Union of Concerned Scientists
Citizens and Scientists for Environmental Solutions

Industry Influence on Drug and Medical Device Safety at FDA

$700 million in lobbying buys significant access

March 29, 2012

2012 is crucial for the Food and Drug Administration, as Congress votes on legislation to renew the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee Act (MDUFA). Every five years, Congress by law must approve negotiations between the FDA and industries it regulates that set the fees these companies pay to the agency. In return, the companies exact performance goals from the FDA aimed at reducing the time it takes to get a drug or device approved.

It is crucial that Congress makes sure that safety, not industry profits, remains the FDA's priority, and that the agency is able to use the best available scientific information to do its job. However, several legislative proposals now before Congress would increase industry influence over FDA and make the agency's scientists more vulnerable to political and corporate pressure. A new analysis by the Center for Responsive Politics commissioned by the Union of Concerned Scientists (UCS) suggests that hundreds of millions of lobbying dollars, combined with millions in targeted campaign contributions, are helping to shape these congressional proposals.

THE CONTEXT FOR THIS ANALYSIS

In 2007, the last time PDUFA and MDUFA came before Congress, the FDA had been shaken by serious scandals and drug recalls. FDA whistleblowers testified at congressional hearings that the FDA attempted to suppress and intimidate them when they raised serious concerns about the safety of specific drugs later found dangerous and withdrawn from the market.

