Statement of

The Honorable Patrick Leahy

United States Senator
Vermont
June 23, 2004

Hearing on "The Law of Biologic Medicine"
June 23, 2004

Mr. Chairman, I appreciate your holding a hearing on this important topic.

Biologic therapies fight life-threatening diseases and disorders. In many cases, these therapies are orders of magnitude more effective than drug therapies.

The most famous biologic treatment saved millions of lives and has eradicated epidemics which, in the 1930s and 40s, created mass panics each summer.

Indeed, the first major outbreak of polio in the United States was in Vermont during the summer of 1894.

Rather than using the powerful tools of molecular biology, physicians back then willy-nilly came up with therapies, such as concocting an emulsion from the ground-up spinal cords of polio-infected monkeys. They then added other chemicals to that witches' brew.
One researcher, Dr. Jonas Salk, added formalin to the mix, and the rest is history.

Now, research for new biologic therapies is no longer an endless guessing game. Potent new technologies hold the promise to develop completely new classes of therapies to prevent, treat or cure otherwise inevitable, untreatable and incurable diseases.

These new technologies are being focused on the horrors of cancer, cystic fibrosis, hemophilia, AIDS, Alzheimer's, and multiple sclerosis, just to name a few.

For example, breakthrough biologic therapies such as Avastin starve cancer tumors of the blood supply they need to grow. Activase is used to greatly reduce the otherwise permanent disabling effects of strokes in adults.

Biologic technologies also hold out the best hope for those suffering from certain rare diseases that afflict 25 million Americans, including 58,000 Vermonters.

However, biologic therapeutics often cost far more than traditional drugs. One reason for this is that biologics are a lot more complex chemically and are more difficult to manufacture.

It is important that we address this approval issue now because the patents on many biologic therapies will expire in the next few years.

With respect to drugs, Chairman Hatch and Congressman Waxman played crucial roles in developing a fast-track process to get less expensive, safe and effective generic drug alternatives into the market place under the Hatch-Waxman law.

But a clear fast-track pathway does not exist for biologic therapies under current law.

So the critical question we face today is, should Congress design a fast-track process for generic versions of these biologic innovations?

My own answer is "yes," but only if what we do is based on sound science, if these alternative therapies are safe and effective, if they will help prevent shortages, and if these biologics would provide less expensive, yet potent, alternatives for consumers.

I know that generic biologics are now available in Eastern Europe and Asia. Many point out that these biologics have been safe and effective and are less expensive than the original products in those counties. Others urge that we can not be sure of the safety or legality of these products made overseas.

It may be that a sliding-scale approach is needed for the United States. The level of scrutiny should intensify with the increasing:

-- complexity of the molecules involved;
-- sensitivity of the formulation process; and
-- the risks of deviation from the patented product.

Science must rule this decision - not politics, not greed, not the clout of powerful vested interests. We need to do the right thing for the millions of affected families.

I hope that we can work together to find a faster way to get more of these valuable therapies available, at lower prices, to consumers, without sacrificing safety.

I hope that all stakeholders will participate in this process. The testimonies of Dr. Ben-Maimon and David Beier present a useful point and counter-point on both sides of this issue. Mr. Beier also raises complex trade-secret issues.

The bottom line is that any such legislation will require a careful balancing of interests and recognition of patent and trade secret rights.

We need to work together for the families who could be helped by this approach. I am therefore pleased to begin our consideration of this important issue with today's hearing, and I welcome the testimony of our distinguished panelists.