# Willful Misconduct:

## How Bill Frist and the Drug Lobby Covertly Bagged a Liability Shield


**Congress Watch**

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## Acknowledgments

The primary author of *Willful Misconduct: How Bill Frist and the Drug Lobby Covertly Bagged a Liability Shield* was Congress Watch Senior Researcher John O'Donnell. Civil Justice Legislative Counsel Jillian Aldebron and Research Director Taylor Lincoln also made significant editing and writing contributions. Research Assistant Lara Chausow and Research Intern Tom Scherer entered and analyzed the data in the report. Public Citizen Litigation Group Director Brian Wolfman provided valuable editing advice.

## About Public Citizen

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# Introduction

Internal documents of the Biotechnology Industry Organization (BIO) show that the group's lobbyists – and lobbyists for individual drug makers – were heavily consulted by the White House and the congressional leadership late last year in the drafting of legislation designed to shield drug makers from legal accountability for injuries or deaths caused by their drugs and vaccines during government-declared health emergencies.

The documents show that the industry got the near-total immunity from liability it wanted.

BIO took the lead in coordinating the industry's response to a Capitol Hill draft proposal and was invited to meetings at the White House and at the office of Senate Majority Leader Bill Frist (R-Tenn.) to make its case. BIO's extensive membership list overlaps significantly with the membership of the Pharmaceutical Research and Manufacturers of America (PhRMA), the trade association of the brand-name pharmaceutical industry. BIO's membership includes the top 10 pharmaceutical companies in terms of U.S. sales – firms that collectively held 56.8 percent of the U.S. market in 2005, with sales of $143.5 billion.

The internal BIO documents and e-mails show that the organization successfully pushed for a much broader liability shield than had been proposed on Capitol Hill or by the Bush White House. The drug makers were awarded a shield so impenetrable that it is extremely unlikely they would ever face lawsuits over products used to treat pandemic illnesses, even in cases of gross negligence or gross recklessness. The final law stipulated that the drug makers could only be sued if they engaged in "willful misconduct." In short, they would have to act "intentionally to achieve a wrongful purpose knowingly without legal or factual justification and in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit."

At the same time as it insulated pharmaceutical companies from lawsuits, Congress also established a "process fund" to assist those injured or killed by vaccines, drugs or other countermeasures they receive in response to a government-declared health emergency. But Congress failed to appropriate any money for the fund

The measure, which was never considered in committee, was surreptitiously set up for passage under cover of darkness. Senate Majority Leader Bill Frist (R-Tenn.) inserted the 40-page text into the Department of Defense appropriations bill late on a Sunday night. His maneuver was conducted with the approbation of Speaker of the House Dennis Hastert (R-Ill.) after House and Senate conferees had completed work on the bill – and without the knowledge of at least some conferees. In fact, those conferees had already received assurances from the leadership that the controversial liability shield would not be included in the spending bill.

The two main conspirators in the liability shield insertion, Hastert and Frist, have long been darlings of the pharmaceutical and biotechnology industries. They rank third and ninth, respectively, among members of the current Congress in campaign contributions from the two industries since the 2000 election cycle. Sen. Richard Burr (R-N.C.), who drafted a bill that

provided the basis for Frist's measure, ranks No. 4. In sum, the three have received more than $1.2 million from the two industries in this time period.

But the drug industry did not rely on campaign contributions alone to sway lawmakers. Its members also turned to their tried-and-true technique of blanketing Capitol Hill with influence peddlers. Pharmaceutical companies and trade associations deployed a platoon of at least 158 lobbyists to influence vaccine and pandemic-related issues in 2004 and 2005.

Many of those lobbyists brought insider knowledge of the government's machinations to their influence-peddling jobs, and a few were especially well positioned to tweak the liability shield measure to satisfy their employers' wishes. Their forces included at least 84 revolving-door lobbyists – influence peddlers who were previously employed by the federal government – of whom seven were former members of Congress.

Conveniently, these former public servants included two former top health care aides to Frist, a former assistant to the HHS secretary, and a former House staffer who had helped draft language for a 2004 law that served as a predecessor to Frist's liability shield provision.

Also lobbying on pandemic issues was Joshua Hastert, son of the speaker of the House.

# Section I: Drug Makers Invited to Craft Liability Shield

On Nov. 12, 2005, Dave W. Boyer, director of federal government relations for BIO, received from a Senate staffer a draft of legislation that would shield makers of vaccines and drugs to prevent and treat pandemic diseases from liability. The language barred legal recourse against drug makers whose products killed or injured those who received them unless a drug maker's action amounted to "willful misconduct." It said that, at a minimum, willful misconduct would be an act or failure to act taken with "actual knowledge" that it would represent "a significant or unreasonable risk to human health," with "actual knowledge that injury to human health or death" would result and with a "conscious failure to act to avoid presenting a significant or unreasonable risk to human health." The draft left the details of defining the more precise parameters of willful misconduct to the Department of Health and Human Services, then added, "'willful misconduct' shall not include any act or a failure to act constituting mere negligence or strict liability in any form."[1]

This wasn't good enough for BIO.

