

## **Six Ways Congress Could Hurt Big Pharma**

Matthew Herper, 11.16.06, 10:00 AM ET

Forbes

Has the drug industry's fabled political lobbying machine finally met its match?

Even before the Democrats took control of both houses of Congress in the recent election, drug firms were already facing half a dozen bills that could do serious damage to the profitability of pharmaceuticals. California Rep. Nancy Pelosi, the incoming Speaker of the House, has said that changing Medicare law in a way that could conceivably give the government the power to set drug prices is a top priority.

Wall Street is getting worried. In a note to investors, analysts at Prudential Equity Group fret, "Democrats are well positioned to force action on drug prices, and contrary to conventional wisdom, a [presidential] veto is not a sure thing."

Medicare buys half of all drugs in the United States, and if it can control its own costs, pill prices may be pushed down across the board. But that is only the first of many legislative battles drug firms are now facing. A recent report from investment bank Credit Suisse counts six legislative threats.

After years of battling pharma over the issue, Congress is widely expected to enact legislation allowing cheaper drugs from Canada to be shipped into the U.S., the report says. A law that has sped up drug approval times is up for reauthorization, giving Congressional leaders considerable leverage. Fundamental reforms of patent laws could make it easier to launch certain kinds of generic drugs. And there are two bipartisan bills that aim to reform the Food and Drug Administration, giving regulators more power to ensure drug safety.

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### Six Battles For Big Pharma

Legislation	What it is	Impact
Medicare reform	Would remove a clause that prevents the U.S. government from negotiating directly with drug firms.	Could allow the government to force lower drug prices
Drug importation	A law allowing patients to get cheap drugs from Canada looks increasingly likely.	Probably minimal, but the industry would lose face.
Prescription Drug User Fee Act reauthorization	The law that lets the drug industry fund the FDA in return for faster drug approvals is up for review.	A delay could slow the FDA; drug safety laws could be attached to it.
Patent reform	Basic reforms might make it more difficult to file multiple patents on a drug.	Limits on whether big pharmaceutical firms can make deals with generic drug makers are possible.
Medicaid reform	The system purchases drugs for the poor. A 2005 law already sought to save money.	Many prescription drugs, like those for schizophrenia, actually have much of their market share here.
Drug safety	Two bipartisan bills aim to make the FDA more powerful.	Will likely force the drug industry to disclose more data and do more studies. Drugs may carry stronger warnings.

*Source: Catherine Arnold, Credit Suisse First Boston*

Today, even before the Democrats take over, pharma is facing the first of these legislative battles. The Senate Committee on Health, Education, Labor and Pensions (HELP) is holding a hearing on building a "21st-century FDA." It will focus on the leading FDA-reform bill, which is being sponsored by the committee's current and future chairs: Mike Enzi, R-Wy., and Ted Kennedy, D-Mass. A prepared statement from Enzi's office says the bill will "ensure that drug safety is not an afterthought." The pair began drafting the bill two years ago, when Merck pulled the painkiller Vioxx from the market after it was found to cause heart attacks.

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The Enzi-Kennedy bill may actually be softer on big drug firms like Pfizer, Johnson & Johnson, and Amgen than another bipartisan bill, from Sens. Charles Grassley, R-Iowa, and Chris Dodd, D-Conn., that would have created a powerful office of drug safety within the FDA. But a draft that has been available on the HELP committee's Web site since July has teeth. It would put data from all major company-funded studies of drugs up on the Web. And it would give the FDA the power to fine companies to force them to do safety studies or change the labels of drugs.

The bill got a major push when a report from the influential Institute of Medicine, which the FDA had requested, seemed to back many of its claims--and also recommended that drugs be re-evaluated five years after they are approved. But in a Democratic Congress, the bill could get even tougher. In her note to investors, Catherine Arnold of Credit Suisse speculates that Democrats in the house could favor "more draconian" measures than the Enzi-Kennedy bill.

Drug safety legislation could be coupled to the re-approval of the Prescription Drug User Fee Act, a 1997 law that sped up drug approvals by getting drug firms to help pay for the process. That law must be reauthorized by September 2007.

Five years ago, drug re-importation, which would allow cheaper drugs to be imported from Canada, was the biggest threat facing the drug business. Now, analysts say that Congress will allow it--but that it is unlikely to have a significant effect on the industry's profits, because the number of pills brought into the U.S. in this way would actually be tiny.

Instead, the big focus is on Medicare reform. The Medicare Prescription Drug Benefit that went into effect this year pays industry health plans to cover the drug expenses of senior citizens. Since all of these plans are competing against one another, they don't have much leverage when negotiating with pharmaceutical giants or drug wholesalers.

But just to make sure drug firms don't have to negotiate with an 800-pound gorilla, the law contains a provision specifically forbidding the government from negotiating directly with drug firms. This is the sentence that the Democrats want to change or strike from the law. Depending on how a change was enacted, that could lower drug prices a little--or create a system where the government can basically dictate drug prices by saying what it will pay.

Drug firms say that the increasing focus on the risks and costs of drugs miss the point. The industry's trade organization, Pharmaceutical Research and Manufacturers of America, frequently points out that the FDA already sets the worldwide standard for drug safety and that many of the medicines drug firms invent are lifesavers.

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"I think it's been easy to beat up on the drug industry," says **Tony Zook**, who heads **AstraZeneca's** U.S. operations. But he worries that the industry might have trouble surviving if people forget about the good that medicines do and only focus on side effects. "If society is looking for the perfect pill, it doesn't exist," he says.

