1) Lobby expenditures: CRP analysis: **$700 million** on lobbying Congress and Exec Branch in 2009, 10 and 11 – the years leading up to Congressional passage of FDA law that must be approved every five years.
    - $487 million by drug firms;
    - $126 million by biotech and
    - $86 million from device industry.
    -

Between 1988 and 2012, drug makers alone spent $2.6 billion lobbying the federal government. (CRP)

Public Citizen reported that in the last half of 2011, 225 lobbyists for the device industry walked the halls of Congress and executive branch agencies. That is close to one lobbyist for every 2 legislators.

What did they get?
FDA and Congress both approved a law and negotiations between the agency and Congress that emphasize **speed over safety.**
Law also rolls back some protections against conflict of interest on FDA panels that make recommendations to approve or reject new drug applications, withdraw a drug or device from the marketplace if it proves to be unsafe, or place a "black box" warning label on a drug.
Crucial that these panels, whose recommendations carry a lot of weight with FDA, do not include members with financial ties to industries they are overseeing.
But new FDA law weakens those protections against conflict of interest. FDA no longer directed to reduce the number of conflicted members it recruits. No caps on total number of conflicted members. **Caps placed in 2007 were removed from current law. Industry groups had lobbied hard to overturn the ban, falsely claiming that it was impeding the FDA's work.**

- **Law will permit any devicemaker to challenge any significant FDA review decision and ask for it to be evaluated by a supervisor.**

- **The law imposes many new reporting requirements on FDA, micromanaging the agency and reinforcing political pressure and accountability to members who states and districts include major drug and device employers and biotech firms.**

- **The law failed to do something that should have been a no-brainer. More than 90 percent of devices now approved because a company makes the case that this new device is very similar to devices already on the market. Law did nothing to change the current state of affairs that makes it nearly impossible for the FDA to do anything to protect the public from**

devices approved because they were similar to earlier ones. Even after the earlier models are then found to be unsafe.

- **The law does push FDA to move on a long overdue ID system that will design a tracking system for medical devices, so that if a device is recalled, your doctor will know and you will be informed. The system will focus first on the devices that are the riskiest such as pacemakers or stents. Even now, we've been told that device industry is trying to slow down tracking for certain implantable devices.**

The FDA depends on user fees paid by the drug, device and generic drug industries to pay for the agency's drug review work. For fiscal 2013, the Obama administration has requested about $2.5 billion in taxpayer funds for the FDA. An additional **$2 billion in industry fees are supposed to be collected as well; including $720 million for brand-name drugs, $299 million for generics, and $98 million from device makers. User fees account for more than 40 percent of FDA's total budget. There are several ways that reduces the importance of safety and science**

The sheer amount of money from industry that FDA depends on gives industry strong leverage.

Fees are negotiated. The industry demands faster reviews, more responsiveness from FDA in return for its fees. And these negotiations held in secret. FDA reports to "stakeholders" but very vague about details.

Indirect pressure on drug and device reviewers. They know who pays their salary and know they will be held accountable if they raise questions or concerns that holds up the process. This last round of negotiations inserts the role of FDA "liaisons" to facilitate communication between industry and drug review staffs. But not clear what this role means. And whether it will simply give industry an advocate within the agency. Will a drug reviewers performance review be based on how well he/she interacts with industry?

Agreement itself between agency and drug industry elevates "timely access" to new drugs far and above either safety or efficacy. A search of entire document reveals that FDA uses "timely" or "timeliness" 36 times, while the terms "safe" or "safety" only get 28 mentions.

Tone of the agreement and the performance goals send a very strong message: We want you to do faster reviews. It will be a lot harder to raise concerns than to just go along. E.G. everytime a drug company appeals an FDA review decision, a rejection of the sponsor's appeal requires a written explanation. Don't need to explain if you cave to the drug sponsor. It appears that nearly every time that drug

review team may disagree with sponsor, the review team has to explain what's wrong and is on the defensive.

They are contracting with an independent third-party expert on the regulatory process to assess how well the FDA is doing to improve the "efficiency and effectiveness of the first cycle review" of drugs, not to assess how FDA is doing in protecting the public from unsafe and/or ineffective drugs. This independent contractor will also be interviewing staff and assessing them. Could be very intimidating.

Fact that so much money goes to focus on new drugs and devices means that other aspects of FDA's work, like ensuring safety of existing medical products is placed more on the backburner.

Borne out by 2011 FDA survey results, 997 FDA scientists responded:
Of the respondents,

55 percent felt that FDA decisions were overly influenced by political interests;
40 percent felt undue influence by corporate interests
More than a third – 338 scientists in all -- had personally experienced interference in their work in the past year.

What can we do? Let your member of Congress know that you believe in drug safety, an independent FDA, and an agency where independent experts give advice. We should not tolerate corporate influence over FDA decisions. We should not accept FDA advisory panels with whose members have significant financial ties to the very companies they are overseeing.

