Statement of

The Honorable Orrin Hatch

United States Senator
Utah
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"The Law of Off-Patent Biopharmaceuticals"

Today, the Judiciary Committee will consider a complex subject area that involves law, economics, science and medicine.

The purpose of the hearing is simple -- although the law and science surrounding these issues are not. We will explore some of the key issues concerning the legality, feasibility and advisability of creating a new, abbreviated regulatory pathway at the Food and Drug Administration for the review and approval of off-patent biological products.

First, for those of you who may not be sure what a biologic is, I would like to offer a simple working definition: Biological medicines are large complex protein molecules, derived from living cells, often by recombinant DNA technology. The area of biologics is of growing medical and economic importance. The biotechnology market posted a total of about $30 billion in sales last year, which is expected to double to over $60 billion by 2010.

We will see a concurrent explosion in the numbers of biologics; there are now over 150 FDA-approved products on the market, with an additional 350 in various stages of human clinical testing and over 1,000 others in the development pipeline.

But more important than commercial considerations, it is the hope of many that biological products, such as those that may one day be developed from embryonic stem cells, could lead to cures to many diseases that cannot be successfully treated today. Biopharmaceuticals appear to represent the future of medicine. For example, now that we have mapped the structure of the human genome, we are in position to unravel the mysteries of the function of human genes and the proteins they encode. Nothing less than a revolution in our understanding of human health and disease is well underway. I am proud of the fact that scientists at the Huntsman Cancer Institute at the University of Utah are helping to lead the way.

The old model of large patient population, small molecule medicine is giving way to large molecule, small patient population therapies. The day may even come when individualized therapies will become common. These developments will not occur overnight and without great effort and ingenuity and they will not be done on the cheap. One thing is certain: when medical breakthroughs occur, patients will want access to these new products and their families and third party-payers will want to pay as little as possible for them.

Experts remind us that this new wave of therapeutic protein molecules is more complex to discover, manufacture, and use than conventional small molecule drugs. We know that many of

these new biological products tend to be more expensive than old-line chemically synthesized drugs. Some of these new wonder therapies cost over $10,000 per year or per course of treatment. For example, human growth hormone can cost $25,000 per year.

Cost factors alone compel a thorough examination and public discussion of the merits of developing a fast track review and approval system that can reduce the price of biopharmaceuticals once patents expire. Moreover, from a regulatory reform perspective, it should always be the goal of government to employ the least burdensome regulatory approach without compromising other important considerations such as, in this case, patient safety and protection of intellectual property.

Former Commissioner of Food and Drugs and current CMS Administrator, Dr. Mark McClellan -- who took time from his busy schedule last week to visit Utah and meet with me and other Utahns on the new Medicare drug program -- has recognized the confluence of medical, economic, and regulatory forces at play.

Our society can ill-afford to avoid a debate over the proper regulation of follow-on biologics. We simply cannot sustain over time programs such as Medicare unless we seriously explore what steps might prudently be taken to end an FDA regulatory system that effectively acts as a secondary patent for off-patent biological products.

Patient safety and product efficacy must remain of the forefront of this discussion. The task before policymakers is to consider how to maintain product safety and efficacy as we consider ways to eliminate unnecessary regulatory hoops for off-patent biological product license applications.

I will stipulate that it will be difficult to manufacture some generic equivalents of off-patent biologicals. Some products will no doubt be more difficult than others to reverse engineer. There will be technical issue galore. Some may actually prove impossible to duplicate without trade secret information but, from what I have heard, many products will be able to be safely duplicated.

I believe that many, if not all, follow-on biological will require at least some form of human clinical testing. I also believe that the federal government would be wise to consider providing taxpayer funding for the development of process validation guidelines that will help establish the critical manufacturing steps and assay parameters for medically or commercially significant off-patent biological products.

I think it would be wise to consider commissioning or otherwise sanctioning studies by organizations such as the United States Pharmacopeia or the Institute of Medicine, in collaboration with the FDA and other interested parties, to identify and address the technical issues that need to be resolved in order to fast track approvals for off-patent biopharmaceuticals.

I have known and worked with Acting Commissioner of Food and Drugs Crawford for many years and look forward to working with him and other experts at the FDA on this important issue. I know that Dr. Crawford will make this an important priority and look forward to seeing the draft guidelines when they are issued later this year. I trust that Chief Counsel Dan Troy and

Deputy Commissioner Amit Sachdev and Liz Dickinson and Jerilyn Dupont will provide sound legal and policy advice.

As a co-author of the Drug Price Competition and Patent Term Restoration Act of 1984, I firmly believe that whatever we do on the legislative front should observe a principle of attempting to balance incentives for both pioneer and generic drug firms. While I am all for rolling up our sleeves to work to help develop an abbreviated approval system for off-patent biologics, we must be properly respectful of the intellectual property of research-based firms because this is what undergirds the whole pharmaceutical enterprise.

As we proceed into this new era of drug discovery, it is important to ask whether our current intellectual property laws relating to pharmaceutical research and development are adequate to promote the large molecule, small patient population medicine of the future? For example, I have long thought the way we treat process patents under Hatch-Waxman should be re-examined in this new era of patient population medicine in which process patents will become more important in which the relative importance of such patents will increase.

Difficult policy questions will crop up in a very difficult climate for the research-based pharmaceutical industry, everyone's favorite whipping boy in an election year. Senator Lieberman and I have advanced an aggressive set of private sector incentives in our bipartisan bioterrorism bill. I plan to hold a hearing on the Lieberman-Hatch Bioterrorism bill, and we urge all interested parties to review the IP provisions of this legislation.

Twenty years ago, we faced many challenges in fairly balancing the incentives and various interests when we came together on Hatch-Waxman. Frankly, I recognize that many in the biotechnology industry believe that the creation of a fast track approval process for off-patent biologics is the worst nightmare of a highly competitive, inherently risky industry struggling to attract the capital necessary to bring new products through FDA approval and to the marketplace.

Let me close by suggesting an alternative, and perhaps preferable, strategy to scorched earth litigation. Rather than just saying no, please consider engaging in a constructive public policy dialogue that focuses on identifying the legitimate scientific and legal obstacles that must be overcome to create a fast track approval system for off-patent biologics. At the same time, come forward with ideas that will improve the legal environment for pioneer biotechnology firms.

That is what we did in 1984 and that is what we can do again today if we all work together on follow-on biologics and other matters. If we have the right balance in the law, the American public only stands to benefit.