TESTIMONY

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U.S. PIRG, the federation of state Public Interest Research Groups, is a non-profit, non-partisan public interest advocacy organization. U.S. PIRG's mission is to deliver persistent, result-oriented public interest activism that protects our health, encourages a fair, sustainable economy, and fosters responsive, democratic government. We uncover threats to public health and well-being and fight to end them, using the time-tested tools of investigative research, media exposés, grassroots organizing, advocacy and litigation.

In recent years, medical and pharmaceutical science has produced a new, powerful class of medicines, known as biologic drugs. Rather than a chemical admixture like most drugs on the market, these medicines are developed using biological materials and processes. Often, biologics can only be manufactured using very expensive, state of the art processes.

This new class of drugs has already offered hope to millions of patients suffering from previously untreated diseases. Yet because they were excluded from the procedures to incentivize generic versions of prescription drugs contained in the 1984 Hatch Waxman legislation these already expensive drugs are rendered more expensive. As health care costs skyrocket and biologic drugs gain a greater share of the pharmaceutical market, many now advocate for a pathway to create generic diseases. Opponents suggest that such a pathway would stifle innovation within this vibrant business sector and slow invention of new biologic medicines.

In our view, the best way to understand how to best incentivize innovation and balance other policy goals is to look at an example. Consider the cancer biologic drug Herceptin. Approved by the FDA on September 25th 1998, this amazing medication, produced by the biotech firm Genentech, helps women fight off a particularly tough form of breast cancer that is positive for the protein HER2.

Herceptin has made a serious difference. Its use increases the disease-free survival rates of this type of breast cancer by 12%.[i] Doctors estimate that it can save 7000 women from relapse in a year.[ii]

On average it costs $1.2 billion to take a biologic drug to market, and companies like Genentech should be rewarded for that investment. Genentech should profit from bringing a product to market that saves lives. In fact, they have recouped their development costs and much more, earning $5.5 billion from 2003-2008 alone.[iii]

But there's a catch. Herceptin's patent protections, the legal mechanism that protects intellectual property in most industries, expired in 2005. The available evidence, namely Genentech's enormous annual profits, suggests that the patents on the drug provided an

ample incentive for the important research that Genentech did on this drug. Yet today, without a pathway for follow-on biologics, Genentech continues to enjoy monopoly pricing power. They have certainly made the most of it, charging $48,000 a year wholesale for the Herceptin treatment.[iv] Some reports have indicated that some consumers paying twice that amount or more.[v] But under current law, it's unlikely that a generic company will introduce a cheaper version of the drug anytime soon, and Genentech recognizes that.

Intellectual property protection is important. The success that Herceptin brought Genentech will encourage other manufacturers to make the long-term investments needed to produce the drugs that can vanquish cancer and other diseases.

All the available evidence is that the patent system provides adequate protection for innovator biologics and provides an adequate incentive to raise capital for investments everywhere in the world. I recognize that the biotech companies argue that 14 years of exclusivity is necessary for them to invest in these products. But it is obviously in their interest to get the maximum amount of exclusivity to maximize their profits. Thus it is important to look to an independent source to evaluate the validity of the biotech industry's argument that 14 years is essential to create a sufficient incentive for investing in these products. A recent report by the Federal Trade Commission provides a very helpful evaluation. As you know the FTC is an independent federal regulatory agency. It does not always side with the generic or brand companies. Recently it has vigorously argued against patent settlements, a position which the generic companies vigorously dispute.

The FTC studied the issue of generic biologics and issued a comprehensive report in June 2009, *Emerging Health Care Issues: Follow-on Biologic Drug Competition.* In its report the FTC examined the question of whether the existing patent system provides adequate intellectual property protection to biologics. It found that "The patent system has a proven record of protecting and stimulating biotechnology innovation." (p. 35)

Interestingly, the FTC concluded that in some ways biologics patents are stronger than patents on chemical drugs. It stated that "pioneer biologic drugs are covered by more and varied patents than small-molecule branded products, including manufacturing and technology platform patents." (p. 26) Thus the FTC stated that "there is no evidence that patents claiming a biologic drug product have been designed around more frequently than those claiming small-molecule products." (p. 26; see p. 36) In summary, the FTC found that the pioneer biologic drug manufacturer can continue to earn significant revenues many years after FOB entry. (p. 26).

The FTC's conclusions are important because chemical treatments have flourished without the 12 or 14 years of exclusivity that the biologics manufacturers are demanding. Under the Hatch-Waxman legislation, enacted 25 years ago, chemical drug manufacturers are entitled to only 5 years of exclusivity. Because patents almost always run longer than 5 years, the purpose and effect of this exclusivity is to provide market protection for the unusual products for which patents have expired or which have less than 5 years of patent

protection remaining. For most chemical drugs, it is the patent system which provides the basic intellectual property protection.