These scandals paved the way for real reform. That year, the PDUFA law greatly increased the transparency of the drug approval process and curbed conflicts-of-interest at the agency. It also strengthened the role of FDA scientists, requiring the agency to respect and encourage their right to publish in peer-reviewed journals and stipulating that the views of dissenting drug reviewers were to be part of the public record when a drug was approved by the agency.

But the political climate has changed. Congress, far from building on the reforms of 2007, seems eager to roll them back and pass legislation that reads like an industry gift list: relaxing FDA's review standards, particularly for medical devices; rolling back needed financial conflict-of-interest rules; and even changing the mission of the FDA to include job creation.

In part, this new direction reflects a change in political priorities in Congress. The unemployment picture has led many members of Congress of both parties to attack regulations and regulatory frameworks they have long despised, falsely believing that their actions will create jobs. But is another factor the role of special interest money on Capitol Hill?

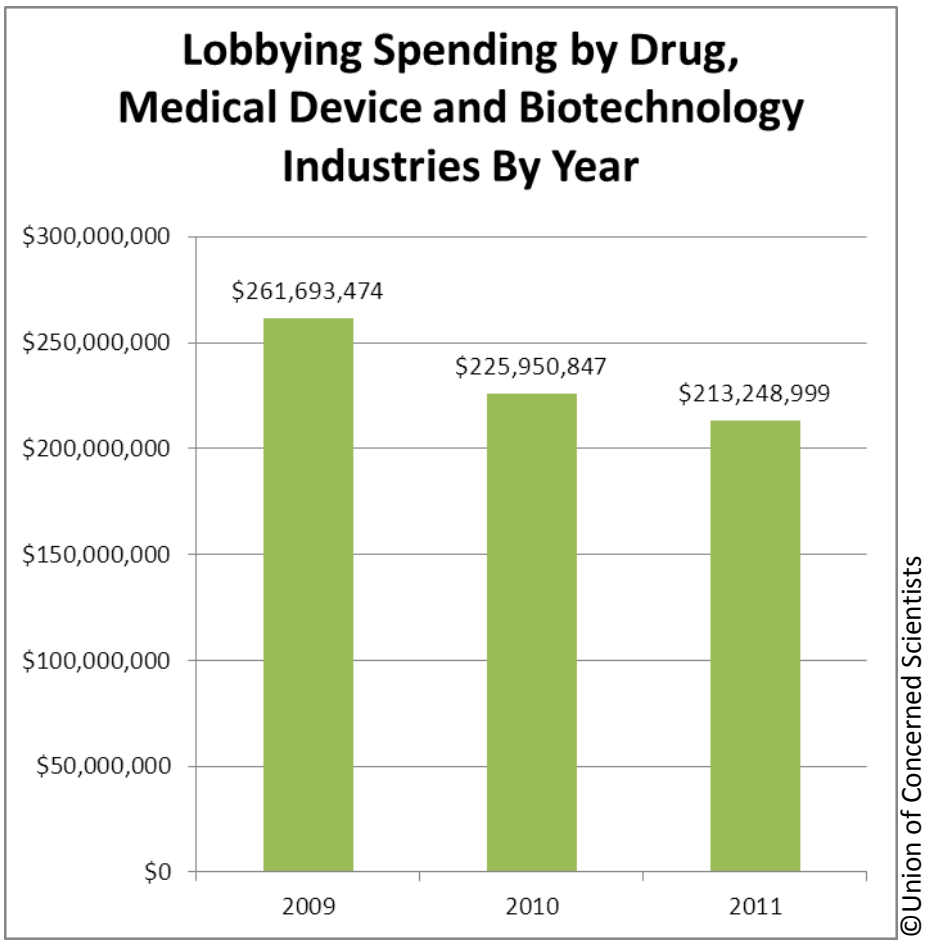
www.ucsusa.org
Two Brattle Square · Cambridge, MA 02238-9105 · TEL: 617.547.5552 · FAX: 617.864.9405
1825 K Street NW · Suite 800 · Washington, DC 20006-1232 · TEL: 202.223.6133 · FAX: 202.223.6162
2397 Shattuck Avenue · Suite 203 · Berkeley, CA 94704-1567 · TEL: 510.843.1872 · FAX: 510.843.3785
One North LaSalle Street · Suite 1904 · Chicago, IL 60602-4064 · TEL: 312.578.1750 · FAX: 312.578.1751