On Nov. 13, Boyer sent an e-mail to an undisclosed list of recipients, telling them that BIO had sent an analysis of the draft to the Hill "in response to their request for comment on a bicameral majority pandemic/biodefense liability proposal." He attached a BIO's comments, which claimed that the language in the draft could conceivably leave drug and vaccine makers on the hook for actions that the law recognizes as "gross negligence," a lower standard that does not require a defendant to *intend* to cause harm in order to be found liable.[2]

"The bill seems to open up liability for conduct that might be characterized as gross negligence and other lesser (i.e., non intent) standards," BIO's analysis said. "We believe that this creates an unclear and overly broad standard and the bill should clearly and categorically restrict manufacturer liability to such an intent standard."[3]

BIO said, "We have strong concerns about the proposed definition of 'willful misconduct,' since it eliminates the intentionally wrongful nature of the act or failure to act."[4]

In other words, BIO was arguing that the legislation should stipulate explicitly that drug and vaccine makers must mean to cause harm in order to face liability.

The analysis also touched on a number of other "key areas where it will be important to modify or clarify the bill's language."[5]

BIO's goal, it said, was "to achieve the right balance in the event that patients are injured following the administration of a countermeasure under this program."[6]

The analysis expressed concern that plaintiffs could nonetheless have their cases heard by a jury.

"While these provisions are helpful, the lack of any restriction on jury trial is problematic," BIO said. "Where injured parties have no other avenue for relief, juries are likely to find ways to award damages."

On Nov. 15, Boyer sent a message to an undisclosed e-mail list announcing that BIO had been called to a White House meeting and that he and two BIO colleagues attended along with Sean Callinicos, a lobbyist who represented Sanofi Pasteur, and Greg Levine, an Arnold and Porter lawyer. At that time, Levine was representing Pfizer and Hoffman LaRoche on the issue of "Department of Defense Appropriations Act for Fiscal Year 2006, provisions related to pandemic influenza." Indeed, he had only signed on to represent Roche on the issue a week earlier, on November 8, according to a lobbying registration form later filed with the Senate.[7]

Boyer wrote, "The meeting started with Barry Jackson, Karl Rove's deputy, explaining that it was important to the President that a bill move this year, and that they had invited industry to discuss what they understood to be a few key remaining points of contention."[8]

Three days later, Boyer and lobbyists for three pharmaceutical companies were summoned to a meeting with the staff of Senate Majority Leader Bill Frist (R-Tenn.), along with officials from the Justice Department, the Department of Health and Human Services and the White House office of legislative affairs.[9]

"At Senator Frist's staff's request, this morning, BIO (Tom and I) participated in a meeting with three other industry representatives (Sanofi and an outside counsel who works for both Pfizer and Roche, I believe), administration staff (HHS, DoJ and WH Leg Affairs), and Liz Hall to further discuss liability," Boyer wrote in an e-mail to undisclosed recipients.[10]

The e-mail revealed the extent to which Frist was coordinating the legislative push with the White House and the urgency with which Frist intended to pass the legislation.

"Frist's staff indicated that the Leader would not be inclined to move a bill that the Administration didn't support, much less opposed," Boyer wrote, adding, "Senate leadership is pushing for a final deal to be cut before staff go home for Thanksgiving."[11]

Frist's deadline came and went.

On Dec. 1, Boyer sent another e-mail to his undisclosed list of recipients. He wrote that Republican House and Senate staffers were still discussing the liability provisions for makers of pandemics drugs and vaccines. Boyer also disclosed that the staffers were aiming to insert the liability shield measure into the DoD appropriations bill.[12]

## Section II: Frist Shepherds Law to Fruition in the Dead of Night

In the following week, rumors swirled that the congressional leadership would seek to insert a liability shield for the makers of pandemic drugs and vaccines into the Defense appropriations bill, along with funding to purchase these products. The DoD bill was seen as a strategic vehicle because a legislator who voted against it risked being accused of not supporting U.S. troops in Iraq.

Democrats objected to the strategy of including an unrelated and contentious liability measure in the DoD appropriations bill. Rep. David Obey (D-Wis.), the senior Democrat on the House Appropriations Committee, said conferees were given written assurances that this would not happen.[13]

On Dec. 18, a Sunday, the 38 conferees – 21 Republicans and 17 Democrats – on the 422-page DoD appropriations bill gathered in a large Capitol meeting room to finalize reconciliation of House and Senate versions of the bill. In addition to funds for the military, the $453 billion measure contained some non-military provisions, including authorization for gas and oil exploration in the Arctic National Wildlife Refuge, $29 billion for hurricane relief on the Gulf coast, and a 1 percent across-the-board cut in government discretionary spending for fiscal year 2006. It also included $3.8 billion in emergency funding for avian flu protection, less than the $7.1 billion sought by President Bush.[14] The measure the conferees considered contained no language pertaining to pharmaceutical company liability.

Conferees asked at the meeting whether a liability shield would be in the final version of the bill, according to Keith Kennedy, the staff director of the Senate Appropriations Committee. They were assured it would not.[15]

Conference participants, including Obey and Rep. James P. Moran (D-Va.), also reported receiving such assurances.

"The conference committee ended its work with the understanding, both verbal and in writing, that there would be no legislative liability protection language inserted in this bill," Obey said.[16]

Later that same evening, however, according to Obey, Frist went to Hastert and asked him to authorize insertion of the liability shield measure into the bill. Frist evidently was in possession of a 40-page text that had evolved considerably from the language that BIO had received five weeks earlier.