Ask your doctor about drugs prescribed? How long on the market? What are the common side effects? Are there older drugs that would work as well?

Union of Concerned Scientists
Citizens and Scientists for Environmental Solutions

PDUFA Factsheet

Prescription Drug User Fee Act (PDUFA)

The Prescription Drug User Fee Act (PDUFA) allows the Food and Drug Administration (FDA) to collect fees from drug manufacturers for the review of new drug applications for human use. The law, enacted in 1992 to supplement the FDA budget outside of appropriations, brings drugs to market more quickly and is re-negotiated and approved by Congress every five years.

AT A GLANCE

The FDA issued **45** drug recalls in 2011.[3]

Vioxx is believed to have caused over **100,000** unnecessary heart attacks in the U.S.[4]

75% of all drugs are approved on the first cycle.[5]

Though the dangers of Reglan were realized soon after approval, it took **23 YEARS** to add a black box warning to the label.[6]

Since the first PDUFA in 1994, time to approvals has been **CUT IN HALF.**[7]

In 2011, FDA review panels met their deadlines over **90%** of the time.[8]

US vs. Europe

MYTH: *The U.S. approves new drugs more slowly than other regulatory agencies, particularly the European Medicines Agency (EMA).*

In reality, **75%** of the new drugs approved by both the FDA and the EMA between 2006 and 2010 were first approved in the U.S.[1]

What's more, the FDA approved **32** of 35 prospective cancer drugs from 2003 to 2010 – only 26 were approved by the EMA.[2]

23 of these drugs were approved by both the FDA and EMA – FDA approved **91%** first.[2]

ALL 23 drugs came to the U.S. market before the European market.[2]

AN INDUSTRY BURDEN?

In 2012, PDUFA user fees provide $702 MILLION to FDA – less than 1% of the combined 2010 net profits of the 10 largest pharmaceutical companies.[11,12]

Company	2010 Net Profits (billions)
Pfizer	6.1
Novartis	9.8
Merck	7.9
Sanofi	8.5
GlaxoSmithKline	6.2
AstraZeneca	8.1
Johnson & Johnson	13.3
Roche	9.2
Eli Lilly & Co.	5.1
Abbott Laboratories	4.6
Bristol-Myers Squibb	3.1
Bayer	2.2

Clinical Trials

MYTH: *The public and the FDA have all the information they need about the success or failure of clinical trials.*

In 2008, FDA inspected 1.9% of domestic clinical trial sites and 0.7% of foreign clinical trial sites.[9]

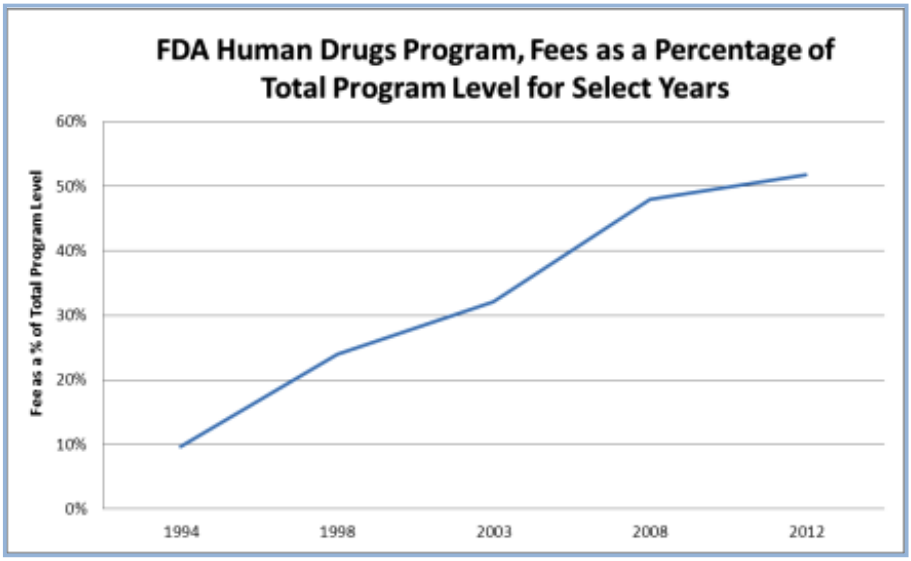
The 10 largest US-based pharmaceutical companies conduct approximately 33% of their clinical trials exclusively at foreign sites.[9]

Statistically significant (positive) drug outcomes are more likely to be reported to the FDA than non-significant findings.[10]

80% of approved marketing applications for drugs and biologics contained data from foreign clinical trials.[9]

An estimated 40-65% of clinical trials for FDA approval are conducted outside the US.[9]

In the first year of PDUFA contributions to the FDA budget, the revenue accounted for 9.7% total funding for the Human Drugs Program. For FY2012, fees provide 52% of total funding.[11]



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