

**Remarks of Congressman Henry A. Waxman
Biosimilars 2007 Conference
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I am pleased to have the opportunity to join you at this Conference. As you probably know, I have a long-standing interest in bringing down the cost of prescription drugs. I believe that fair marketplace competition is one of the best ways to do that.

In 1984, I co-authored the Hatch-Waxman Amendments, which introduced competition into the drug marketplace by authorizing the FDA to approve low-cost generic drugs. Before 1984, drugs had what amounted to permanent monopolies. Hatch-Waxman permitted abbreviated testing for generic drugs and has been amazingly effective at bringing down the price of prescription drugs.

And, despite the claims of the drug industry before Hatch-Waxman passed, generic competition has lowered drug prices without harming patient safety or squelching drug innovation. In fact, I have been told more than once by members of industry that generic competition has been a spur to innovation.

Generic drugs give millions of people access to life-saving medicines they wouldn't otherwise be able to afford.

I am very proud of the role that the Hatch-Waxman Amendments have played in making drugs affordable by ending permanent monopolies.

Unfortunately, there is one category of drugs that still has permanent monopolies: biotech drugs, or “biologics.”

Biotech drugs are the future of medicine. There are close to 500 biotech drugs currently in development for a host of serious diseases. In 2006, U.S. biotech sales grew by 20% to \$40.3 billion. By way of comparison, this 20% growth in biotech sales is far greater than the 8% sales growth experienced by traditional pharmaceuticals.

But biotech drugs are also dramatically more expensive than traditional drugs. They frequently cost tens or even hundreds of thousands of dollars per year. They can be life-saving. But their price tag can put them out of reach for uninsured patients, and place huge financial burdens on governments and payers.

In 2005, for example, every one of the top 5 drug expenditures for Medicare Part B was for biotech drugs.

A recent CNN Money article describes at least part of the reason for the tremendous growth in biotech drugs' share of the market, and I quote: "Biotech drugs are an attractive investment for Big Pharma for two reasons: the industry is fast-growing, and generic competitors can't touch it."

As you well know, the article correctly describes the current state of the law. Biologics were not covered under the original Hatch-Waxman Act. So FDA currently lacks a clear pathway for approving low-cost competing versions of these drugs, even after patents have expired.

The economics of permanent monopolies for biotech drugs is not sustainable. The staggering cost of these drugs will overwhelm our health care system unless we introduce competition into this market.

Since this time last year, we have made remarkable progress toward a goal I have long sought: creation of a pathway to approve generic biologics. A pathway is essential if millions of people are going to be able to afford these life-saving new drugs.

There have been huge changes to the landscape on this issue in the last 12 months.

Before last September, despite years of hypothetical musings on the subject, no one had ever even introduced a bill to permit approval of generic biologics. I am proud to have co-sponsored the first such bill, along with Rep. Emerson in the House, and Senators Clinton and Schumer in the Senate.

But I must confess that I initially assumed that the bill would inaugurate a long debate on the topic. I believed that progress would be inevitable but that it would take time.

I clearly underestimated the strength of demand for affordable biotech drugs now. An impressive coalition of businesses, consumer and patient groups, and purchasers who are no longer willing to tolerate permanent monopolies for biologics has quickly formed.

Within a few months of the introduction of the bill at the end of the last Congress, they had come together to push for the rapid passage of a generic biologics pathway. They were remarkably effective in pushing this issue to the top of the agenda.

The Senate HELP Committee reported out a bill and urged its inclusion in the FDA omnibus bill.

Although generic biologics did not ultimately get included in the omnibus bill, the issue is squarely on the table – and I remain very hopeful that before this Congress ends, we will see legislation enacted.

Many members of Congress have joined me in recognizing that something must be done. The success of the Senate HELP Committee in passing a bill out of Committee is one sign of this. But another sign is that we now have a total of three different legislative proposals that have been circulated.

To be sure, I do not agree with key aspects of the proposals that have been introduced to compete with mine. And I do not underestimate the role of the biotech industry in the drafting of one of those proposals. But it is still striking that this issue has become so important that that we have three proposals pending at the same time, after decades when there were no bills on the topic at all.