"After the conference was finished at 6 p.m., Senator Frist marched over to the House side of the Capitol about four hours later and insisted that over 40 pages of legislation ... that had never been seen by conferees be attached to the bill," Obey said on the House floor. "The speaker joined him in that insistence so that without a vote of the conferees, that legislation was unilaterally and arrogantly inserted into the bill after the conference was over in a blatantly abusive power play by two of the most powerful men in Congress."[17]

Kennedy, the Senate Appropriations Committee staff director, said a month later. "It was added after the conference had concluded. It was added at the specific direction of the speaker of the House and the majority leader of the Senate." Kennedy, speaking at a budget seminar for reporters, called the act "an absolute travesty."[18]

Democratic conferees were stunned. Moran said he found out about the late-night addition as House members were voting on the conference report at 5 a.m. on Monday, December 19.[19]

"My understanding is that the staff discovered this after the bill was put on the floor," Moran told Public Citizen. "This is a big issue," he said, likening it to the asbestos legislation now stalled in the Senate after years of work. [20]

"This should have been properly debated," he added. [21]

### Members Object

Frist and Hastert's actions drew criticism from both sides of the aisle.

"It was not until the dead of night on this past Sunday, after signatures had already been collected on the conference report, that the Republican majority slipped these provisions into the bill," Sen. Robert C. Byrd, the senior Democrat on the Appropriations Committee, told his colleagues in a floor speech. "What an insult to the legislative process."[22]

While most of the criticism came from Democrats, some prominent Republicans, too, looked askance at the maneuver, though in more muted terms.

Hours after Frist's duplicitous act of legislative misconduct, Rep. Jerry Lewis (R-Calif.), the chairman of the House Appropriations Committee, took to the House floor to complain of a "tendency for these bills to become Christmas trees for unrelated legislative proposals and for spending to grow out of control. This is simply not acceptable"[23]

It was 4:30 a.m. Monday and the House was preparing to vote on the DoD bill. Lewis's remarks followed those of Obey, who complained about the late insertion of the liability shield and the ANWR provision (which was in the bill when conferees considered it less than 12 hours earlier), and Rep. Steny Hoyer (D-Md.), the House minority whip, who criticized the last minute additions of what he called "very controversial issues."

Lewis seemed to agree with Hoyer. He said, "At the eleventh hour, controversial legislative language has been attached" to the measure. "My fear is this language has the potential to sink the entire package once it reaches the Senate."

He did not specify what he was referring to, but his comments were prescient. When the bill reached the Senate, a filibuster forced the removal of the provision to open ANWR to oil and gas drilling.

Sen. Orrin Hatch (R-Utah) was more pointed in his criticism of the liability shield than his colleagues in the House.

Saying that he and Sen. Joseph I. Lieberman (D-Conn.) had been working for four years "on comprehensive legislation to address this concern," Hatch told his colleagues during Senate debate on the DoD spending bill on Dec. 21 that he had urged Frist not to include the liability shield provision in the defense spending measure or any other "must pass vehicle."[24]

"This is the type of issue that takes time, money, creative energy and patience," he said.

He said he would oppose the liability shield measure if it were a standalone bill because of its manifest flaws, including the absence of secured funding to compensate victims of drug and vaccine injuries, and potential constitutional problems.

By the same token, however, Hatch sharply took his colleagues to task for criticizing drug companies, saying "I also think it is way past time that members of this body and others stop unjustifiably vilifying the pharmaceutical industry."

That didn't persuade Senate Minority Leader Harry Reid (D-Nev.)

"It was the Republican leadership's big Christmas present to their friends in the drug industry," he said in a floor speech the next day.[25]

"This is the second time that this Congress has supinely done the bidding of the pharmaceutical industry in the dead of night," Obey said on the House floor, citing House passage of the Medicare drug bill, which was accomplished by a five-vote margin only after House Republican leadership held the vote open for three hours – making it the longest vote in House history – while arms were twisted.[26]

## Frist Had Tried in the Past

It was also not the first time Frist had tucked a special favor for drug company friends into unrelated legislation.

Frist appears to have been behind the inclusion of a liability shield for Eli Lilly in the Homeland Security bill in 2002. The 39 lines of text would have given Lilly immunity from lawsuits over injuries caused by its controversial mercury-based vaccine additive thimerosal.[27] At the time, Frist was chairman of the National Republican Senatorial Committee, for which he raised $4.6 million from the pharmaceutical industry for the 2002 election, including $459,000 contributed by Eli Lilly.[28] The company also bought 5,000 copies of a new book Frist had authored, "When Every Moment Counts: What You Need to Know About Bioterrorism From the Senate's Only Doctor." The firm distributed the book to doctors across the country, while Frist donated profits from the sale to charity.[29]

In March 2002, Frist introduced a stand-alone bill that protected the drug maker from lawsuits alleging that thimerosal had caused autism in children who received vaccines containing the preservative.[30] That bill would have required dismissal of thousands of pending court cases and

prohibited future lawsuits against Lilly in return for allowing claimants to seek damages from the no-fault National Vaccine Injury Compensation Program (NVICP).[31] Claimants who prevail in that process are compensated out of a $2.2 billion trust fund financed by a surcharge on each dose of vaccine.[32]