While drug costs are the main focus of discussion and debate, Zook points out that companies do a great deal to make their medicines available to those who cannot afford them. And the Medicare plan, he says, is already costing less than anyone, including the Congressional Budget Office, thought it would.

"The plan has already served seniors well," Zook says. "The focus should be on the 40 million people who are uninsured."

The drug industry has been struggling to move on from the Vioxx debacle, and it seemed that it had already won the battle over Medicare. But it looks like both issues are back on the table. Investors are already worried. Since the election, major drug stocks have dropped more than 5%.

[http://www.forbes.com/2006/11/16/fda-congress-bills-biz-cz\\_mh\\_1116fda.html?partner=alerts](http://www.forbes.com/2006/11/16/fda-congress-bills-biz-cz_mh_1116fda.html?partner=alerts)

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## **Drug Makers' Politics**

Produces a Bitter Pill

November 15, 2006; Page A2

Since Election Day, drug stocks have gotten clobbered. Pfizer, Wyeth, Eli Lilly and Novartis have tumbled 5% or more; GlaxoSmithKline, Merck and Johnson & Johnson are down 4% or more; and Bristol-Myers Squibb is down 3.5%.

Add it up, and you've got nearly \$50 billion in market value wiped out by Democratic victories.

That's the price big pharma is paying for a badly bungled political strategy. For years, the industry operated on the assumption it could get what it wanted out of Washington. Then, when the going got tough, it doubled down on Republicans and ignored a groundswell of public anger over high drug prices.

[Talking Business] TALKING BUSINESS

Should the government negotiate drug prices for senior citizens directly with the big drug companies? Join the discussion.1 Alan Murray will read your thoughts and post replies.

Even ex-congressman Billy Tauzin, the Democrat-turned-Republican who heads the industry's trade group, acknowledges that before he took over two years ago, the group used "a scorched-earth policy" to get its way.

The most conspicuous example of overreach was a line inserted in the Medicare Modernization Act of 2003 that prohibited the U.S. government from negotiating prices directly with drug companies. That prohibition was unnecessary; the law created a structure in which private insurers and health plans did the negotiating on the government's behalf.

But someone allied with the drug industry -- it's still a little unclear who -- insisted on making the implicit explicit, and in the process, created a campaign issue for Democrats.

As a result, the industry's big bet has now gone bad. Allowing the government to negotiate prices directly with drug companies has become Democratic dogma. And a few moderate Republicans are toeing the line as well.

That doesn't make it a good idea.

Truth is, drug companies can't really "negotiate" with the government, any more than a backwoods hiker can negotiate with a 900-pound grizzly bear.

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With a market share of about 46%, the government would set drug prices, not negotiate them, and then establish "formularies" telling seniors which drugs they could use and which ones they couldn't. Would that make seniors feel better off? I doubt it.

The challenge facing the industry is to balance the legitimate desire for lower prices against the equally legitimate desire for new drugs, which cost large sums of money to develop. The marketplace doesn't always get that balance right. But there's no reason to think government bureaucrats would do it better.

Moreover, negotiated prices would force drug companies to redouble their lobbying efforts in Washington. That would be unfortunate. One reason the industry is in such a mess is because its leaders have spent too much time trying to get Washington to solve their problems, and too little time fixing a broken business model.

In the past two years, there's been a purge -- Henry "Hank" McKinnell of Pfizer, Raymond Gilmartin of Merck and Peter Dolan of Bristol-Myers Squibb have all been pushed out of their jobs. A new generation of chief executives is looking to blaze a fresh trail, and the government should encourage them, not force them to reverse course.

And here's the biggest surprise: The new prescription-drug benefit for America's senior citizens, created by the Medicare Modernization Act, is working pretty well. Oh sure, there was a lot of confusion at first over the "doughnut hole" and the complexity of choices. But a year into this grand experiment, the cost of the drug benefit is going down -- it now averages \$24 a month, instead of the \$42 estimated by actuaries, according to Health and Human Services Secretary Mike Leavitt -- and the satisfaction of seniors is going up. Why mess with it now?

If Democrats need their political pound of flesh, there are other ways to extract it without causing such damage to consumers.

One option, being pushed by Sen. Ron Wyden, an Oregon Democrat, would give the administration limited negotiating power to be used only in extreme cases, when drug companies with a monopoly product refuse to negotiate with Medicare's middlemen. Another option would be to push measures that help the marketplace, rather than hamper it -- creating a pathway for generic versions of biotech drugs, for instance.

Meanwhile, drug companies should be allowed to get on with the tough task of developing new drugs and fixing their businesses. They've got a lot of work to do. With price pressures rising around the world and blockbuster drugs going off patent, they need to figure out how to cut costs without sacrificing the critical research that leads to lifesaving cures.

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It's in everyone's interest they succeed. The pharmaceutical industry's bad bedside manner has earned it a lot of enemies. But its lifesaving and life-enhancing products should make it many more friends.

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URL for this article:

<http://online.wsj.com/article/SB116355141789823288.html>

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**Trouble Ahead?**

Ok. It is over. Republicans are out. What does this mean for the drug industry and DTC? Let me reassure everyone and say DTC will not go away. A new Congress will not be drug industry friendly, but that does not mean draconian laws on advertising drugs.

It does mean embarrassing hearings on drug prices, safety and promotion. Expect to see CEO's of the major drug companies in front of the television cameras to explain why they price higher in the United States, why they fight re-importation and why drugs get withdrawn for safety reasons. This will make great theater for the Democrats.