The entire framework of the debate is changing. After years of insisting that generic biologics are impossible, BIO has finally abandoned this argument. Even BIO itself now understands that they have to address this issue.

The proposals in which they have had a hand are, of course, weighted heavily towards incentives for innovation, and include provisions likely to delay rather than hasten access to affordable generics.

Nevertheless, it is extremely encouraging to see this major shift occur in an extremely short time period. But there is obviously a great deal of work left to do.

We need to make sure that there are, on the one hand, adequate incentives for innovation and, on the other, rapid access to lower-cost generics once valid patents have expired.

Obviously, we learned some valuable lessons about how to balance these competing needs 20 years ago when we drafted the Hatch-Waxman Act.

In the current debate, the industry is calling for 10 or even 14 years of exclusivity. Those periods are so long that they are not only unbalanced, they make the bill a huge give away. Brand companies should receive a reasonable term of exclusivity, but not one that is so long that it would rob the American people of the cost-savings appropriate generic competition brings.

If the Congress ignores the lessons we learned about balance in Hatch-Waxman and passes a bill that puts too much weight on one side of the scale – and replaces adequate incentives with windfall profits – we will lose a huge opportunity.

As Hatch-Waxman should make clear, I am not opposed to appropriate periods of exclusivity to permit innovators to recoup their investments. Since the beginning of this debate, I have repeatedly asked the biotech industry to provide Congress with evidence to support whatever amount of exclusivity they claim is necessary to ensure continued innovation.

BIO's arguments for those ever-increasing terms of exclusivity have morphed over time. Unfortunately, none the arguments has been backed up with anything like persuasive evidence.

Early on, we heard that 10 years was the appropriate term because that's what the EU has. That argument disappeared when it was pointed out that the EU also has price controls. The economic value of 10 years of exclusivity in our system with no price controls would far exceed the value of 10 years of exclusivity in the EU market.

More recently, we heard that 14 years was necessary because that's what brand companies receive in patent term restoration under Hatch-Waxman. And I've even heard the argument that Congress intended, in Hatch-Waxman, that companies always get 14 years of protection from competition.

This last claim is simply not true.

I have some experience with that law, and I feel confident stating that Congress did not intend for every company to get 14 years in patent term restoration. We intended for that to be a ceiling on patent extensions—not a floor. Moreover, we recognized that FDA-enforced exclusivity is significantly more valuable than patent extensions, because exclusivity is unbreakable.

If we had thought exclusivity was interchangeable with patent protection we would have provided a comparable ceiling of 14 years of exclusivity for those products lacking patent protection.

We did not.

We determined that 5 years of exclusivity was adequate.

And of course, neither their argument for 10 years nor the argument for 14 years is based on any evidence that that amount of time is necessary for recoupment of investment. The only allusions to evidence that I have heard have been vague and unquantified.

I've heard assertions that the higher cost of producing biotech drugs entitles their manufacturers to longer exclusivity. But if this argument were correct, shouldn't we also assign variable patent terms based on the cost of product development? Perhaps a 30-year patent for a biotech drug, 20 years for a new molecular entity, 10 years for a me-too drug, 5 years for a new dosage form?

Of course, patent law makes no such distinctions. And the major reason it doesn't is that manufacturers of expensive products recoup their costs principally by charging higher prices, not by demanding longer monopoly periods.

I've also heard allegations that the patents on biotech drugs are not as strong as the patents on traditional drugs. This argument certainly might be relevant, if true. But unsupported assertions are not evidence.

The industry needs to provide some supporting facts -- something it has not done.

There is certainly no shortage of patent litigation in the biotech industry. If the argument that biotech patents are more difficult to enforce is true, it should not be hard to provide evidence of a lower success rate in relevant patent infringement cases.

Of course, the recent news that Amgen had successfully defended its EPO [EE' POE] patents against Roche didn't do much for the argument that biotech patents are weak.

If I'm doing the math right, Amgen's patents, which don't run out until 2012 at the earliest, will have given the company 23 years of exclusive marketing rights. That's 23 years after the approval of the drug.