But because the 1986 law applied only to the vaccines themselves and not additives, Lilly could still be sued over thimerosal. The Frist legislation aimed to close this loophole.[33]

After the Frist bill stalled, nearly the exact wording of the provision was inconspicuously inserted at the end of the 475-page bill creating the Department of Homeland Security. The bill was signed by President George W. Bush in November 2002, the month before Frist became majority leader. However, belated discovery of the provision provoked such an outcry by parents claiming that thimerosal was responsible for their children's autism that Congress stripped the provision from the law in February 2003.[34]

The *New York Times* reported, "One aide said the language mysteriously appeared in the House version of the bill in entirely different type than the rest of the measure, as though someone had clipped it out of Mr. Frist's legislation and simply pasted it in."[35]

Then-House Majority Leader Dick Armey (R-Texas) took responsibility for inserting the Frist legislation in the bill, his spokesman, Richard Diamond, said.[36] Nevertheless, Frist was widely suspected of being behind the move.

Diamond would not say who inserted the language. "If you want to give somebody credit for it, Mr. Armey takes ultimate credit. It's his bill. We are happy to wrap ourselves around it, but Mr. Armey is not a doctor, like Senator Frist. He's the source of the language."[37]

# Section III: The Morning After: Industry Celebrates

*"The bill includes provisions that will greatly reduce the risk of frivolous lawsuits and minimize litigation burdens, while ensuring that bad conduct by manufacturers or others is appropriately punished through both government enforcement action and private civil lawsuits for damages."*

– Dave W. Boyer, BIO Director of Federal Government Relations, discussing BIO's "Talking Points" on the DoD pandemic drug provision, Dec. 19, 2005.

Frist furnished the pharmaceutical industry with extraordinary protections that exceeded all previous proposals – including those made by the Bush administration. The law exempted drug makers from liability entirely during a health emergency, making an exception only for injuries caused by "willful misconduct." Furthermore, even in cases of "willful misconduct," the law erected an array of statutory obstacles to filing a lawsuit.

"It is hard to imagine a successful willful misconduct action under the law," Duke University School of Law Professor Erwin Chemerinsky told Public Citizen.[38] Chemerinsky, a constitutional law expert, submitted an analysis of the bill to Congress in December that questioned the constitutionality of numerous provisions.[39]

BIO had also sought a different form of legal protection in the event of a lawsuit, according to Tom DiLenge, the organization's deputy general counsel and acting general counsel.[40] BIO wanted plaintiffs restricted to filing suit under the Federal Tort Claims Act (FTCA), which permits lawsuits against employees or agents of the government if the government grants a limited waiver of its immunity. The FTCA does not provide for jury trials. It also allows for defenses that would guarantee that a drug company would not likely have to defend the claims of an injured plaintiff in court. BIO was justified in seeking these terms, said DiLenge, because the government would be the pharmaceutical industry's "partner" in dealing with a pandemic or other health emergency.

"We're not making these products because they're going to make a lot of money," he said in an interview with Public Citizen. "We're making them because the government wants them."[41]

Drug companies that make vaccines and other products to combat pandemic diseases may be performing a service to the government, but that does not mean there are not substantial rewards. Back in 2001, the tiny British biotech firm Acambis and its U.S. partner Baxter International beat out Merck and Glaxo for a $428 million smallpox vaccine contract at what the company estimated would be a 30 percent to 40 percent profit margin. At the time, Acambis did not even have a product on the market and had never made a profit.[42] BioPort Corp., sole maker of the anthrax vaccine, was transformed by $450 million in government contracts over seven years from a $4.5 million start-up to a biotech behemoth, splurging on $100 million buy outs of other drug companies and a manufacturing expansion in 2005.[43] Gilead Sciences, the company that developed the antiviral flu treatment Tamiflu, saw its stock price surge 25 percent in six months largely due to sales of the drug sparked by fears of avian flu in the latter half of 2005.[44]

The following are the major provisions of the law that industry fought for and won – at great risk to the general public.

### The Liability Shield Confers Virtually Complete Immunity from Lawsuits

The law creates an expansive liability shield that acts as a "bar on all state and federal claims for loss arising out of the use of a covered countermeasure pursuant to a secretarial declaration [of a health emergency] except for a new federal cause of action for willful misconduct proximately causing serious physical injury or death," BIO Deputy General Counsel Tom DiLenge wrote hours after Frist's midnight gambit.[45] The shield extends to all companies, state officials, healthcare workers and others involved in combating a health emergency or potential health emergency. It encompasses all aspects of drug, vaccine and medical device production and delivery, including design, development, testing, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use.

Frist's gift to the drug industry far exceeded the scope of the Bush administration's proposal, which would have applied the shield only to drugs and vaccines created specifically to combat the avian flu.[46] Instead, as BIO Deputy General Counsel DiLenge explained in an analysis prepared for the group's members subsequent to passage of the bill, "Definition of covered countermeasure is broad – includes any qualified pandemic or epidemic product, any security countermeasure (BioShield), and any product authorized for emergency use under Section 564 of [the Federal Food, Drug and Cosmetic Act]."[47] This provision of the FFDCA allows the secretary of HHS to authorize emergency use of unapproved products or use of approved products for unapproved uses.

