Remarks of Congressman Henry A. Waxman
Food and Drug Law Institute
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Over the course of the years that I've been in the United States Congress, and over a wide range of issues, I have repeatedly seen a certain dynamic play out. Progressive forces will mobilize and successfully move the country forward in some important way, and then entrenched interests will fight back and, at least for a while, chip away at the gains that have been won. America can be a bit like the old saw about taking two steps forward and one step back – we will make our nation better in some way, and then retreat for a while from that progress.

I could point to dozens of illustrations of this dynamic, but few areas would better make the point than the regulation of the monopoly power that a small number of companies have had over a great many prescription drugs.

Twenty years ago, we took a great step forward towards creating common sense and reasonable limitations on the monopoly power of the large pharmaceutical companies.

This is the 20th anniversary of the law that is commonly referred to as Hatch-Waxman, and I'm proud to say that it has enjoyed a great deal of success in promoting competition and lowering drug prices.

While the Hatch-Waxman Act was a great step forward, however, there has also been a counter-reaction. With literally billions of dollars of monopoly profits at stake, the major pharmaceutical companies have attacked every complexity, gap, and ambiguity that they could find or generate in the law. I understand that Hatch-Waxman may have earned the dubious distinction of generating more lawsuits than any other law under FDA's jurisdiction.

Let's start at the beginning, though, and look at what a big step forward Hatch-Waxman was. Twenty years ago, as now, Americans were concerned about the high cost of prescription drugs.

While frustration with drug prices is greater today, even then there was a great deal of concern.

All too often, those drug prices reflected monopoly profits. Before 1984, there were very few generic drugs on the market, and very little true competition in the prescription drug marketplace.

Newer drugs enjoyed what amounted to permanent monopolies, because the only legal way to market a generic copy was to repeat all of the safety and effectiveness studies conducted on the original drug. The result was that many Americans found their drug bills increasing out of reach.

I believed that we could increase competition and help Americans find affordable prescription drugs by streamlining approval of generic drugs.

It was important to move carefully, though. We knew that faster generic approvals, alone, could weaken the industry's incentives for innovation. The pharmaceutical industry is responsible for tremendous advances in health care and we did not want to interfere with their ability to produce important new medicines.

So, working with Senator Hatch, we guaranteed generous patent protection and monopoly periods to brand name companies, at the same time that we made it easier to market generic drugs. These monopoly protections were intended to allow brand name companies to recoup their research and development costs and to support future innovation.

While we were improving competition, we were also protecting innovation. We knew that both elements were vitally necessary to our nation's health. Our citizens need effective new medicines to treat their illnesses. Yet those medicines are useless to many Americans if only the insured and the rich can afford them.

Hatch-Waxman was a large step forward for American consumers. And, for many years, the balance we worked so hard to achieve held. The generics' share of the market grew steadily,

lowering drug prices by over 2/3 for those drugs with generic competition. This was significant progress toward making prescription drugs affordable. Meanwhile, the pharmaceutical industry continued to flourish. Throughout the 1980's and 1990's the industry continued to produce innovative medicines (as well as enviable profits). This too served Americans extremely well.

But there was also a counter-reaction, a step backward. There was too much money on the table for the major drug companies to easily give up their monopoly profits, and they looked for ways to hold on. Several large pharmaceutical companies exploited loopholes in the law to keep generics off the market. As a result, progress toward rapid access to low-cost generic drugs significantly slowed.

Also, in the last few decades it has become clear that there are two important areas in which Hatch-Waxman has not succeeded in making prescription drugs affordable. These are areas where we need to take additional steps to make sure that Americans have access to reasonably priced drugs.

The first area involves biologic products. This is a major category of drugs that were not even covered by the original law.

The second area involves the period of time after a drug is first marketed, during which Hatch-Waxman exclusivity and patent protection preclude generic competition. During this period, consumers still pay monopoly prices for prescription drugs. And because of the tiered pricing policies of the prescription drug industry, Americans without insurance pay far more than those with greater bargaining power. All too often, these discriminatory pricing policies impose the costs of the exclusivity and patent provisions of the law on those least able to afford them.

Hatch-Waxman was an important step toward making drugs affordable for all Americans, but we have more work to do in each of these areas. It's worth talking about each of them in more detail.

Let me begin with the step that we have taken backwards. Sometime in the 1990's, some companies began to deliberately undermine the balance between competition and innovation that had been struck in Hatch-Waxman. As a result of these abuses, Americans began to lose timely access to generic drugs.

Why did this happen? Because, as their pipelines began to dry up, some brand name companies began to create and exploit loopholes in Hatch-Waxman to protect their monopolies on existing drugs. These companies apparently saw delaying generic competition as the answer to keeping their profits high. So, rather than innovate new drugs, they began to innovate new legal strategies.