MEASURING SPECIAL INTEREST INFLUENCE

UCS asked the Center for Responsive Politics for data on lobbying expenditures and political contributions for three industries: pharmaceutical companies; medical device companies, and biotechnology firms for the three-year period beginning January 1, 2009 and ending December 31, 2011. Among the top findings:

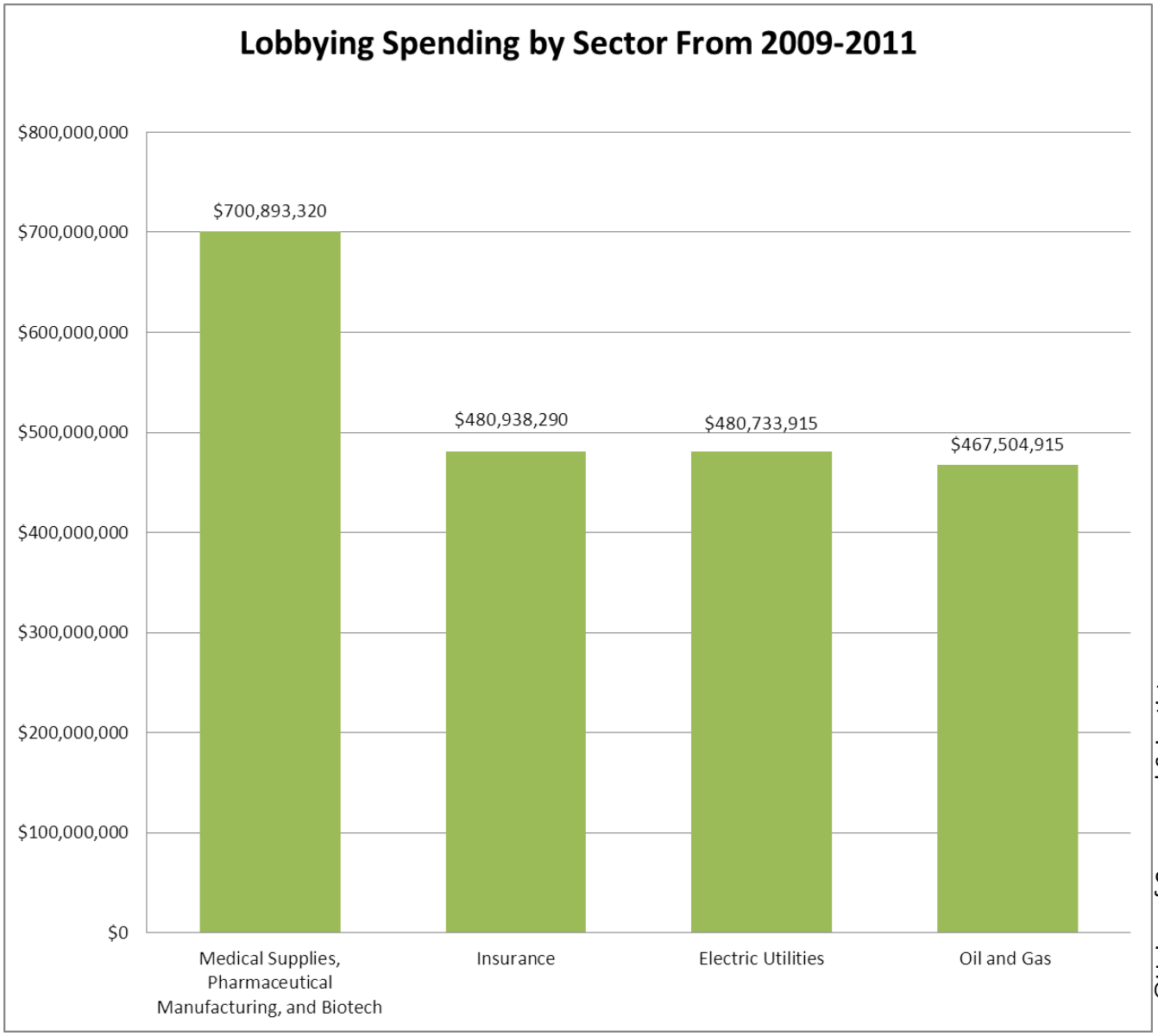
Lobbying

From 2009 through the end of 2011, prescription drug, biotechnology and medical device companies and their trade associations spent more than $700 million lobbying Congress and the Administration. Drug companies and their associations alone spent more than $487 million. Biotechnology and medical device companies and their associations also made significant investments, spending $126 million and $86 million on lobbying respectively. Here is the spending by all three industries broken down by year:



These industries, of course, lobbied on a variety of issues pending before Congress and the Executive Branch (such as the Affordable Care Act). Since registered lobbyists and their clients do not have to report the specific issues on which they lobbied, there is no way to break down how much money was spent to lobby on PDUFA and MDUFA. That said, money builds relationships and buys access, and we know that PDUFA and MDUFA are critical to each of these special interests.