The open-ended definition of a covered countermeasure means that it could apply to a long-used drug to which a patient experiences an adverse reaction, or one that causes injury because it comes from a contaminated batch. If that drug were taken to treat a condition related to a health emergency declared by the HHS secretary, the liability shield would kick in.

Hatch identified this problem in his Dec. 21 remarks on the Senate floor. "In the case of dual use products," he told his colleagues, "such as antibiotics, it appears that, should a bad batch of drugs be made due to ordinary negligence, a patient injured when taking the product for a normal, garden-variety infection will have a much greater range of legal remedies than a person who took a pill from the same adulterated production batch but under a secretarial declaration of a public health remedy."[48]

Moreover, the law creates a rebuttable presumption that, during a declared emergency, use of a covered drug is to treat the emergency condition. A patient injured by a dual use drug that he or she took for a condition other than the health emergency has the burden of proving that it was not taken to treat the emergency condition.

### "Willful Misconduct" – The Exception to the Shield

BIO's major preoccupation throughout drafting was making sure that the "sole exception" to legal immunity applied only in the most remote of circumstances – where an injured party can show by "clear and convincing evidence," a heightened standard of proof, that a defendant's

"willful misconduct" caused serious injury or death. The key was the definition of "willful misconduct" – more specifically, ensuring that it did not encompass "gross negligence" or "gross recklessness," but only "intentional, voluntary and conscious actions, or failures to act, undertaken to achieve a wrongful purpose."

Frist was assiduously responsive to industry's concern. The law defines "willful misconduct" as "an act or omission that is taken intentionally to achieve a wrongful purpose; knowingly without legal or factual justification; and in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." To leave no room for ambiguity, the law adds a rule making it clear that willful misconduct "shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness."

Here is an example to illustrate the difference between "willful misconduct" and "gross negligence" or "gross recklessness."

- **Gross recklessness or gross negligence**: A man walks into a room with a loaded semi-automatic pistol and in showing it off to friends, he twirls it on his forefinger. It goes off, killing someone.

- **Willful misconduct under the statute**: A man walks into a room with a loaded semi-automatic pistol and in showing it off to friends, he twirls it on his forefinger. He then points it at someone and shoots him in the head, killing him.

"That's a very good analogy," Chemerinsky said in an e-mail to Public Citizen. "Obviously, they were trying for a formulation that would make it very difficult for them ever to be sued."[49]

But the exceedingly narrow definition of willful misconduct was not enough security for the drug industry. For good measure, the law adds mitigating factors that make the possibility of a defendant being found guilty of willful misconduct extremely remote.

- The secretary of HHS and the attorney general are instructed to "promulgate regulations … that further restrict the scope of actions or omissions … that may qualify as 'willful misconduct.'"

- For the manufacturers and distributors of drugs, the law says there can be no willful misconduct for acts or omissions subject to FDA regulation unless the FDA or the Department of Justice has taken enforcement action against the company.

  This suggests that either the secretary of HHS (which oversees the FDA) or the attorney general could prevent a court from a finding of "willful misconduct" simply by refusing to investigate or ending a probe without a finding of culpability. This raises constitutional red flags with legal scholar Chemerinsky. This "unfettered and unreviewable discretion … violates the constitutional guarantee of access to justice, secured under both the First Amendment's Petition Clause and the Fifth Amendment's Due Process clause," he wrote

in a letter to Congress. "The Supreme Court has recognized that official inaction cannot prevent a claimant from being able to go forth with a legitimate lawsuit."[50]

- As for state and local authorities and other personnel involved in treating a health emergency, the law provides a different but equally imposing shield. It says that "as a matter of law" there can be no willful misconduct on their part if they "acted consistent with applicable directions, guidelines, or recommendations by the [HHS] secretary" regarding the health emergency – as long as HHS or a state or local health authority was notified of an injury or death within a week after the defendant learned of it.

  This provision suggests that a defendant who learns of a death or injury caused by an intentional act can completely avoid liability by reporting the incident to the authorities and then convincing the court that it was a matter of just following orders.

## An Emergency Declaration is Not Subject to Judicial Review

*"The United States Supreme Court has repeatedly stressed that the preclusion of all judicial review raises 'serious questions' concerning separation of powers and due process of law."*

– Letter of Professor Erwin Chemerinsky to the U.S. Senate, Dec. 20, 2005

Although the secretary of HHS has sole discretion to issue a declaration of emergency at any time – for any reason, for any duration, and under any circumstance – that declaration may not be challenged in a court of law. Indeed, the language of the provision is so broad that it empowers the secretary to declare an emergency when he or she deems that a disease or condition constitutes not merely a present, but a future risk. In the past, the bar on judicial review has led to what some have described as an abuse of power. They cite actions taken by former HHS Secretary Tommy Thompson in 2005 with regard to anthrax.

