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Exactly 100 years ago, this country elected a Republican president. His name was Teddy Roosevelt and he campaigned on his record of regulating monopolies to foster competition, and promised a "square deal" to American consumers. During his presidency, Teddy Roosevelt busted trusts in the railroad and steel industries. He gave federal protection to over 230 million acres of American wilderness. He secured historic passage of the very first Pure Food and Drug Act. He even reduced the national debt by 90 million dollars.

Well, the Republican Party isn't what it used to be. Among other things, it sure isn't interested in curbing monopolies or giving a square deal to American consumers. In the world of pharmaceuticals, the Republican Party is all about curbing competition, not curbing monopolies. The brand-name drug companies have made many millions of dollars of contributions to the Republican Party to get the Republicans to try to block competition, and all too often in recent years the Republicans have done their bidding.

Now when I agreed to do this speech several months ago, I wasn't sure whether our next President would be a Republican or a Democrat. One thing I thought I could predict, though, was that the Democrats would gain some Senate seats, and that we would see some greater balance in Congress. Greater Democratic strength in the Senate would have given us leverage to push forward on one of the most important issues facing America, the unreasonably high cost of health care.

I have always viewed broad access to generic drugs as one of the most important ways to lower the high cost of prescription drugs, and I thought that the likely results in the election would make it easier to improve access to these drugs.

As you all know, I was wrong about the election. The Republicans' hand has been strengthened in both Houses of Congress.

So what does the surprisingly broad victory of the Republican party in this election mean for generic drugs?

Of course, I've already admitted that my political predictions are not always accurate. To make matters worse, my crystal ball is clouded by the fact that there are new Chairpersons for the Committees in both Houses that are most central to pharmaceutical policy. Neither Congressman Barton on the Energy and Commerce Committee in the House or Senator Enzi, who will presumably chair the health Education, Labor, and Pensions Committee in the Senate, has much of a track record on generic drug issues.

Nonetheless, I can offer you some educated speculation.

In two recent cases, Republicans have actually called for improving access to generic drugs as the answer to lowering the price of prescription drugs. Surprising? Not really. In both cases, the Republicans were actually supporting the brand-name industry. The Republicans were fighting against cost-containment alternatives that the brand-name companies liked even less than generic competition.

The first case involved the debate over re-importation of drugs from Canada. Why would brand name companies prefer generic competition to re-importation?
The reason is that the brand name companies see drug re-importation from other countries as importation of price controls. Generic competition, which is limited by statute and can be gamed in many ways, isn't nearly as scary as price controls.

The second case was in the Medicare debate. The Republicans fought against allowing the government to negotiate drug prices on behalf of Medicare beneficiaries. Big businesses do it, insurance companies do it, the VA does it, but the Republicans made sure that the administrators of the Medicare program were forbidden to do it. Because the brand-name drug industry was terrified of letting the market work to bring down drug

prices. Once again, the Republicans turned to generic competition as their answer to high drug prices, because, to them, the alternative was much more frightening.

Does this mean that we can expect the Republican majority to embrace generic drugs and fight for broader access to them in the 109th Congress? That we can expect to see them introducing legislation to permit approval of generic biologics or enacting bills to end the practice of so-called "authorized generics"?

I'd be reluctant to make such a prediction. As far as I can tell, the Republicans are still largely doing the brand-name industry's bidding. In the cases I mentioned, Republicans supported greater access to generic drugs only when pushed into a corner. And even in that situation, the Republicans are often more interested in giving lip service to generic drugs than in actually improving access to them.

Let's look at what they did to increase generic competition in the Medicare prescription drug bill. The Medicare bill became the vehicle for several reforms of the Hatch-Waxman legislation the generic drug industry had been supporting.

As you all know, the impetus for these reforms was exploitation by the pharmaceutical industry of loopholes in Hatch-Waxman to delay the entry of generic drugs into the marketplace. Some companies were prolonging their monopolies and delaying competition by months and sometimes years beyond the time intended by Congress.

