

Remarks of Congressman Henry A. Waxman
Center for Business Intelligence
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Good afternoon. It's a pleasure to be here with you again. The topic of generic drugs has always been near and dear to my heart, never more so than now. Frustration with the high price of prescription drugs is at an all time high in this country. As tangible proof that Americans are extraordinarily concerned with prescription drug prices, the Congress has been deeply enmeshed in three different legislative initiatives that could have a significant impact on the issue.

Two of those initiatives have been in the works for a number of years, but the other one took most observers completely by surprise. All three have now been caught up in the Medicare bill that is coming to the floor in the next few days.

The major legislative battle has of course focused on expanding Medicare to create a prescription drug benefit. I have long argued that creating a meaningful prescription drug benefit is a crucial step towards making drugs affordable for seniors.

Unfortunately, the agreement being advanced by the Republican leaders in the Congress falls far short of what is needed. It would not only provide an inadequate drug benefit, but would undermine the integrity of Medicare itself.

The second legislative battle related to drug prices is one that I have spoken to you about before: a serious attempt to close loopholes in the Hatch-Waxman generic drug law that have been used to delay access to generic drugs. Many insiders have expressed surprise that the bills that passed the House and Senate could have advanced this far without greater concessions to the brand name drug industry.

For most observers of the American political scene, however, the third legislative battle over drug prices has been the most dramatic and unexpected. It has almost been a truism in American politics that PhRMA is politically invincible. After the last election, many pundits predicted that PhRMA's enormous contributions, mostly to the Republican leadership of the Congress, guaranteed that it could block any bill that would do anything to reduce drug prices.

Those predictions may yet prove true, and the Medicare conference has turned out to be a telling measure of PhRMA's power in this Congress. But, whatever the final outcome of the Medicare fight, everyone was surprised when PhRMA lost a major battle in the House earlier this year. The American people were so angry about high prescription drug prices that a large bipartisan majority stood against PhRMA and passed a bill that would permit Americans to purchase cheaper drugs from other countries.

Now, while I take a back seat to no one in my concern over high drug prices, I believe that importing drugs from other countries is a potentially ineffective and possibly dangerous way to address this problem. But putting aside the wisdom of the specific policy at issue, the re-importation debate teaches a valuable lesson: no matter how much money the pharmaceutical companies give to Congressional Republicans, their contributions can't protect them forever from the anger of the American people at unreasonably high prescription drug prices.

I want to talk in more detail about each of these three legislative battles.

First, let me say a few words about the Medicare drug bill itself.

I oppose it. It does not provide the drug benefit that seniors need. It has a complicated and inadequate benefit design, filled with periods of no coverage that will surely disappoint seniors who have waited so long for help.

But there is more. The bill explicitly bars the program from using the purchasing power of Medicare's 40 million beneficiaries to get better prices. In fact, it does not add a drug benefit to Medicare, where it should be. It fragments the clout of Medicare beneficiaries by sending seniors into the private market to try to find insurance that will cover just prescription drugs.

These so-called "drug-only" policies don't exist today. If they do come into being in response to this bill, they will cost more both for the beneficiary paying the premium and for the Government which has to make extra payments and assume the risk in order for the private plans to agree to "compete." That is a strange and very expensive form of competition.

It is clearly part of an agenda by the Republican majority and the Administration to privatize the Medicare program. Their \$12 billion slush fund to entice HMOs and PPOs into the program—so they can unfairly compete against regular Medicare—is just another example of their agenda. And the move to so-called premium support—thinly disguised as a demonstration, but one that can adversely affect nearly 7 million Medicare beneficiaries—is the final step. If

that becomes the model for Medicare, the program that seniors and disabled beneficiaries like and depend on today will be destroyed.

All of that is too high a price to pay for an inadequate and unreliable drug benefit that will bring profits to the insurance industry but little real help to seniors.