Thompson, responding to a request from the Pentagon, declared an anthrax emergency under the Bioshield Act of 2004, a declaration that critics claim was aimed at thwarting a court order.[51] The declaration permitted the military to continue administering anthrax vaccinations to troops after a U.S. District Court judge in the District of Columbia had issued an injunction to halt the six-year-old Department of Defense "Anthrax Vaccine Immunization Program."[52] The judge had enjoined further inoculations after finding that the FDA had never given final approval to the vaccine, although it had been in use for years. (Indeed, the product was so widely distrusted that back in 2001, after the anthrax scare closed the Capitol mailroom and several offices, Frist cautioned his staff against taking this same vaccine because of potential adverse effects.[53])

Shortly thereafter, the FDA approved the vaccine, ending the need for Thompson's emergency declaration. "Because [FDA] action removed the basis and need for" the emergency declaration, "it will not be necessary for DoD to seek renewal … for use of anthrax vaccine to prevent inhalation anthrax," William Winkenwerder Jr., assistant secretary of defense, wrote in a memorandum to military surgeons general."[54]

Critics have pointed to this sequence of events as confirmation that the emergency had been declared solely to get around the court's injunction.

"This emergency was declared to circumvent a federal court injunction against the Pentagon ordering that military personnel be given the right to informed consent prior to be administered the improperly licensed, experimental Bioport anthrax vaccine," Barbara Loe Fisher, president of the National Vaccine Information Center, wrote to a Senate aide in November.[55]

## Emergency Declarations Preempt State Law

A declaration of an emergency by the secretary of HHS would automatically trigger preemption of relevant state laws. Thus, during an emergency, states may not adopt new laws or enforce existing laws that conflict with the statute or relate in any way to any vaccine or drug or other countermeasure involved in the declaration. That means that state laws prohibiting administration of thimerosal-containing vaccines to pregnant women or infants, for example, would be unenforceable in the event of an emergency declaration that covered such a vaccine.[56] State laws requiring that high-risk patients give informed consent before receiving a vaccine would be unenforceable. Any individuals injured as a consequence would be barred from pursuing a lawsuit for compensation.

## A "Process Fund" With No Money In It

*"The legislation provides generous compensation to those injured by administration of countermeasures."*

– Dave W. Boyer, BIO director of federal government relations, discussing BIO's "Talking Points" on the DoD pandemic drug provision, Dec. 19, 2005.

*"Perhaps the cruelest feature of this infamous provision is that it includes a sham compensation program with no funding"*

– Sen. Edward Kennedy (D-Mass.), referring to the liability shield measure during Senate debate on the emergency supplemental appropriations bill, May 1, 2006.

An emergency declaration by the secretary of HHS triggers establishment of a "Covered Countermeasure Process Fund" to provide "timely, uniform and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to such declaration."

But this is a fund in name only. There is no budgetary allocation and no designated source of money. Instead, funding is available only if Congress approves an emergency appropriation under the 2006 Congressional Budget Resolution that, in any event, "shall remain in effect through October 1, 2006." The illusory fund provides meager benefits for injured people: 1) the uninsured cost of medical products and services that the secretary of HHS deems effective, 2) two-thirds of lost income, minus any income benefits the victims may be due from other sources (e.g., workers compensation, short-term disability, Social Security disability, etc.), with an annual income cap of $50,000 and total lifetime cap of $250,000, and 3) a death benefit of up to $250,000. Of course, even this meager level of compensation is available only if there are funds, and then only for injuries appearing on an HHS-established table, not subject to judicial review, that are "presumed to be directly caused" by the covered drugs or vaccines during the relevant time period.[57]

Even Hatch expressed skepticism about the "process fund" during the Dec. 21 floor debate leading up to the vote. "Many will question whether this bill, in its current form, contains too much indemnification and not enough compensation," he said. "This is a fair question … I cannot say that I would recommend such an important program to be subject to the uncertainties of less than stable, certain funding."[58]

HHS will decide who is awarded compensation "based on compelling, reliable, valid, medical and scientific evidence," and on a table that details injuries "presumed to be directly caused" by the covered drugs or vaccines and time period when the first symptom must occur for the presumption to apply. The law prohibits judicial review of the injury table.

In its "talking points" for a "communications call" on the day after its victory, BIO painted a far rosier picture of the empty fund: "The legislation provides generous compensation to those … individuals who are injured through the administration or use of products that are specifically designed to diagnose, mitigate or treat a pandemic or epidemic or other public health emergency," Boyer wrote. "The compensation program provides for all reasonable and necessary medical expenses, lost employment income and a death benefit equal to given to [sic] policemen and firefighters killed in the line of duty."[59]

### High hurdles make it difficult to get to court even when there is willful misconduct

Getting to court is nearly impossible. And, if a plaintiff ever gets there, he or she will face numerous obstacles.

- **Do not pass Go – Start at the Process Fund**
  Before pursuing a willful misconduct claim, injured parties must first apply for compensation from the Process Fund – provided that it is operable. After 240 days, a plaintiff can pursue a lawsuit if the Fund has not acted on the claim. A plaintiff who gets a favorable decision from the Fund must choose between accepting the compensation offered or taking a chance in court.

- **Suits may only be filed in D.C. Federal Court, regardless of where the plaintiff lives**
  To avoid inconveniencing BIO members who objected to having to defend lawsuits across the country, the law establishes sole jurisdiction in the U.S. District Court for the District of Columbia. A three-judge screening panel hears pre-trial motions, and those cases deemed meritorious are assigned to a single judge. Defendants can appeal when they lose motions asserting legal immunity or FDA regulatory exclusivity. Plaintiffs must cope with the need to travel long distances and with delaying tactics afforded by the appeals process.