The Senate version of the Medicare bill contained relatively strong responses to these abuses. The final Medicare bill, however, did not close all of the loopholes as tightly as I would have liked.

The reason is that the House Republicans deferred to PhRMA and watered down some of the key provisions.

The bill did limit manufacturers to one 30-month stay per drug, 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.

Indeed, I would have eliminated all 30-month stays because they are no longer necessary and cause delays in access to generic drugs.

Another provision of the Hatch-Waxman reforms was more significantly diluted. Under the Senate version of the bill, generic drug companies would have had the right to institute a lawsuit to determine whether the brand name drug patent was being violated, even if the brand name company itself did not sue for patent infringement.

This matters because the elimination of multiple 30-month stays also eliminates the brand name company's incentive to resolve patent disputes early, while the generic drug is still under review at FDA.

But, the House Republicans watered down the declaratory judgment provisions in the Medicare bill. The final provisions are murky as to whether generic companies can bring such suits before marketing. While, there is a declaratory judgment provision in the final bill, and it should give the generic industry a small boost in its efforts to bring declaratory judgment actions against patent holders, it is not the robust provision it once was.

So the Republicans were willing to support some reforms that increase access to generic drugs. But they certainly were not willing to go as far as the generic drug industry wanted, nor as far as I believe was needed to really close the loopholes in Hatch-Waxman. And, of course, the Medicare bill, as a whole, was a huge win for the brand-name pharmaceutical industry. It gave a miserly benefit to seniors, while providing give-aways to the pharmaceutical and insurance industries. Best of all, it put off to another day the need to face the crisis in prescription drug costs.

There are also signals from the Bush Administration's treatment of generic drugs on the international stage that should give us pause. The Administration's actions in implementing its international AIDS initiative, known as PEPFAR, and its actions in negotiating international trade agreements raise serious questions about the Republicans' sincerity in embracing generic competition.

These signals only reinforce the evidence here at home that the Republicans' allegiance is, first and foremost, to the brand-name drug industry, and that its commitment to affordable medicines has a much lower priority.

PEPFAR, as you probably know, is the President's initiative to substantially increase US support of AIDS prevention and treatment efforts in Africa and the Caribbean. A major part of the initiative is to provide drugs to treat a substantial number of those already afflicted with AIDS.

Because AIDS treatment is so expensive, widespread treatment would have been virtually impossible before low-cost generic versions of AIDS drugs became available internationally.

Specifically, the advent of low-cost, three-in-one, combination pills, manufactured by foreign generic drug companies, has made widespread, convenient treatment of AIDS in developing nations a real possibility.

With 40,000 Africans dying of AIDS every month, spending limited resources on unnecessarily expensive brand-name medicines is the difference between life and death for many thousands of human beings.

In his State of the Union message announcing PEPFAR, President Bush specifically endorsed the use of generic drugs to make broad treatment a reality. Since then, however, the Administration has thrown up one roadblock after the next to the purchase

of generic drugs, insisting instead on purchasing much more expensive U.S.-approved brand-name drugs.

It is obviously critical that the HIV medicines we distribute are safe and effective. But the U.S. has repeatedly proposed unnecessarily high standards for reviewing generic AIDS drugs.

The quickest way for the US to assure itself that these drugs were safe and effective would have been to participate, with other developed countries, in the pre-existing review process run by the World Health Organization, building on and strengthening that process. The Bush Administration has refused to do this.

Instead, under tremendous international pressure to begin purchasing generic combination AIDS drugs for use in Africa and the Caribbean, the US announced in May, with great fanfare, that it would provide an expedited review process by the FDA for these drugs. The announcement promised that the FDA would review them in "two to six weeks." This led newspapers and public health experts to congratulate the Administration for finally understanding the urgency of getting generic combination drugs to Africa.

Unfortunately, the promised two-to-six week timetable was highly misleading. It turns out that the two-to-six week review begins only when the manufacturer has submitted a complete and acceptable application. And FDA at least initially refused to accept any of the bioequivalence studies that had previously been conducted.
As many of you here today know, putting together a complete and acceptable ANDA can be a long and laborious process, especially for companies not familiar with the FDA review process.