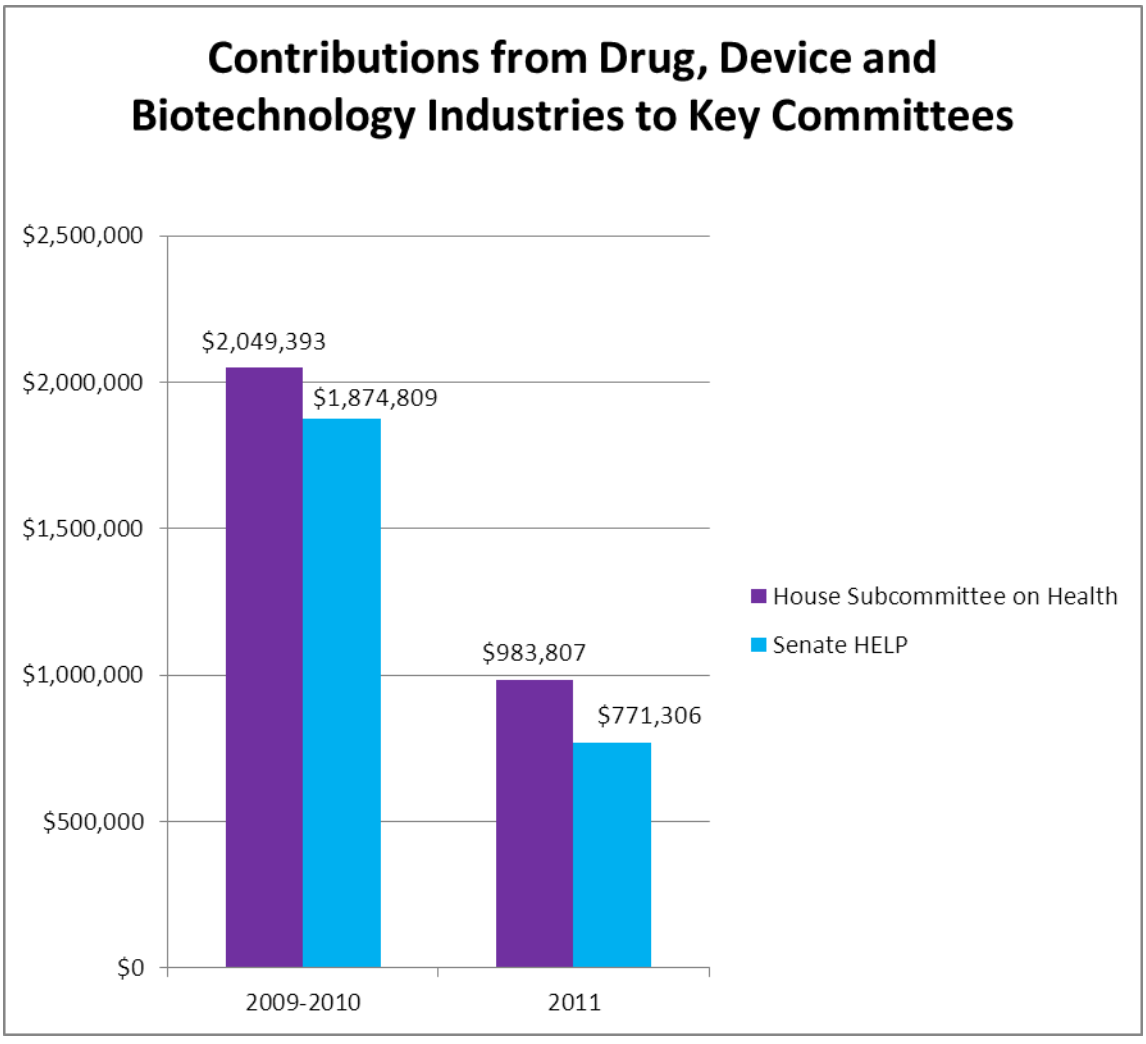
By comparison, in the same time frame, the oil and gas industry spent more than $467 million on lobbying, while electric utilities and the insurance industry each spent more than $480 million, according to the Center for Responsive Politics:



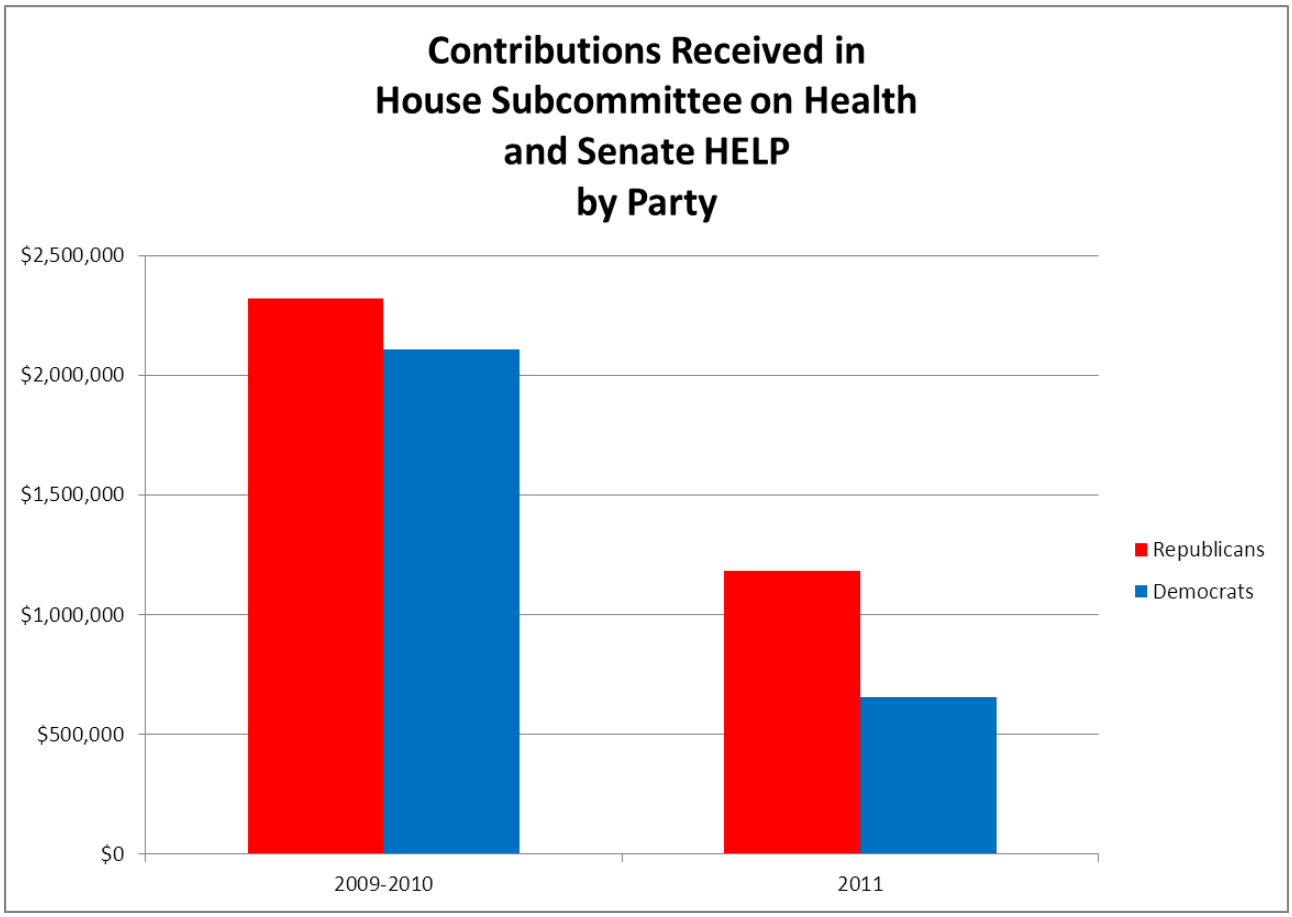
Political Contributions
The prescription drug, biotechnology, and medical device industries were generous with campaign contributions to members of Congress, targeting nearly $6.3 million to the campaign and political action committees of 70 lawmakers who served on key legislative committees overseeing drug and medical device safety legislation from 2009 through 2011.

Two congressional committees do the heavy lifting on PDUFA and MDUFA: the House Energy and Commerce Committee's Subcommittee on Health, currently with 25 members, and the Senate Health Education Labor and Pensions Committee (HELP), currently with 21 members.

During the 2009-2010 two-year election cycle, these industries gave more than $4.4 million to members of the House health subcommittee and the Senate HELP committee. In 2011, the first year of the 2011-2012 election cycle, these same interests gave more than $1.8 million to members of these two key committees:



Drug, device, and biotechnology companies and their trade associations give to both Republicans and Democrats:



LEGISLATIVE CHALLENGES TO FDA'S SCOPE AND AUTHORITY

The power of these special interests is reflected in the number of industry-friendly bipartisan legislative proposals pending before both the House and the Senate. Various proposals would:

- Add job creation to the FDA mission, diluting the agency's focus on protecting the public from unsafe medical products and bringing safe products to market.
- Reduce the scrutiny the agency could give to medical devices by compelling the agency to consider every "least burdensome" alternative to improving device safety.
- Impose more bureaucratic hurdles on the resource-strapped agency.
- Erode the FDA's standard of "substantial evidence" when reviewing drugs and devices, overturning a crucial scientific element of the Food, Drug, and Cosmetics Act.