The result was that generic drugs took months and even years longer to get into the market than we had ever intended when we passed Hatch-Waxman.

Two years ago, the FTC published a report revealing how some companies were gaming the system. Here are just a few of their findings:

- Beginning in the late 1990s, drug companies increasingly began to file multiple new patents when the original patents on a drug expired. These late filings triggered successive 30-month stays of generic drug approvals under Hatch-Waxman. When we had drafted the law, we never imagined that there would be more than one 30-month stay per drug. This tactic of obtaining multiple 30-month stays was used to delay competition on 8 blockbuster drugs. According to the FTC, it delayed the availability of generic drugs between 4 and 40 months *beyond* the initial 30-month period.

- The FTC also found that the patents used to delay generic drugs were almost certainly undeserving of protection. Of the 8 blockbuster drugs with multiple 30-month stays, the FTC found 4 cases in which there had been a court decision on one of these late-filed patents. In all 4 cases, the patent was found invalid or not infringed. And the FTC

questioned whether the patents filed on the other 4 drugs should ever have been listed at all.

- The FTC also found that in that same time period, there were a significant number of agreements between brand and generic companies with the potential to delay competition. These agreements took advantage of the 180-day exclusivity period granted to the first generic applicant to challenge a patent and had the effect of blocking all generic competition for that period. Again, when we drafted the Hatch-Waxman Act, we certainly never intended the 180-day exclusivity period for generics to be used to extend the monopoly on the brand-name drug.

To borrow from the old movie title, "the Empire Struck Back." Healthy competition in the drug marketplace was being seriously undermined because the drug companies successfully invented loopholes in Hatch-Waxman.

The brand-name drug companies exploited these loopholes in ways that cost consumers, the States, the Federal government, and insurers billions of dollars a year. Seniors were among the hardest hit because they use more drugs and frequently have no prescription drug coverage.

Hatch-Waxman may have been two large steps forward for American consumers, but our country surely took at least one step backwards in the years that followed.

This year, we finally made another step forward. While it was not as big a step as it could have been or should have been, I'm glad to say that some of the loopholes in the original Hatch-Waxman Act were closed in the Medicare prescription drug bill. That bill was a bitter disappointment in many ways, but in order to pay for the new benefits that the law created, even the staunchest supporters of the brand-name drug industry were forced to look for ways to bring down drug prices.

I don't mean to overstate the value of that bill. The "headline" of the Medicare prescription bill was grim. As just one example, at the behest of the drug companies, the Republican sponsors of the bill insisted that it include a provision barring the government from using its negotiating power to bring down drug prices. The benefits of the bill have also been overstated. It has a complicated and inadequate benefit design, filled with periods of no coverage that will surely also disappoint seniors who have waited so long for help.

Nonetheless, the bill did include a few positive things. And one of those was a set of provisions narrowing some of the loopholes in Hatch-Waxman.

Now the reforms in the bill could have been and should have been better. The bill limited manufacturers to one 30-month stay per drug, for example, so that companies cannot delay generic competition at the last minute by filing new patents just as the generic drug is ready to be marketed. Limiting companies to a single stay will cut off many of the most egregious delaying tactics. But this provision was not as strong as it should have been. The timing of the 30-month stay may still permit some gaming of the system.

If the Republicans had allowed any amendments to the bill, I would have proposed eliminating all 30-month stays. Those stays are no longer necessary, and they cause delays in access to generic drugs.

But I'm very hopeful that the reforms we did get will help improve the balance between competition and innovation and give Americans better access to low-cost generic drugs. Of course, even as we move forward, there is pressure to move us backward again.

Some drug companies have already begun to search for new tactics to delay generic competition. The growing practice of putting so-called "authorized generics" onto the market just as the first generic competitor is set to begin its 180 days of exclusive marketing is one such tactic. I'm sure

there will be others. Progress will always meet with resistance. But I believe that we will continue to overcome that resistance. The pressure to bring down drug prices is simply too great.

Let me now move to the two areas where Hatch-Waxman has not achieved its goal of making drugs affordable for all Americans. A category of drug products that barely existed in 1984, and that we completely ignored in drafting the legislation, has slowly emerged as a major source of new medicines. In 1984, we didn't even think to cover biological drug products, which are regulated under a different statute than traditional drugs.

This is an area where America has not even made the first step forward. Today, more than 150 biotech drugs, which are regulated as biologics, are on the market. These drugs are commanding a larger and larger share of the pharmaceutical market. Analysts estimate that by 2010 biologic sales will exceed $60 billion.

The failure to guard against monopoly profits in this sector has been enormously costly for American consumers. Patients who need these drugs often have to pay tens of thousands of dollars a year for them.