This lost opportunity is a tragedy. No group is more dependent on prescription drugs for their health than the elderly. And no group feels a greater frustration over high drug prices. Because they don't have drug coverage, seniors not only have to pay for their medicines out of their own pockets, but they also end up paying the highest prices.

They suffer because the pharmaceutical industry practices price discrimination in the U.S., charging the highest prices for prescription drugs to those least able to afford it.

But it's not just the elderly who are frustrated about the exorbitant cost of prescription drugs.

People across the U.S. have begun to realize that they are charged far more for the same drugs than the citizens of other countries. The United States is the only developed country that does not protect its citizens against price discrimination. The citizens of Canada, for example, are guaranteed to pay no more for a drug than the average price paid by seven developed countries for that drug. In the U.S., our citizens pay two or even three times what Canadians pay.

The price of drugs in the U.S. is unfair, and Americans old and young are getting fed up. Frustration about drug costs is spreading rapidly to private employers and state and local governments, whose health care bills are sky-rocketing. So even if a Medicare drug benefit were robust, it would not solve America's prescription drug problem.

That's why reimportation of drugs from Canada or other countries has emerged as a potent political idea. It feeds on justifiable American anger about unfair drug prices. And it provides an apparently simple path to equalizing drug prices across international borders.

Despite my strong belief that current prescription drug prices are untenable, and that Americans are entitled to affordable drugs, I have been reluctant to embrace reimportation as the answer. I want to be very clear that I do not in any way endorse the price discrimination practiced by the pharmaceutical industry in the U.S. It is unconscionable that uninsured citizens in this country pay double or triple for prescription drugs what the citizens of other countries pay.

So, there's no doubt that I sympathize with the goal of reimportation. Nevertheless, I believe it is not the best way to lower drug prices. I have looked hard at how reimportation would work and I remain concerned that it poses real safety risks to American consumers that have not been adequately addressed in the bills before Congress.

It's one thing to take a bus to Canada, walk into a pharmacy, and buy a drug. I have little doubt that a Canadian drug bought in this manner is safe. It's quite another thing, however, to go online, find a website claiming to be a Canadian pharmacy and order a shipment of drugs through the mail. The chances that the Canadian pharmacy is in fact an illicit Chinese or Indonesian drug supplier are getting higher every day.

The Washington Post series on the vulnerability of our current system to counterfeit and substandard drugs should make all of us concerned about what will happen if we open our borders to thousands of shipments of drugs from any company calling itself a Canadian pharmacy.

We should also be concerned about undermining the FDA's powers to ensure that drugs are safe and effective. Some reimportation proposals deprive the FDA of authorities it needs to protect the drug supply. I would hate to see us start down that path at a time when the FDA's authority is already under attack from many sides.

A strong FDA is absolutely essential, and not only for the health of consumers. Our nation's food and drug industries thrive only when there is a strong FDA protecting the public from unsafe and ineffective products. When consumers are exposed to unjustified claims or needlessly dangerous products, consumer confidence evaporates.

Let's be completely clear about reimportation: the brand name pharmaceutical industry could make this problem disappear tomorrow, without any of the legislative interference they dread so much. We wouldn't need to consider relaxing the rules on reimportation if they would voluntarily stop discriminatory pricing against uninsured Americans.

I think we can all agree, though, that the chances of that happening are remote.

PhRMA appears to have effectively killed reimportation in the Medicare conference at the eleventh hour. But we shouldn't assume that reimportation will go away now. PhRMA's may be able to influence Republican members of Congress, but it appears to have very little ability to influence Americans' anger about unfair prescription drug prices.

PhRMA may have won this battle, but I very much doubt that they have won the war on reimportation. The pressure to permit reimportation is growing relentlessly, as each day a new governor or mayor announces his or her intention to begin buying drugs from Canada. As former FDA Commissioner Donald Kennedy said recently, reimportation appears to be a bad idea whose time has come.