DTC will be under pressure in proposed legislation to have an ad moratorium on new drugs, better explain risk and cite alternative treatments. This will probably result in specific regulations for DTC advertising as opposed to the makeshift guidances we now use. FDA would like Congress to write specific regulations for consumer advertising rather than interpret and apply the physician promotion regulations to DTC, never intended by Congress to cover consumers. Any new regulations would likely add restrictions and make broadcast ads more difficult.

The new Congress will want DTC to be less of a factor in creating demand for newer, higher priced drugs since they now cover Medicare drug payments. That is why they will push for a moratorium on new drug ads, partly for safety but also to discourage use. The Congress will also try to discourage all branded ads for the same reason. How much they can limit branded ads is under question for first amendment reasons. They can probably find ways to stay within constitutional limits, however, and still make it hard to do 60 second branded ads.

The likely winners in the DTC space will be companies promoting media with expansive copy capacity such as print, direct, web and point of care. Adding more information is easier for them and they can still make it affordable to drug advertisers. Will drug companies still run branded television ads if they require 75 or 90 seconds? It is likely drug companies would then primarily use television for disease education ads.

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Remember that any new regulations from Congress will take a long time to be finalized, so these potential changes would not be with us until at least 2008 if not longer. What may happen sooner is a tougher FDA because Congress will be watching them to see if they go easy on drug companies. We could see more warning letters and more onerous penalties for violators. The election is not good news for drug companies, but they will adapt and do just fine long term as will DTC.

Bob Ehrlich, Chairman  
DTC Perspectives, Inc.

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**Medicare Price Negotiation and DTC**

The new Congress plans to deal quickly with one of the biggest areas of controversy in the Medicare drug plan. That is, allowing the government to negotiate price discounts, which now is prohibited. Currently, private plans handle the Medicare drug plan, and they negotiate with the drug companies. The thinking is that one negotiator will have more market power to lower prices. By allowing the government to create a formulary negotiation system the thinking is drug prices will go way down.

What does all this have to do with DTC? It is entirely possible that advertised drugs will receive less favorable price treatment than non-advertised drugs. The government as payer and negotiator wants to discourage demand creation for newer, more expensive drugs. DTC advertised drugs may pay a price penalty to be on the formulary or the government could go so far as to pressure drug companies to suspend ads for drugs listed.

It is clear that the Medicare administration will have significant leverage with drug companies if that negotiating power is granted by Congress. Although they cannot, for first amendment reasons, prohibit DTC, they might informally give preference in negotiations to drugs that agree not to advertise. I expect most drug companies would gladly drop DTC if they get a higher price in return for a formulary preference.

My guess is that Medicare reform will not be the end of drug price negotiations. There is tremendous pressure by many consumer interest groups to lower drug prices outside of Medicare. We can expect renewed discussions and interest in creating a government single payer health care system, which would provide national health insurance, as in Europe. Of course this would be a massive undertaking and face significant resistance from the private sector. Drugs would then face price controls and DTC would probably be restricted. There are many good arguments for a single system, and many persuasive counter arguments against.

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From 2006 to 2008 health care will be one of the top 5 issues on the campaign stage. National health coverage will get serious consideration, and not just from Democrats. The moderate Republicans know that many constituents favor some government plan. It is likely we will eventually have some combination of a government plan with private treatment options, as in the UK. It is not likely mass media DTC will be a part of that system, but DTC marketers can relax as it will probably be a decade or more before such a system takes hold.

Bob Ehrlich, Chairman  
DTC Perspectives, Inc.

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**Analysis: CROs may prosper under Democrats**

By STEVE MITCHELL  
UPI Senior Medical Correspondent

WASHINGTON, Nov. 15 (UPI) -- Pharmaceutical stocks are slipping due to concerns about the incoming Democratic Congress, but contract research organizations should thrive in this environment because of an anticipated greater focus on drug safety at the Food and Drug Administration, according to an analyst report issued Wednesday.

"While many other healthcare segments have buckled on concerns about a Democratic Congress, we believe that contract research organizations (CROs) should thrive due to even greater focus on drug safety at the FDA," James Kumpel, an analyst with Friedman, Billings and Ramsey, stated in a research report.

The reason is that Democrats are expected to introduce legislation that will require stricter safety regulations for new drugs, including additional clinical trials and possibly more post-approval studies.

While this will increase the time it takes to get a drug approved and will likely have a negative impact on pharmaceutical companies, it could be a boon for CROs, Kumpel stated.

Companies that will benefit include PPDI, Covance and eResearchTechnology.

Kumpel reiterated his "outperform" rating on PPDI, primarily because the company has focused on late-stage clinical trials.

Another company that may benefit from increased safety concerns is Phase Forward, particularly if the FDA places greater emphasis on electronic clinical trial data, Kumpel said.

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Gene Mannheimer, an analyst with Caris, told United Press International he anticipates eResearchTechnology will do well next year.

"We think 2007 will be a strong year for the company," Mannheimer said.

The reason is that the number of clinical trials and FDA approvals appears to be on the rise. "The number of clinical trials is increasing; the number of FDA approvals was up about 15 or 20 percent for the nine-month period ending in September," Mannheimer said. "This is all positive for eResearch going forward."

The company operates on a relatively fixed cost structure, so as the number of trials increases, there's significant leverage there, he said.

As for the rest of the healthcare industry, Ed Nash, an analyst with Stifel Nicolaus, told UPI he expects it to be an uphill battle.

"Anything in healthcare with a Democratic Congress is going to be negative," Nash said.

