

Chairman Dingell at the Subcommittee on Health hearing entitled "Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States"

Statement of Congressman John D. Dingell, Chairman
Committee on Energy and Commerce

SUBCOMMITTEE ON HEALTH HEARING ENTITLED
"ASSESSING THE IMPACT OF A SAFE AND EQUITABLE BIOSIMILAR POLICY IN THE UNITED STATES"
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Mr. Chairman, thank you for holding this important hearing. We are here to discuss the anticipated impact of a safe and equitable biosimilar policy in the United States.

When the Congress granted the U.S. Food and Drug Administration (FDA) the authority to approve generic versions of pharmaceuticals in 1984, we could not have foreseen the need for a similar pathway for generic biologics. Since then, the biotechnology industry has grown tremendously, and a number of biologic products are on the market, treating a variety of medical conditions, including many life-threatening illnesses such as cancer, multiple sclerosis, diabetes, and HIV/AIDS.

In some cases, these biological products are the only available therapy. In others, biotechnology represents a clear clinical advantage over other available therapies.

As this industry continues to discover potentially life-saving therapies, more patients will depend on their products. Unfortunately, not all patients can afford these needed therapies, and must forego needed treatments. We must find a way to ensure greater access as this science progresses.

There is broad agreement that we should create a pathway for biosimilars. As we explore this idea, we must be certain that our solutions are both grounded in science and fair to consumers. Innovators as well need financial stability to sustain their research into groundbreaking therapies.

One issue that confronts us as policymakers is the science behind biosimilars. What standards will ensure that generic biologics are as safe as the original products? Should clinical trials be required for approval of biosimilars? Can a generic product be created that is genuinely interchangeable? Can and should a manufacturer of a biosimilar product duplicate the innovator's manufacturing process to avoid potential adverse reactions? Patient safety must be our guiding principle in searching for an appropriate pathway.

I am pleased this hearing is being held today and look forward to the testimony of our witnesses, as well as the input of our Members. It is my intention to craft a sensible and fair biosimilars policy, and to work with my colleagues to achieve this goal in the 110th Congress.

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