If nothing else, the surprising momentum behind reimportation should heighten our resolve to do everything in our power to lower drug prices. Ensuring that Americans have access to generic drugs as quickly as possible is one of the best ways I can think of to do that.

As you are all aware, members of Congress have been working for a couple of years now to end abuses of the Hatch-Waxman Amendments. The Hatch-Waxman Amendments balance the need to speed access to low-cost generics with the need to reward innovation. This balance is achieved by providing specific periods of exclusive marketing to brand name drugs, after which generic drugs are supposed to become available.

At the moment, however, access to generics is not reliable. Unfortunately, many brand name drug companies have been exploiting loopholes in Hatch-Waxman to delay the entry of generic drugs far longer than intended by Congress.

When I spoke to you last year, I detailed many of the current abuses of Hatch-Waxman and described early legislative efforts to close loopholes in the law. Since then, the FDA finalized its rule limiting the ability of brand name companies to extend their monopolies through the so-called “30-month stay,” a legal maneuver that delays generic market entry through the filing of lawsuits.

While I believe that this rule is a needed step toward limiting exploitation of loopholes in the law, the rule is vulnerable to legal challenge. In addition, it doesn’t go far enough to make sure that generic products enter the market as quickly as the Hatch-Waxman law intended.

Broader, more effective legislation to address abuses apparently has been negotiated in the Medicare conference. I have strongly supported the Senate version of this legislation, which ensures that generic companies have a way to resolve patent infringement issues quickly, rather than allowing these issues to unnecessarily delay market entry.

Under the Senate version of the bill, generic drug companies would have 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.

Without that incentive, brand name companies may hang back and wait for the generic to enter the market before filing a lawsuit. A post-marketing patent infringement suit is both highly disruptive and potentially bankrupting, because a losing generic is liable for three times the brand's lost profits. The possibility of such a suit is like a sword of Damocles hanging over the generic manufacturer who dares to enter the market.

Many prudent generic manufacturers may decide not to go to market at all, giving the brand name company a de facto extension of its monopoly. To keep that from happening, generic drug companies need the right to go to court themselves and file a lawsuit that would resolve any patent infringement issues. This lawsuit is known as a declaratory judgment action. The brand name drug industry has vehemently opposed including a provision on declaratory judgments.

In the battle over Hatch-Waxman reform, as in the reimportation battle, PhRMA's political power is being tested. Until last week, it appeared that the generic drug industry had succeeded in getting a somewhat weakened version of the declaratory judgment provision that had been in the Senate bill.

At the last minute, however, it appears that PhRMA may have succeeded in a back-room maneuver that further undercut the declaratory judgment provision. The provision still exists, and gives the generic industry a small boost in its efforts to bring declaratory judgment actions against patent holders. But it is not the robust provision it once was.

Overall, will the generic drug provisions in the Medicare bill significantly lower prescription drug costs? I believe the bill's reforms will produce some modest reductions. Do I believe that those modest reductions together with the Republicans' very restricted prescription drug benefit are worth undermining the entire Medicare program? I certainly do not. And I hope that there are enough members of Congress who want to see a real prescription drug benefit for seniors and real reductions in the price of prescription drugs to keep this bill from passing.

Standing here today, I can't predict whether the Republican bill will pass.

Even if I can't predict what will happen in the short term, I believe that I can safely predict something in the long term in this area. I foresee that if the Congress caves in to the major pharmaceutical manufacturers now, and fails to do anything to seriously to make

prescription drugs affordable, the American public will continue to be angry. If you analogize the problem of out-of-control drug prices to an illness, treating this illness with placebos and self-congratulatory words will not make it go away. Our system of drug pricing needs serious medicine to get better, and the illness is too serious for the patient to let it go on forever. The major manufacturers may succeed this year in getting the Republican leadership to run from this problem now, but the problem will just keep getting worse and keep coming back until the Congress does something serious to address it.