There is no currently recognized mechanism for approving generic versions of biological products, and there is relatively little direct competition in the biologic marketplace. So, in many ways, this important sector of the market continues to operate as the market for other pharmaceutical products operated before 1984. As a result, monopoly profits are still the rule of the day for biologics.

Although this strongly suggests the need for further amendments to Hatch-Waxman, there are other ways in which the situation with biological products does not mirror 1984. In particular, we don't have anything like a scientific consensus on how to establish that a generic is the same as the original biological product.

This means to me that we have to address an additional set of competing concerns with biogenerics. On the one hand, we want to make affordable biological drugs available to Americans as quickly as possible.

On the other side of the equation there are two different concerns. First, we want to be sure that the generic versions of those drugs really are what patients need: that is, safe and effective versions of the brand-name product. Second, we don't want the scientific controversy to jeopardize acceptance of generic biologics, or worse, to jeopardize confidence in the generic industry as a whole.

Is it possible to take a step forward here, without creating even greater problems? My personal view is that it is. I certainly don't have all the answers, but I believe that thoughtful people are already beginning to lay out a path that involves a much more case-by-case approval process for generic biotech drugs than we have for traditional drugs. We still have a long way to go before we reach the kind of consensus that will bring about a new approval process for follow-on generics.

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.

Finally, let me address fundamental problems in our healthcare system which, despite much greater access to generic drugs, are keeping prescription drug costs sky-high, and unavailable to many Americans. Even as we talk about the successes of Hatch-Waxman, it's no secret that Americans are unhappier than ever before about the high cost of prescription drugs.

Paradoxically, certain aspects of Hatch-Waxman have contributed to a system in which new drugs can be wildly expensive and out of reach to many Americans. But reforming Hatch-

Waxman won't fix this problem. We need to address discriminatory pricing mechanisms and we need to address the lack of health care insurance.

As we intended when we drafted the law, the Hatch-Waxman Act's patent and exclusivity provisions allow drug companies to recoup their costs of investment by protecting new drugs from competition for several years. This type of incentive recompenses drug companies through higher prices to consumers. Unfortunately, because of how the drug industry tiers its prices, theses protections keep the prices of new drugs at their highest for those least able to pay.

As our health care system works today, exclusivity is a burden felt most heavily by those without health insurance. This is because the pharmaceutical industry charges the highest prices to those without insurance, while those with bargaining power pay much lower prices. Extending the period of monopoly pricing therefore has the effect of placing the biggest share of the cost of drug development on those least able to pay for it.

Although I continue to believe that brand-name drug companies deserve incentives for innovation, the use of patent extensions and exclusivity to provide those incentives is not a perfect solution, at least where drug companies are free to practice price discrimination and many Americans lack drug coverage. In this setting, extended periods of exclusivity mean that a significant portion of Americans must pay disproportionate sums for new drugs or go without them altogether.

Ironically, the pharmaceutical industry continues to lobby for even longer periods of exclusivity, citing the fact that, in Europe, drugs are given 10 years of exclusivity, or twice what they get in the U.S. What the companies never point out is that in Europe there are both price controls and universal drug coverage.

Under such a system, initial prices are not sky-high, and the burden of higher prices is shared equally by all. If we had such a health care system here, exclusivity would be a far more equitable form of reimbursement for drug development costs.

To really address high prescription drug prices, we need to do more than amend Hatch-Waxman. We need to address the disparity between what Americans pay for drugs and what the citizens of other countries pay. Most Americans are beginning to realize that the price that Americans pay for prescription drugs is much higher than the price paid by almost anyone else in the world.

In other industrialized countries, consumers are protected from drug price discrimination and the government uses its bargaining power to affect prices. For example, in Canada, prices of new brand-name drugs can't exceed the average price of those drugs in seven other industrialized nations.

Reimportation of drugs from Canada has never been an ideal solution to the problem of price discrimination, on either safety or economic grounds.

We need to take steps *in this country* to assure that drug manufacturers charge no more for prescription drugs in the U.S. than the average foreign price for those same drugs. And we need to help people without drug coverage. We need a much more meaningful Medicare prescription drug benefit for seniors, and we need to address the shameful fact that in the richest country in the world 45 million people have no health insurance at all.

None of this is easy. We will not give all Americans access to affordable drugs in a single step. But I am convinced that we must do more than we have done. It is not acceptable to stand pat, where we are.

We cannot continue to have a system in which monopoly profits are extended through legal shenanigans. We cannot continue to have a system that enshrines permanent monopoly status for

some of the most important medicines. And we cannot continue to have a system where the least able among us pay the highest prices for essential medicines.

Step by step, we can and will do better. And I hope that you will all walk this path with me.