One area that will hit biotech companies particularly hard is the anticipated drop-off in reimbursements that will probably be set by the Centers for Medicare & Medicaid Services. Nash said he expects the Democrats will seek to lower reimbursement payments in order to reduce healthcare expenditures.

"The quickest and easiest way to remedy high costs is to cut reimbursement rates," he said. "Unfortunately for biotech, for a lot of these newer drugs coming out, there will really be a lot of pushback," he said.

The concerns about rising healthcare costs are not just limited to the United States. Nash noted that an appraisal committee of the United Kingdom's National Institute for Health and Clinical Excellence earlier this week recommending against using Roche's non-small cell lung cancer drug Tarceva because it was not cost-effective.

"Europe has always been cost-conscious and I think the United is going to be forced into following suit," he said.

This cloud will likely hang over the industry for a while. Companies may decide to pursue strategies such as co-packaging drugs to give cheaper pricing or co-formulating multiple drugs in a single pill, but those are longer-term solutions that will take time to implement, Nash said.

"For a lot of these companies, it's going to be a hard game," he said. "We could see less biologics being made and more emphasis on small molecules."

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Companies will also probably be forced to reduce their R&D expenditures, he said, which in turn could inhibit innovation.

"Somebody has to be able to say we've got to cut costs somewhere, but that means we lost out on R&D dollars," Nash said.

<http://www.upi.com/HealthBusiness/view.php?StoryID=20061115-042521-8950r>

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### **Senators Urged to Add Teeth to FDA Bill**

By ANDREW BRIDGES

The Associated Press

Thursday, November 16, 2006; 1:06 PM

<http://www.washingtonpost.com/wp-dyn/content/article/2006/11/16/AR2006111600597.html>

WASHINGTON -- A bipartisan bill represents the best shot in years to improve the safety of drugs the Food and Drug Administration regulates, but needs bolstering to heal the ailing regulatory agency, witnesses told lawmakers Thursday.

The bill, introduced in August by Sens. Mike Enzi, R-Wyo., and Ted Kennedy, D-Mass., comes on the heels of a string of high-profile drug recalls and safety warnings. Among them was the 2004 withdrawal of the popular painkiller Vioxx after long-term use was linked to an increased risk of heart attack and stroke.

"Millions of Americans rely on the drugs that FDA approves. They take them for sickness. And now the FDA urgently needs treatment," Kennedy said.

Two panels of witnesses, including representatives from industry, consumer and patient groups, praised the bill's timeliness, saying it would improve safety \_ and the public's confidence.

"The initiative now before you represents the best opportunity in many years to fix these chronic problems," said Dr. Steve Nissen, a Cleveland Clinic cardiologist who served on an FDA advisory panel that in 2001 recommended new warnings on Vioxx.

Some of the bill's provisions, including a temporary ban on consumer advertising of newly approved drugs, echo proposals made in a September report on drug safety commissioned by the FDA. The report found that the FDA cannot track the safety of new drugs, nor respond quickly to problems, for want of money, people and power.

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"If there ever was a time that it was critical to address these issues, it is now," said Sheila Burke, chairwoman of the Institute of Medicine panel that produced the report.

Jim Guest, president and chief executive of Consumers Union, called the bill "a good first step," but said its provisions, including the power to assess civil penalties, should be strengthened. Nissen, too, said there was a need for further legislative action, including increased taxpayer funding of an agency that relies heavily on user fees paid by industry.

The Kennedy-Enzi bill calls for increasing those industry fees. Because of that, many FDA watchers believe next year the bill will be folded into legislation to reauthorize the fees.

Dr. Adrian Thomas, of Johnson & Johnson, said increased public funding of the FDA would address the perception that the agency is overly reliant on industry fees in a way that compromises its integrity.

The bill would require pharmaceutical companies to devise safety plans for new drugs. It calls for more disclosure of the results of drug trials in human subjects. It also would give the FDA the authority to require companies to carry out safety studies of drugs once they are on the market.

Text of Senate bill S.3807 available at: <http://thomas.loc.gov/>

## Democrats' Rx? Generics

Copycat Drugs May Get Boost to Rein In Health-Care Costs

By ANNA WILDE MATHEWS

November 21, 2006; Page A4 URL for this article: <http://online.wsj.com/article/SB116407085949728949.html>

NEWLY EMPOWERED Democrats' vow to cut health-care costs might spell bad news for the brand-name pharmaceutical industry, but their efforts could provide new momentum for the generic-drug rivals' agenda.

Boosting the generics industry may prove to be a politically palatable way to follow up on the party's campaign promises. That's because making more room for generics is meant to cut prices through increased competition -- a solution that is easier to sell as pro-market than other proposals Republicans will portray as precursors to federal price controls. In addition, some legislation that must be renewed in 2007, including laws providing vital funding to the Food and Drug Administration and encouraging studies of drugs' use in children, could provide gridlock-proof vehicles for generics provisions.



Henry A. Waxman

"Overall, because of the shift in Congress, next year could be the most important year to the generics industry since 1984," when Congress passed the law that opened the door to the modern generics business, says Jake Hansen, a vice president at generics maker **Barr Pharmaceuticals Inc.**, of Woodcliff Lake, N.J.