- **Pleading with particularity, limited discovery, heightened standard of proof stack the deck against plaintiffs**
  Unlike ordinary civil complaints, the lawsuits filed in these cases must detail, at the time of filing, the specific acts or omissions constituting willful misconduct and provide facts supporting the contention that they are the proximate cause of plaintiff's serious physical injury or death. Moreover, a medical expert must attest to the diagnosis and causation. Discovery – the process of each side exchanging information before trial – is prohibited

prior to motions to dismiss, and is generally restricted. That leaves plaintiffs at an extreme disadvantage because evidence needed to prove misconduct is often under the defendant's control. If a defendant cannot be compelled to produce the evidence, the plaintiff may well lack grounds to go forward. Proof of willful misconduct must be shown by "clear and convincing" evidence, rather than the "preponderance of the evidence" standard that is typical in civil matters.

- **Even plaintiffs who prevail risk compensation reductions**
  If the plaintiff wins the case, both economic and non-economic damage awards may be reduced. Economic damage awards will be reduced by a plaintiff's collateral source benefits – amounts received from third parties such as workers compensation, insurance policies, entitlement programs, etc. That makes the defendant that is responsible for the injury a secondary payer. Then, any non-economic damage award will be proportionately adjusted to correspond to the percentage of responsibility of a defendant for the harm to the plaintiff.

# Section IV: Consumers Mourn

Conferring a cloak of immunity on the drug industry comes with a hefty price tag. After all, when people are killed or injured, someone has to pay for medical care, lost productivity, the needs of families deprived of breadwinners. And pandemic drugs and vaccines are certain to cause injuries, as industry itself has acknowledged. In response to the initial draft liability legislation it received, BIO said, "Drugs authorized for emergency use must only pass a risk/benefit analysis (that is, the benefits outweigh the risks), and likely will not have been tested on humans for safety or efficacy prior to use … We also know, in some cases that there are dangerous side effects that will in fact occur in some portion of the population (for ex, the smallpox vaccine)."[60] Indeed, the smallpox vaccine has been blamed for heart attacks, increased risk of heart inflammation and neurological disorders among first responders.[61] The anthrax vaccine, some batches of which have been found to contain squalene, a chemical associated with Gulf War syndrome, has been implicated in neurological disorders among military personnel.[62] Sanofi Pasteur's meningitis vaccine is currently under FDA investigation for its connection to at least five cases of Guillain-Barre paralysis.[63]

There are a number of examples in law where insulating corporations from liability has been found to serve the public interest, often because it is necessary to ensure the provision of some vital product or service that would otherwise not be available.[64] Under such circumstances, the government may stand in the corporation's place for the purpose of defending and compensating injury claims, which are filed under the Federal Tort Claims Act.[65] Alternatively, an administrative mechanism backed up with a designated funding source might be established to handle claims and provide relief. Such arrangements are consistent with the constitutional mandate of establishing a just, adequate *quid pro quo* when an individual is deprived of the right to go to court.

A less-heralded mechanism used to exempt companies from some measure of liability without forcing injured consumers to relinquish any rights is indemnification, which has existed under current law for 50-odd years. This mechanism was called into play by HHS in the weeks before Frist's legislative coup d'etat in the avian flu vaccine contracts totaling $162.5 million that it signed with two drug companies, Sanofi-Aventis and Chiron. The Sanofi-Aventis contract, for example, provides for indemnification by the federal government under Public Law 85-804 as a condition of administering the vaccine to humans. The statute permits indemnification of a contractor engaged in an activity important to national security that involves "unusually hazardous risks," where insurance is not sufficient to cover those risks, for the amount of damages and litigation expenses that exceed the contractor's insurance coverage. In addition, Sanofi's contract requires HHS to help the company explain to the public why it needs a liability shield and what the government is doing about it.

While indemnification under the statute ensured limited financial relief, it still left companies facing the specter of a jury trial, which could be always turn into a public relations nightmare. Industry really wanted to get as close to full immunity from liability as possible, and ensure that a compensation program was set up to short-circuit outraged sympathy for drug injury victims that might pose the threat of commercial or political backlash.

Frist gave the companies immunity, but then went still further and stripped victims of meaningful recourse. In this regard, the bill was a drastic departure from precedent, shielding corporations from legal and financial accountability, but failing to replace them with a government surrogate or establish a guaranteed source of funds to cover losses. The recipients of pandemic products, their families, and society at large would be forced to shoulder the consequences of industry's gross negligence, recklessness, deceptive claims, and failure to warn, among other egregious acts. Had such a law been in place during the 1976 swine flu scare, none of the 4,000 people who claimed injury from the vaccine, including over 500 who developed a paralyzing nerve disorder and some 35 who died, would have been able to get compensation for medical expenses, income replacement, long-term care or other needs.[66]

# Section V: Big Pharma's Big Sway

Drug makers have long been among the most generous contributors to members of Congress and among the biggest financers of lobbyists to bend those members' ears. The debate over a liability shield for pandemic countermeasures was no exception.

## Campaign Contributions

The three lawmakers who were most responsible for Frist's assault on consumers' safety and rights were Sen. Richard Burr (R-N.C.), who drafted a liability shield bill that served as a predecessor to the text Frist dropped into the DoD appropriations bill; Hastert, who enabled Frist to make his move; and Frist, who inserted the legislation.

