Remarks of Congressman Henry A. Waxman
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Most Americans believe that the Government should spend enough money on the public health to protect the health of our people, but they also believe that the Government must find ways to control costs so that the health care budget doesn't bankrupt our economy. And most Americans believe that we should encourage the development of new domestic energy sources, but not by adopting policies that will devastate our environment.

A recurring theme in my 30 years in the Congress has been the effort to craft policies that reach the right balance between these types of competing concerns.

In 1984, when the Congress passed the original Hatch-Waxman Amendments, the debate over generic drugs was cast in terms of competing policy concerns. On the one hand, the major drug manufacturers stressed the need for a strong incentive to research and develop new medicines.

On the other hand, consumers and generic manufacturers believed that encouraging competition between brand name drugs and generic drugs would reduce the price of medicine and make it easier for Americans to afford the already skyrocketing cost of prescription drugs.

My view in 1984 was that our laws then had not yet found the proper balance between these two policy concerns. Our laws were heavily tilted in favor of the brand name manufacturers, so that competition from generic drugs was largely choked off. The drug approval process, as it existed at that time, effectively created permanent monopoly rights for individual drugs. In all but a few cases, the FDA required a would-be competitor to repeat all the original studies on safety and effectiveness to gain approval. Innovation was well-protected, but the law failed to address the need for access to affordable drugs.

The Hatch-Waxman Amendments sought to address this imbalance. Our goal was to encourage competition from generic drugs, while still giving drug manufacturers adequate incentives to do the research needed to find new drugs. The Act has certainly not been perfect, but it greatly redressed the extreme imbalance between innovation and competition.

In 1984, generic drugs accounted for less than nineteen (19) percent of all prescriptions filled. Today, generic drugs represent more than fifty-one (51) percent of all prescriptions

dispensed in the United States. And they have been highly successful in bringing down drug prices, when they are available. It is has been estimated that generic competition can reduce the price of drugs by as much as two-thirds. In the 20 years since passage of the Hatch-Waxman Amendments, I have been pleased and surprised at the law's success in making drugs more affordable for Americans.

But a funny thing happened in those 20 years. A category of drug products that barely existed in 1984, and that we completely ignored in drafting the legislation, slowly emerged as a major source of new medicines. Unfortunately, they also emerged as a major force causing drug prices to rise. I'm talking, of course, about biological drug products.

In 1984, we didn't even think to cover biological drug products, which are regulated under a different statute than traditional drugs.

Yet today, more than 150 biotech drugs, which are regulated as biologics, are on the market. In the past year alone, more than 30 new biotech drugs were approved. These drugs are commanding a larger and larger share of the pharmaceutical market. Analysts estimate that by 2010 biologic sales will exceed $60 billion.

And biotech products pose significant affordability questions. Patients who need these drugs often have to pay tens of thousands of dollars a year for them. And there is evidence that the price of biotech drugs is rising faster than the price of traditional drugs.

I believe that improving competition in the biotech marketplace will be critical to improving access to life-saving drugs and lowering healthcare costs in the coming years. However, because we did not anticipate the rise of biotech drugs in 1984, there is no recognized standard for obtaining approval of generic versions of biological products.

As the patents on many of these products have begun to expire, we are facing many of the same dilemmas with biotech drugs that we faced 20 years ago with synthetic drugs.

To create a scientifically and economically sound biogenerics approval process, we will need to balance the same competing concerns that we faced 20 years ago. On the one hand, the biotech industry needs incentives for innovation. But, on the other, once patents have expired, consumers should have access to safe and effective and affordable medicines: competition is needed to bring down drug prices.

Current law does not strike the right balance. We cannot continue to have a system that effectively enshrines permanent monopoly status for some of our most important medicines. Of course, some intellectual property protections are needed to encourage innovation by brand-name manufacturers. But permanent monopolies are neither needed nor wise.

I believe that the time has come to design a system for testing and approving biogenerics. Certainly there are contentious scientific issues surrounding such a system. And we must be mindful of getting the science right. We must get the science right because if the science behind approving biogenerics is not sound, all of this room know that many in the brand-name industry will make it their mission to destroy the credibility of those products in the eyes of physicians and patients.

Fortunately, the science of establishing the safety and effectiveness of biogenerics is evolving faster than many in the biotech industry would have us believe. Although recent news stories have suggested that I believe that a scientific foundation for biogenerics is lacking, in fact I believe that an adequate foundation has already been laid.

Two important facts give me hope. First, the FDA may soon set out the studies it will require for approval of generic versions of insulin and human growth hormone, two of the simplest biotech drugs. Since these products are regulated as drugs rather than biologics, approval of biogenerics would be on sound legal footing.