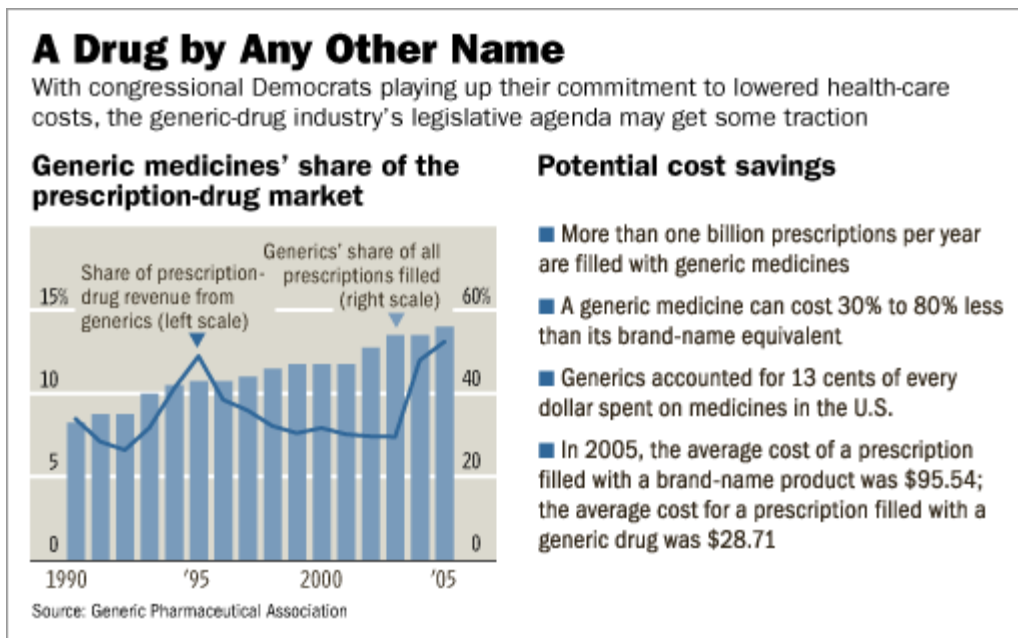
The most important question will likely be how and whether to create a legal pathway for the FDA to approve generic versions of biotechnology drugs. The 1984 law that created a framework enabling the FDA to approve generic drugs focuses on traditional, chemically derived drugs such as Prozac, but didn't give the agency a way to approve generic versions of most biotech products. Now, the issue will get a push from several key Democrats, though it will be difficult to pass such a complicated and contentious change in 2007.

An array of other measures aimed at smoothing the way for traditional generic drugs will also get attention, and could well be tucked into broader bills next year. Among them are proposals to limit branded-drug company tactics that thwart generic competitors, such as licensing additional companies to sell their drugs and thus diluting the profits to be made from copying them.



Kathleen Jaeger

The FDA generics office is likely to get more funding to speed its reviews now that the Democrats are in charge, and there may be limits put on FDA petitions filed by brand-name makers that can delay generic-drug approvals. Another likely goal for Democrats: shortening a six-month period of exclusive marketing that branded-drug makers get in exchange for their pediatric research, a benefit that can be worth millions of dollars because it delays generic competition.



Makers of traditional chemical generics sell versions that can be substituted for the originals, typically at a substantially lower price. The generics companies have far smaller development costs, since they don't have to duplicate years of research and regulatory review borne by branded-drug makers.

A number of Democrats who have been allies of the generics makers are slated for positions that could help in pushing forward such changes. In the Senate are Vermont's Patrick Leahy, the expected Judiciary Committee chairman, as well as high-profile lawmakers such as New York's Hillary Clinton and Charles Schumer. Sen. Edward Kennedy of Massachusetts, who will head the health committee, is among the Democrats who have signaled that health-care costs will be a major focus for next year.

Sen. Herb Kohl, a Wisconsin Democrat who is expected to head the Senate Appropriations subcommittee that handles the FDA's funding, says, "We really want to promote the use of generics because of the savings."

In the House, California Rep. Henry Waxman, a sponsor of the 1984 generics law, will be chairman of the Government Reform Committee, while FDA appropriations will go through a subcommittee headed by Connecticut Rep. Rosa DeLauro. The generics makers count some Republican supporters as well: Mississippi's Trent Lott, who will be the new Republican whip in the Senate, co-sponsored a bill supported by the industry last year with Michigan Democrat Debbie Stabenow.

"I'm obviously supportive of whatever we can do to make generics more available," says Democratic Rep. Frank Pallone of New Jersey, who may become chairman of the House Energy and Commerce health subcommittee. Drug prices are the kind of "affordability issue" that drew votes to Democrats, he says, adding that he supports the idea of generic

biotech drugs. Mr. Waxman, with Sens. Schumer and Clinton, has introduced a bill to create a generic biotech pathway, which he says is "very, very much needed."

Generics makers are leaning on a coalition that has worked in the past, drawing on big employers and others scared by rising health-care costs. European regulators, meanwhile, have already begun crafting guidelines for what they call "biosimilars."

The generics makers' pitch is simple, and likely to resonate with many lawmakers: Helping them means lower drug costs, and doesn't involve government-imposed price controls or the controversies surrounding imported medicines.

The generics industry complains about remaining "loopholes" in law and regulation exploited by branded-pharmaceutical makers to delay generic competition. On the issue of generic biotech drugs, they argue that they can safely create copies without duplicating all the expensive studies done by the original manufacturers. "Right now, there's a regulatory monopoly" for biotech drugs, says Kathleen Jaeger, chief executive of the Generic Pharmaceutical Association.

Branded-drug companies defend their tactics. In a statement, the Pharmaceutical Research and Manufacturers of America says licensing additional competitors increases competition and brings down prices beyond the introduction of a generic version. The group also says the FDA needs to consider safety issues raised by petitions before it approves a drug, and such petitions allow consumers and others to "present their views on important FDA issues."