Some in Congress also want to give companies more influence over the FDA scientific advisory committees that evaluate the safety and effectiveness of prescription drugs by relaxing financial conflict-of-interest standards for these committees.

Representatives of the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO) criticized the current process for vetting advisory panel members for financial ties to the industries with products under review by a panel. David Wheadon, senior vice president for regulatory affairs for PhRMA, questioned the need for screening for conflicts in the first place, contending that industry expertise should not be considered a "penalty" by the FDA.

BIO representative Richard Pops went even further. In his testimony, Pops charged: "In recent years, arbitrary limits and unnecessarily restrictive interpretations of conflict of interest rules have created barriers that have prevented FDA from consistently recruiting highly qualified scientific advisors."[i]

FDA Commissioner Margaret Hamburg paints a different picture. In testimony before Congress this year, she made clear these strengthened conflict-of-interest standards were not creating problems for the agency, while admitting the agency faced some challenges in finding enough experts for some of its advisory panels. Commissioner Hamburg told Congress that the agency had experienced no problems keeping the number of waivers it issues within the limit set by current law.[ii]

PROGRESS ON CONFLICTS-OF-INTEREST MADE IN RECENT YEARS

Conflicts-of-interest and their influence on FDA science long has been a concern to medical experts. The Institute of Medicine, in an exhaustive report on conflicts in medical research, science and education, observed that "*concerns are growing that wide-ranging financial ties to industry may unduly influence professional judgments involving the primary interests and goals of medicine. Such conflicts-of-interest threaten the integrity of scientific investigations, the objectivity of professional education, the quality of patient care, and the public's trust in medicine.*[iii]

In 2006, the concern about financial conflicts was shared by a bipartisan group in Congress. Republican Senators Michael Enzi and Chuck Grassley both raised questions about conflicted experts in the FDA approval process. Concluding an investigation of the role of certain plastic surgeons with ties to implant makers on an advisory panel that in 2005 recommended the reentry of silicone breast implants into the market, Sen. Enzi remarked, "We will build on the findings of this investigation by including provisions to address the problem of potential conflicts of interest among advisory committee members in the drug safety bill Sen. Edward Kennedy (D-Mass.) and I are preparing for introduction." [i]

In 2007, Congress approved the Food and Drug Administration Amendments Act (FDAAA), which strengthened conflict-of-interest provisions at the agency. [iv] The law required FDA to:

- Reduce the number of waivers it granted to conflicted experts by 5 percent over each of 5 years. This reduction covered the number of conflicted experts in the aggregate.
- Tell the public when the agency granted a waiver that allowed a conflicted expert to serve on a committee. The law required the FDA to publish the name of the expert and specific information about the nature of the conflict on the agency's website.
- Be more aggressive in recruiting non-conflicted experts.

Many believe that Congress should ban conflicts-of-interest outright. Ideally, individuals with expertise that panels needed who have conflicts-of-interest would be permitted only to present before a committee and answer questions, and would be precluded from voting to approve or deny a drug or medical device application. Because human lives are at stake, conflicted experts should not be able to inappropriately influence advisory committee decisions.

[i] Hearing on Prescription Drug User Fee Act Reauthorization before House Energy and Commerce Subcommittee on Health, Political Transcript Wire, 3 Feb. 2012.

[ii] Anna Yukhananov, "No need to loosen conflict rules, U.S. FDA head says," Reuters, 1 February 2012.

[iii] "Conflict of Interest in Medical Research, Education and Practice, Institute of Medicine, Washington: The National Academies Press, 2009, 1.

[i] http://www.fdanews.com/newsletter/article?issueId=6334&articleId=61354

[iv] Erin D. Williams and Susan Thaul, "FDA Amendments Act of 2007 (P.L. 110-85)," Congressional Research Service, April 27, 2010, 61.