If the FDA issues guidance on approval of these drugs, it will demonstrate for the first time that there is sufficient scientific knowledge to establish safety, effectiveness and equivalence of at least some biogenerics.

It will also provide the first test of the FDA's ability to create a defensible case-by-case approval process for biogenerics.

Because, ultimately, that seems to be where we are headed.

If we wait for a universal test that works for all biogenerics, like the bioequivalence test for traditional drugs, it could be decades before a patient sees the first generic. That makes no sense since these products range in complexity and in the type of studies that will be necessary to demonstrate the safety, effectiveness and equivalence of their generic counterparts. .

The second fact that heartens me is that experience suggests that we can go without a universal test. Within a few years of passage of the Hatch-Waxman Amendments, the FDA was faced with applications for topical and inhaled generic drugs for which traditional bioequivalence studies were not useful.

The FDA was forced to establish and defend new methods for establishing the comparable bioavailability of topical and inhaled drugs in order to approve generic applications for these drugs.

This case-by-case approach to establishing equivalence, while not without controversy, was successful. This suggests to me that we will be able to create a legislative scheme in which the methods of establishing equivalence for each class of biologics are left to be developed by the FDA, as the science evolves.

Perhaps the trickiest part of developing a biogenerics scheme will be in reaching agreement on an incentive to the biotech industry to support continued innovation that doesn't break the bank. I strongly support the need for adequate incentives to ensure that the industry continues to develop life-saving medicines.

I am concerned, however, about some of the suggestions I've heard about what the trade-off should be for a biogeneric approval system. For example, it has been suggested that in exchange for biogenerics, all new drugs (not just biotech drugs) should get increased periods of exclusivity.

This is very troubling for two reasons. Though exclusivity has been very successful in producing new medical products, it has become clear that it is not the fairest way for society to subsidize pharmaceutical innovation.

First, the size of the reward often bears little relationship to the importance of the innovation.

A five-year exclusivity period may reward a company that develops the 10^{th} cholesterol-lowering drug in its class far more highly than the company that develops a cure for multiple sclerosis. This is because the value of 5 years of exclusive marketing is determined not by the amount of suffering that will be ended, but by market share.

The second way in which exclusivity is unfair is that extending exclusive marketing

periods has the effect of placing the biggest share of the cost of drug development on those least able to pay for it.

Exclusivity rewards drug companies by allowing them to charge higher prices. Unfortunately, as our health care system works today, the pharmaceutical industry charges the highest prices to those without insurance, while those with bargaining power pay much less. It's hard to argue that drug innovation, which benefits all of us, should be largely subsidized by a segment of society that has to choose between buying medicines and paying the rent.

So when people suggest that, in exchange for a biogeneric approval system, all new drugs, both biotech and synthetic, should get 10 years of exclusivity, rather than the 5 years they get now under Hatch-Waxman, I have to ask why.

The advocates of this proposal cite the fact that, in Europe, drugs are already given 10 years of exclusivity. However, what they never point out is that in Europe there are both price controls and universal drug coverage. Ten years of exclusivity may be a reasonable incentive in Europe, where initial prices are not sky-high, and where all citizens equally share the burden of higher prices. In the United States, 10 years of exclusivity means something far different. Something much more profitable to the industry and, at the same time, far less fair to American consumers.

As long as we continue to have a healthcare system in which drug prices are completely unregulated and in which the industry charges those without insurance much higher prices than anyone else, we should all scrutinize proposals that rely on exclusivity to reward innovation very closely. For biogenerics, I believe it is reasonable to consider exclusivity for biotech drugs to compensate for the loss of revenue they will incur as a result of competition from biogenerics. However, I would strongly oppose substantial increases in exclusivity for drugs that are not affected by biogeneric approval process.

In closing, I believe the proposals to encourage biogenerics are necessary, because right now there is no balance in the biologics marketplace. Brand-name drug companies have essentially unfettered monopoly power now, and we need to introduce a balance. And I believe the proposals are timely: the science is sufficiently developed to permit the institution of a biogenerics approval process, based on case-by-case determinations by the FDA.

As I look toward the future of generic drugs in this country, I am hopeful we will not have to wait too much longer for a system for approving biogenerics. The important thing will be to make sure that the reforms that will inevitably come are thoughtful, careful, and strike the right balance between encouraging innovation and encouraging competition. And I'm hopeful that I'll be able to join together with thoughtful colleagues on the other side of the aisle to find that balance.