The biotech industry, for its part, is pushing its own case on Capitol Hill. One argument: Science isn't advanced enough for generics makers to produce truly identical duplicates of their medications. It is likely to get a good hearing from Democrats, partly because of biotech companies' base in Democratic strongholds of California and Massachusetts.

Some biotech officials argue that generics makers will need to redo all the studies performed by the original manufacturer, in order to guarantee their copycat products are effective and safe for patients. That would likely eliminate much, or all, of the price advantage offered by the generics rivals. "There is no way to characterize a biological," says James Greenwood, a former congressman who heads the Biotechnology Industry Organization, a trade group.

Biotech companies also argue that their products take longer to develop, and are often tested for use in fighting more illnesses than traditional drugs. For small start-ups, they say, generic competition could be devastating. So if legislation moves forward, they will press for trade-offs such as extra years of exclusive marketing. Such a compromise was the basis for the 1984 passage of the generics bill.

"I would like to see Congress be fair to the innovators," says Jim Green, a senior vice president of **Biogen Idec** Inc., of Cambridge, Mass. "The level of research-and-development investment in the next product is not going down.

## **Success of Drug Plan Challenges Democrats**

Medicare Benefit's Cost Beat Estimates

By Lori Montgomery and Christopher Lee  
Washington Post Staff Writers  
Sunday, November 26, 2006; A01; <http://www.washingtonpost.com/wp-dyn/content/article/2006/11/25/AR2006112500919.html>

It sounded simple enough on the campaign trail: Free the government to negotiate lower drug prices and use the savings to plug a big gap in Medicare's new prescription-drug benefit. But as Democrats prepare to take control of Congress, they are struggling to keep that promise without wrecking a program that has proven cheaper and more popular than anyone imagined.

House Democrats have vowed to act quickly after taking power in January to lift a ban on Medicare negotiations with drugmakers, which they hope will save as much as \$190 billion over a decade. But House leaders have yet to settle on a strategy and acknowledge that negotiation is, in any case, unlikely to generate sufficient savings to fill the "doughnut hole," the much-criticized gap in coverage that forces millions of seniors to pay 100 percent of drug costs for a few weeks or months each year.

Drug-company lobbyists, Bush administration officials and many congressional Republicans are preparing to block any effort to increase federal control over drug prices, saying the Medicare benefit is working well. They contend that instead of saving money, government negotiations could raise drug prices for all consumers while limiting choices for people on Medicare.

"This is going to be much more of a morass than people think," said Marilyn Moon, director of the health program at the American Institutes for Research and a former trustee of the Social Security and Medicare trust funds. Negotiating drug prices is "a feel-good kind of answer, but it's not one that is easy to imagine how you put into practice."

The Medicare drug benefit, one of the Bush administration's signature domestic programs, was created in 2003 and took effect in January. It has enrolled 22.5 million seniors, some of whom had no previous drug coverage.

Polls indicate that more than 80 percent of enrollees are satisfied, even though nearly half chose plans with no coverage in the doughnut hole, a gap that opens when a senior's drug costs reach \$2,250 and closes when out-of-pocket expenses reach \$3,600. By the latest estimates, 3 million to 4 million seniors will hit the doughnut hole this year and pay full price for drugs while also paying drug-plan premiums.

The cost of the program has been lower than expected, about \$26 billion in 2006, according to the nonpartisan Congressional Budget Office. The cost was projected to rise to \$45 billion next year, but Medicare has received new bids indicating that its average per-person subsidy could drop by 15 percent in 2007, to \$79.90 a month.

Urban Institute President Robert D. Reischauer, a former director of the Congressional Budget Office, called that a remarkable record for a new federal program.

Initially, he said, people were worried no private plans would participate. "Then too many plans came forward," Reischauer said. "Then people said it's going to cost a fortune. And the price came in lower than anybody thought. Then people like me said they're low-balling the prices the first year and they'll jack up the rates down the line. And, lo and behold, the prices fell again. And the reaction was, 'We've got to have the government negotiate lower prices.' At some point you have to ask: What are we looking for here?"

Republicans contend that Democrats were looking for a campaign issue.

In the Nov. 7 elections, public anger over the doughnut hole helped many Democratic candidates, who pointed to the ban on government negotiations and accused Republicans of selling out to the pharmaceutical industry.

Republicans, by and large, did a poor job of defending the program, said Thomas A. Scully, a Republican and the former head of the federal unit that runs Medicare. He played a key role in creating the drug benefit.

"Black voters, poor voters -- people who generally vote Democratic -- they got the biggest benefit in 40 years and nobody told them that," Scully said.

According to those involved in the 2003 negotiations, even some Democratic bills to create a Medicare drug benefit included a ban on direct government negotiations. The reason: Seniors purchase half of all prescription drugs. The drug industry argued that a government program representing seniors would not negotiate prices, it would set them.

If government price controls were effective, the theory goes, they could significantly lower drug-company profits and discourage medical innovation. If price controls were not effective, they could drive prices higher. If companies were required to sell to Medicare at 15 percent off the average wholesale price, for example, they might just raise the wholesale price.

"At the extreme, if everybody gets a discount, then nobody does," said Mark B. McClellan, who took over from Scully in running Medicare and recently left the job.

Proponents say the program, as it now operates, avoids that problem by relying on dozens of private insurers, which bid to offer coverage to Medicare recipients. Some offer low premiums and lots of generic drugs, while others have high premiums but offer brand-name drugs and full doughnut-hole coverage. Medicare averages the bids and sets a per-person subsidy. Pressure falls on the insurers to negotiate the best drug prices.