This is also more than twice what PhRMA claims is the average post-approval patent life for a traditional drug. And, I need hardly point out that this is 3 years more than the maximum 20-year patent term.

This is only one case, of course. But before I accept the argument that biotech patents are weaker than traditional pharmaceutical patents, I'd like to see some real evidence that the EPO patents are somehow the exception that proves the rule.

Given that the industry arguments on this issue have not been based on reliable evidence, we need better information to guide our decision about the appropriate balance between rapid access and incentives for innovation. Before granting any specific term of exclusivity, Congress should demand that the brand industry demonstrate—with specific data—what they need to continue to innovate and to explain why they need it.

Exclusivity issues are ultimately focused on the price for these medicines. As important as that issue is, though, we can never let it be our only concern. We have got to ensure that generic versions of biologics are as safe and as effective as their brand-name counterparts.

So whatever legislative pathway we put into place must establish a scientifically rigorous process for approval of copies of biotech drugs. We need to authorize FDA to determine, on a product-by-product basis, what studies will be necessary to show that a new product is clinically indistinguishable from the brand name product.

But giving FDA—the scientific expert here—the flexibility it needs to make this decision is critical. We should not tie FDA's hands and require that there be a clinical trial in every case.

In some cases, this would not only waste a lot of resources, but could also put patients at risk unnecessarily. A knee jerk requirement of trials in every case would violate ethical standards of science. Present and former FDA officials have made clear in Congressional testimony that they agree with me on this point.

I'd like to make a final point about the role of FDA in the evolution of this legislation. Congress has now held several hearings on generic biologics and has heard testimony from a number of current and former FDA scientists. When questioned, these scientists have consistently testified that creating an abbreviated approval process for safe and effective copies of biologics is eminently doable.

They have also testified that with appropriate studies of immunogenicity, it will be possible in many cases to establish interchangeability of biologics. They stress that this ability will evolve over the next several years, allowing approval of the simpler biologics first and progressing to more complex biologics over time.

Unfortunately, the "official" statements of the Bush Administration on a pathway for generic biologics often contradict the views of FDA scientists. These official statements are significantly more negative about such a pathway than the testimony of FDA scientists.

Sometimes, they are diametrically opposed to what the scientists have said.

I have little choice but to conclude that the official statements are politically driven.

It is extremely disturbing to me to see yet another example of the politicization of science at FDA. Those of you in the industry may see the Bush Administration's political opposition to a generic biologics pathway as serving your interests. I urge you to take a longer view.

The drumbeat of examples of FDA decisions based on politics rather than science is inexorably undermining FDA's credibility to the public and to the Congress.

I know that many of you believe, as I do, that FDA desperately needs more resources. But every new demonstration that FDA has become a political rather than a scientific agency makes the appropriators less willing to throw good money after bad. Sadly, I saw this happen first hand in this year's appropriations cycle.

Ultimately, the losers will be not only consumers but the regulated industry as well.

Because the credibility of American drugs rises and falls with the credibility of the agency that America trusts to regulate them. That credibility is reaching all time lows.

I still think we can turn it around. The first step is to make sure that FDA is perceived as making scientific, not political calls on regulated products. I hope we can start with generic biologics.

Conclusion

Congress has taken a giant leap forward on generic biologics. We are no longer standing by and watching as our reliance on biologics increases, along with their cost. These medicines save lives. I believe that we are finally ready to do something to address the fact that often the only thing standing between patients and the drugs they need to survive is the price tag.

The momentum gained on this issue in the last year tells me that success is near at hand. The Senate Health Committee reached bipartisan agreement on an approach. While I don't agree with it in all its particulars, it indicates that agreement is within our grasp.

Senator Kennedy is invested in getting a good bill. Senator Hatch wants to see this done. Senator Clinton has been a tireless champion. Senator Schumer is committed to the bill. And the interest in the House is very high. I continue to believe that this legislation can and should become law before this Congress is over.

I look forward to continuing to work with you in our shared struggle to provide effective and affordable health care.