The basic compromise that led to the enactment of Hatch-Waxman was not the 5 years of exclusivity. Instead the brand companies demanded and received patent extensions to compensate patent time lost as a result of the FDA drug approval process, which includes both the time needed to test the drugs and the time the FDA takes to approve products. Under Hatch-Waxman, companies are eligible for a patent extension of up to 5 years as long as the extension does not extend patents to more than 14 years. Importantly, these patent extensions already apply to biologics. Thus, even though Hatch-Waxman did not establish a generic program for biologics, it did give biologic innovators the same patent extensions that it gave to the chemical brands.

Hatch-Waxman has been a tremendous success. It gave the medical research industry a sufficient incentive to innovate and it established a safe and effective generic drug program.

But there is a serious danger to conferring too much intellectual property protection. In the case of a drug like Herceptin, every year the drug's manufacturer benefits from the high monopoly prices conferred by exclusivity will cost patients both in dollars, and in lives. Herceptin's high monopoly prices make it less likely and more expensive for insurers to cover it. And thus, fewer patients with breast cancer have access to this life-saving medicine.

It is also significant that every year that Herceptin is enjoying monopoly profits is one more year that Genentech has no overriding incentive to develop additional products. Instead Genentech's principal incentive is to preserve the market for its most profitable drugs, including Herceptin.

Rewarding yesterday's innovation too much can prolong the day that we see the next life saving biologic drug. By granting additional protection to biologic products, above and beyond the manufacturer's patent, we not only keep the drug expensive and out of reach of many Americans. We strip away the incentives to develop the next generation of life-saving drugs.

What is true of Herceptin is even more true of other biologic blockbuster drugs:

US PIRG's Recommendations

In determining where to strike the balance on this issue: we encourage you to keep focused on three important considerations:

- the affordability of these drugs to consumers across the country;
- the impact of your actions on the efficiency of the American economy; and
- the incentives you're creating for innovation for the next generation of life-saving drugs.

The original Hatch-Waxman legislation successfully addressed all these priorities, and it makes sense to learn from those successes. U.S. PIRG believes that an approach such as that included in the Access to Life Saving Medicine Act of 2009 sponsored by Representative Henry Waxman and Senator Chuck Schumer represents the best option before Congress today. This bill is modeled on the Hatch-Waxman Act, which established the generic drug program at FDA for chemical drugs and which conferred the patent extensions and the five-years exclusivity described above.

Evaluation of the Alternatives

Several alternatives to this approaches have been advanced. These approaches would combine longer periods of exclusivity for generic biologic drugs with additional steps to protect the original manufacturer of the pioneer drugs.

Proponents of more protection for pioneer drugs claim that biologics are different from chemical drugs. They argue that the investments needed in sophisticated manufacturing and development of biologics would render patents or even Hatch/Waxman style 5 year exclusivity periods inadequate.

In fact, if their position was true, we should first consider extending protection to industries who face the greatest cost of capital. But that would mean providing monopoly power to investing in several industries with higher capital costs long before we got around to biotechnology. These dubious arguments serve primarily to defend and preserve the monopoly position enjoyed by a few powerful manufacturers.

It's no wonder recent Federal Trade Commission argues clearly that a short exclusivity period strikes a better balance. They find that "

> *The potential harm posed by such a period [if 12-14 years] is that firms will direct scarce R&D dollars toward developing low-risk clinical and safety data for drug products with proven mechanisms of action rather than toward new inventions to address unmet medical needs. Thus, a new 12- to 14-year exclusivity period imperils the efficiency benefits of a FOB approval process in the first place, and it risks over-investment in well-tilled areas.*[vi]

So when it comes to encouraging innovation, we can only conclude that the industry is selling a cure that's worse than the disease. Fundamentally, the choice before Congress this year is whether to reward yesterday's life saving innovation or tomorrow's.

We need strong vibrant markets for biologic drugs in this country. But we need markets that drive innovation not those that reward monopoly. We urge you to make the right choice.

Thanks you for the opportunity to testify. I would be happy to answer any questions.

[i] MSNBC Health, *Drug Found Effective Against Early Breast Cancer,* October 2005
[ii] Ibid.
[iii] AARP Public Policy Institute, *Biologics in Perspective: The Case for Generic Biologic Drugs,* May 2009
[iv] MSNBC Health, *Drug Found Effective Against Early Breast Cancer,* October 2005
[v] The Assertive Cancer Patient, *The True Cost of Herceptin,* March 2007
[vi] Federal Trade Commision, *Emerging Health Care Issues: Follow-on Biologic Drug Competition,* June 2009.