Consumer advocates contend that if Medicare were permitted to negotiate prices, its purchasing power would produce drug discounts similar to those obtained by the

Veterans Affairs Department, which covers 4.4 million people. As it is, Medicare prices are significantly higher than VA prices, according to Families USA, a nonprofit association of health-care consumers that analyzed 20 drugs commonly prescribed to seniors.

Even Medicaid, the federal health program for the poor, appears to employ better negotiators than the private Medicare plans. On Jan. 1, 6 million elderly and disabled people were switched from Medicaid pharmacy plans to the new Medicare program. Overnight, many drugmakers began selling the same drugs at higher prices. Pfizer, for example, reported saving \$325 million in Medicaid discounts during the first six months of this year "due primarily to the impact of" the Medicare drug benefit, according to a company report to the Securities and Exchange Commission.

"At some point, someone has to stand up to these industries that are doing so well in this program," said Robert M. Hayes, president of the Medicare Rights Center, a New York advocacy group. "It only makes sense that if the industries do less well, the taxpayers and the consumers will do better."

Medicare officials say it's not fair to compare their prices with those of Medicaid and Veterans Affairs, which do not reflect certain overhead costs in their drug prices and offer a limited number of drugs. Limiting choice would be unacceptable to many Medicare beneficiaries, said [Sen. Charles E. Grassley](#) (R-Iowa), outgoing chairman of the Senate Finance Committee. "I don't think seniors want the government in their medicine cabinets," he said.

For now, it is not clear how aggressively Democrats are willing to push price negotiation. Ideas range from simply repealing the ban on negotiations -- which would accomplish little if the Bush administration refuses to negotiate -- to creating a separate, government-run Medicare drug program with strong negotiating power.

Rep. Fortney "Pete" Stark (D-Calif.), who is in line to become chairman of a key health subcommittee, said he prefers a middle path, with Medicare setting ceilings from which private insurers could negotiate downward.

But [Sen. Max Baucus](#) (D-Mont.), the incoming Senate Finance chairman, is cool to the idea of government negotiation, and has committed only to holding hearings to "determine what the result would be of eliminating" the no-negotiation clause.

W.J. "Billy" Tauzin, president of the Pharmaceutical Research and Manufacturers of America, said the drug lobby will "aggressively defend" the current plan. But John C. Rother, policy director for AARP, the powerful lobby for elderly Americans, said he has no doubt that the next Congress will give government some role in negotiating Medicare drug prices.

"This is an idea that's favored by 90 percent of the American public," Rother said. "It's not like you have to convince the American public that this is a good idea."

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[http://www.nytimes.com/2006/11/24/washington/24drug.html?\\_r=2&th=&emc=th&page\\_wanted=all&oref=slogin](http://www.nytimes.com/2006/11/24/washington/24drug.html?_r=2&th=&emc=th&page_wanted=all&oref=slogin)

## Drug Industry Is on Defensive as Power Shifts

By [ROBERT PEAR](#)

WASHINGTON, Nov. 23 — Alarmed at the prospect of Democratic control of Congress, top executives from two dozen drug companies met here last week to assess what appears to them to be a harsh new political climate, and to draft a battle plan.

Hoping to prevent Congress from letting the government negotiate lower drug prices for millions of older Americans on Medicare, the pharmaceutical companies have been recruiting Democratic lobbyists, lining up allies in the Bush administration and Congress, and renewing ties with organizations of patients who depend on brand-name drugs.

Many drug company lobbyists concede that the House is likely to pass a bill intended to drive down drug prices, but they are determined to block such legislation in the Senate. If that strategy fails, they are counting on President Bush to veto any bill that passes. With 49 [Republicans](#) in the Senate next year, the industry is confident that it can round up the 34 votes normally needed to uphold a veto.

While that showdown is a long way off, the drug companies are not wasting time. They began developing strategy last week at a meeting of the board of the Pharmaceutical Research and Manufacturers of America.

[Billy Tauzin](#), president of that group, a lobbying organization for brand-name drug companies, recently urged Representative Edolphus Towns, Democrat of New York, to seek a position as chairman of a powerful House subcommittee, said Karen Johnson, a spokeswoman for Mr. Towns. The subcommittee has authority over Medicare and the [Food and Drug Administration](#).

[Democrats](#) have yet to decide who will head the subcommittee.

Mr. Tauzin, a former congressman, also met with Senator Byron L. Dorgan, a North Dakota Democrat who has been trying for six years to allow drug imports from Canada. The industry vehemently opposes such legislation.

James C. Greenwood, president of the Biotechnology Industry Organization, another trade group, said, "There is a lot of pent-up animosity among Democrats against the pharmaceutical industry."

Mr. Greenwood, a former Republican congressman from Pennsylvania, said he had a list of 37 Congressional Democrats whom he intended to call in the next month.

Amgen, the biotechnology company, recently disclosed that it had retained as a lobbyist George C. Crawford, a former chief of staff for Representative [Nancy Pelosi](#) of California. Ms. Pelosi, the House Democratic leader, is in line to become speaker in January and has said that the House will immediately take up legislation authorizing Medicare to negotiate prices with drug manufacturers.

The 2003 Medicare law prohibits the federal government from negotiating drug prices or establishing a list of preferred drugs.

Amgen is also seeking strategic advice from the Glover Park Group, a consulting firm whose founders include Joe Lockhart, a former press secretary for President [Bill Clinton](#).

Other major drug companies have been snatching up Democratic former-aides-turned-lobbyists. Merck recently has hired Peter Rubin, a former aide to Representative Jim McDermott of Washington, one of the more liberal House Democrats. Cephalon has hired Kim Zimmerman, a health policy aide to Senator Ben Nelson, a conservative Democrat of Nebraska.

