will obviously be only "similar" to the innovative products they compete with, giving biotechnology companies a greater challenge to prove patent infringement and less legal protection for massive investments.

Today, the ability to work around patents has limited appeal to a prospective biosimilar producer. Innovative biotechnology companies 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 does not permit "free riding" on their data.

My legislation proposes allowing competitors access to this data and a shortcut into the market, but also preserves the existing incentives for innovators by maintaining a 12-year period of concurrent data protection as a "backstop" to existing patent protections. The bill also sets forth a process to resolve all patent litigation prior to launch of biosimilars, providing the opportunity to resolve important intellectual property issues and certainty to all parties without market disruptions. Unlike any other proposal, my bill also provides an opportunity for third parties (universities, medical centers) to protect their rights.

I've been joined by a diverse group of more than 100 bipartisan cosponsors in the House, including lead cosponsors Jay Inslee (D-Wash.) and Joe Barton (R-Texas). Our bill is the only legislation endorsed by the Association of American Universities, the National Venture Capital Association, the Biotechnology Industry Organization, the governors of four states, and a wide array of patient and industry groups, including the AIDS Institute and the ALS Association.

The time has come to provide a regulatory pathway for safe — and cheaper — versions of the biologics that save thousands of lives and improve the quality of life

for countless more.

Eshoo is a member of the House Energy and Commerce Committee's health subcommittee.