It is now six months since the Administration's two-to-six week review process was announced, and there have been no FDA approvals of generic combination AIDS drugs, nor do any appear to be imminent. Delay benefits the brand name companies who make

the individual components of these drugs, but it surely does not serve the millions of HIV-infected people around the world.

The Administration's actions in negotiating trade agreements with developing nations also reveals their willingness to put the interests of the brand-name drug industry above the need for affordable medicines. In one agreement after the next, the Administration has insisted that poor countries adopt stringent intellectual property protections for brand-name pharmaceuticals, in the form of patent extensions and exclusivity periods. These agreements have the effect of barring generic drugs from the market in these countries for many years. For most of the citizens of these countries, generic drugs are the only drugs they can afford, and requiring them to buy brand-name drugs is tantamount to removing their access to any drugs at all.

The Administration claims that these agreements are appropriate because they are just imposing the same Hatch-Waxman-like protections we have in the US. But this obscures key differences between the situation in the US at the time Hatch-Waxman was adopted and the situation in developing countries.

As you well know, when we fought to enact Hatch-Waxman, there was almost no access in the US to generic drugs because there was no legal way to approve generic versions of new drugs. The patent protection and exclusivity provisions of Hatch-Waxman were included as a trade-off for the new authority to approve generic drugs on the basis of bioequivalence studies. Americans got rapid access to generics in exchange for limited economic incentives to drug companies. The truth is, Hatch-Waxman took away monopoly rights from the brand-name drug industry by putting an end to the permanent monopoly created by the drug approval system in effect at that time.

In the developing world, the situation could not be more different. There is no beneficial trade-off being offered to these countries.

Generic drugs are widely available already in many developing countries. Imposing a Hatch-Waxman-like scheme in these countries benefits only the brand-name drug industry by undermining generic competition. It provides no corresponding benefit to the citizens of these countries. Indeed, by limiting access to generic drugs these trade agreements reduce access to medical care rather than improve it.

These signals from the international front certainly suggest that, in settings where they think few people are paying attention, the Republicans continue to blindly support the interests of the brand-name pharmaceutical industry even when this means a tragic loss of access to medicine for thousands of people.

So what does this tell us about what the next four years will bring for the generic drug industry?

It tells us that the Republicans, left to their own devices, would probably be willing to do whatever they can to help the brand-name drug companies choke off competition from the generic drug companies.

But, as I suggested earlier, even as they work to advance the interests of the brand-name drug companies, on the domestic front, the Republicans may still be backed into supporting broader access to generic drugs. Why? Because they may see generic drugs as the lesser of several evils.

There are pressures building here that the Republicans can not afford to ignore. Post-election surveys show that Americans still view prescription drug costs as one of the top items on the domestic agenda. Big businesses increasingly feel the same way. The anger and suspicion is so great that Americans now view the pharmaceutical industry as no more trustworthy than the tobacco industry.

I don't believe that Americans can or will stand for prescription drug prices to continue to rise several times faster than the rate of inflation. The passage of the Medicare bill, which Republicans hoped would take the pressure off, has not done so.

The Republicans don't have many choices to significantly reduce drug prices and improve access to health care. Or at least they don't have many choices that they can stomach.

They can let foreign governments effectively impose price controls on drugs through a substantial foreign re-importation program. They can impose their own price controls. They can provide a truly meaningful prescription drug benefit in which the government is free to negotiate fair prices for drugs. I don't think the Republicans will voluntarily choose any of these options.

They can also take steps to improve access to generic drugs, such as creating a program for approval of generic biologics. If we're lucky, they may choose this option if only as a way of avoiding the others.

In the last session of Congress, the Republicans tried to duck the hard choices in the Medicare bill. When people duck choices, though, most times the same choices come back again. The only difference is that they are harder.

Drug prices are still going up. Seniors still lack adequate prescription drug coverage. Forty-one million Americans don't have health insurance of any kind. The next time around, the need to do something serious will be harder to evade.