The Biotechnology Industry Organization has retained Paul T. Kim, a former aide to two influential Democrats, Senator [Edward M. Kennedy](#) of Massachusetts and [Representative Henry A. Waxman](#) of California.

A Medicare expert who works for House Democrats said he recently received three job offers in one day from the drug industry, by telephone and in person.

At a dinner last week at the Hotel Monaco here, as part of their board meeting, pharmaceutical executives dissected the midterm election results with experts including Ed Goetas, a Republican pollster, and Stuart Rothenberg, the editor of a political newsletter.

Drug makers have not set a budget for their campaign. They and their trade groups already spend some \$100 million a year on lobbying in Washington.

“We have new political realities to attend to,” Mr. Tauzin said in an interview after the board meeting. “We and our allies will do everything we can to defend the Medicare drug benefit, to get out the message that it is working.”

To reinforce that message, drug companies plan to mobilize beneficiaries and urge them to contact Congress.

“I’m putting my trust in beneficiaries,” said Mr. Tauzin, who represented Louisiana in the House for more than two decades, first as a Democrat and then as a Republican. Several

recent surveys suggest that at least three-fourths of the people with Medicare drug coverage are satisfied.

But Representative Frank Pallone Jr., Democrat of New Jersey, who hopes to head the health subcommittee of the Energy and Commerce Committee, said price negotiations for Medicare were his priority.

“The 2003 Medicare law was essentially written by the drug industry,” Mr. Pallone said in an interview. “That’s why you don’t have negotiated prices. Republican policies have served special interests like the pharmaceutical industry, and the American taxpayer is paying the price.”

Drug lobbyists believe that the Senate will be receptive to their argument that price negotiations lead inevitably to price controls, and to restrictions on access to drugs, likely to be unpopular with beneficiaries.

[Michael O. Leavitt](#), the secretary of health and human services, said the White House opposed federal price negotiations because they would unravel the whole structure of the Medicare drug benefit, which relies on competing private plans.

Among leaders who attended the board meeting last week were Kevin Sharer, chairman of Amgen; Jeffrey B. Kindler, chief executive of Pfizer; Sidney Taurel, chairman of Eli Lilly; and Richard T. Clark, chief executive of Merck.

Drug lobbyists say they want to work with the new Democratic majority, but that will not be easy. In its campaign contributions, the pharmaceutical industry has overwhelmingly favored Republicans over Democrats. Drug companies infuriated many Democrats in 2003, when they worked closely with Republicans to create the Medicare drug benefit, in a process from which Democrats were largely excluded.

On other issues, Democrats are pushing for stricter regulation of drug safety and for legislation to encourage development of low-cost generic versions of expensive biotechnology drugs. They are determined to allow imports of drugs from Canada, where brand-name products are often cheaper.

They want to investigate drug pricing and profits, drug advertising aimed at consumers and the marketing of drugs to doctors for purposes not approved by the Food and Drug Administration. Democrats may try to repeal some of the liability protections that have been given to vaccine manufacturers.

Outspoken critics of the pharmaceutical industry will gain power as a result of Senate committee assignments made last week. Senators Debbie Stabenow, Democrat of Michigan, and Maria Cantwell, Democrat of Washington, are joining the Finance Committee, which has sweeping authority over Medicare and Medicaid. Three liberal senators — Sherrod Brown of Ohio, [Barack Obama](#) of Illinois and Bernard Sanders of

Vermont — are joining the Committee on Health, Education, Labor and Pensions, which oversees drug regulation and biomedical research.

The pharmaceutical industry lost one of its most effective defenders when Senator [Rick Santorum](#), Republican of Pennsylvania, was not re-elected. The new Senate Republican whip, [Trent Lott](#) of Mississippi, is no friend of the brand-name drug industry. He supports bills to allow imports from Canada and to increase access to generic drugs.

Top pharmaceutical executives are hurriedly planning a response to the Democratic agenda.

“It’s all hands on deck,” said Ken Johnson, a senior vice president at Pharmaceutical Research and Manufacturers of America. “It’s like a hurricane warning flag. You don’t know where it will hit. You don’t know who will be affected. But everybody has to be prepared.”

Drug companies may be open to some changes in the Medicare drug benefit, but they say they cannot accept any form of price negotiation.

“The new Medicare program is clearly benefiting seniors and people with disabilities and has exceeded initial expectations,” Mr. Tauzin said. “But we are open to new ideas that could make it even better. We will propose at the same time we are opposing.”

Specifically, Mr. Tauzin said, drug companies would like permission to fill a gap in coverage that has angered many Medicare beneficiaries.

Many drug companies have programs to provide free drugs to people with limited incomes. When such programs are used to fill the gap in the Medicare drug benefit, they may run afoul of federal law — the anti-kickback statute — because they steer patients to products made by one particular company.

The drug industry is anxiously waiting to see details of the Democratic proposal. Lawmakers are weighing several options. At a minimum, Congress could simply repeal the ban on price negotiations, without requiring Medicare officials to do anything. Many House Democrats want to go further. They would direct Medicare officials to negotiate prices for a government-run prescription drug plan, which would compete with dozens of existing private plans.

The government could negotiate prices for all drugs or just for brand-name drugs that have no competition. Alternatively, Congress could require manufacturers to provide a specified discount, so Medicare would get the “best price” available to any private buyer.

Such details, defining the federal role, are immensely important and could determine the outcome of any votes in Congress.