These three members of Congress enjoy a special relationship with drug makers. Each ranks in the top 10 among current members of Congress in contributions received from pharmaceutical manufacturers and the biotechnology industry since the 2000 election cycle. [See Figure 1] And Frist has felt the pharmaceutical industry's generosity in others ways. In 2002, while Frist was head of the National Republican Senatorial Committee (NRSC), the committee raised $4.6 million from the pharmaceutical industry. Only one other industry – securities and investments – exceeded the pharmaceutical industry's contributions to the NRSC. Frist's success in raising money for the NRSC helped the Republicans capture control of the Senate in 2002 and was widely viewed as a chief reason he was tapped to become Senate majority leader with barely more than a single term of service under his belt.[67]

**Figure 1: Campaign Contributions Received from the Pharmaceutical and Biotech Industries Since the 2000 Election Cycle**

| Member of Congress | Total Contributions* | Rank ** |
|---|---|---|
| Dennis Hastert | $465,200 | 3 |
| Richard Burr | $414,188 | 4 |
| Bill Frist | $332,207 | 9 |
| **Total** | **$1,211,595** | **--** |

* Includes contributions to campaign accounts and to leadership PACs.
** Rank refers to the sum of contributions received from the pharmaceutical and biotechnology industries since the 2000 election cycle compared to all members of the 109th Congress.

## Lobbying

With an influence-peddling tab of $758 million since 1998, more than any other industry, the drug industry has never failed to make sure its voice was heard on issues it cared about – and the companies that cared deeply about vaccines and other pandemic countermeasures were no exception.[68] In 2004 and 2005, the pharmaceutical and biotechnology industries deployed a platoon of at least 158 lobbyists to press their causes on these issues.[69]

Twelve firms and two trade associations that lobbied on vaccines and other pandemic-related issues in 2004 and 2005 spent at least $90.8 million to lobby Congress and the executive branch on a wide variety of issues in those years. [See Figure 2]

**Figure 2: Lobbying Expenditures of Drug Makers that Lobbied on Vaccines or Pandemic Issues, 2004-2005**

| Organization | Total* |
|---|---|
| Bayer | $4,680,000 |
| Biotechnology Industry Organization | $11,000,000 |
| Chiron Corporation | $5,864,758 |
| Genaco Biomedical | $20,000 |
| GlaxoSmithKline | $9,760,000 |
| Hoffmann-La Roche | $4,605,114 |
| Hollis Eden Pharmaceuticals | $380,000 |
| Johnson and Johnson | $4,780,000 |
| MedImmune Inc. | $440,000 |
| Merck | $210,000 |
| Pfizer | $12,250,000 |
| Pharmaceutical Research and Manufacturers of America (PhRMA) | $29,000,000 |
| Sanofi Pasteur | $2,000,000 |
| Wyeth | $5,840,000 |
| **Total** | **$90,829,872** |

Source: Public Citizen analysis of lobbying disclosure records filed with the secretary of the Senate. Only semi-annual periods in which organizations reported lobbying on vaccines or pandemic-related matters were included.

## Revolving Doors

In its pursuit of a liability shield, the pharmaceutical and biotechnology industries drew on a cadre of well-placed lobbyists with previous government employment. They included two former top health care aides to Frist, a former House staffer who had helped draft language for a 2004 law that served as a predecessor to Frist's liability shield provision, and the son of the speaker of the House.

These revolving-door lobbyists were not the exception to the rule. The companies and their trade associations paid for at least 84 former federal employees-turned-lobbyists to lobby Capitol Hill, the White House and other executive branch agencies on vaccine issues and other pandemic issues in 2004 and 2005. These lobbyists included seven former members of Congress. [See Figure 3] [The full list of revolving-door lobbyists is furnished in Appendix A]

**Figure 3: Former Members of Congress Who Lobbied on Vaccines or Pandemic Issues, 2004-2005**

| Member | Client | Firm | Service in Congress |
|---|---|---|---|
| Dale Bumpers | Sanofi Pasteur | Arent Fox Kintner; Plotkin and Kahn | U.S. Sen. (D-Ark.), 1975-1998 |
| Dennis DeConcini | Chiron Corp. | Parry, Romani, DeConcini and Symms | U.S. Sen. (D-Ariz.), 1977-1994 |
| Vic Fazio | Chiron Corp. | Clark and Weinstock | U.S. Rep. (D-Calif.), 1979-1998 |
| Jack Fields | Sanofi Pasteur | Twenty-First Century Group | U.S. Rep. (R-Texas), 1981-1996 |
| Paul Rogers | Biotechnology Industry Organization | Hogan and Hartson | U.S. Rep. (D-Fla.), 1955-1978 |
| Steve Symms | Chiron Corp. | Parry, Romani, DeConcini and Symms | U.S. Rep. (R-Idaho), 1973-1980; U.S. Sen. (R-Idaho), 1981-1992 |
| Vin Weber | Chiron Corp. | Clark and Weinstock | U.S. Rep. (R-Minn.), 1981-1992 |

Source: Public Citizen analysis of lobbying disclosure records filed with the secretary of the Senate.

In particular, there were three groups of lobbyists who were strategically positioned to aid their cause: those who migrated from Congress or the executive branch to influential positions at BIO, those with ties to Frist and those with ties to Hastert.

## BIO's Point People Came from Influential Government Positions

- **Dave W. Boyer,** the chief lobbyist for BIO when the liability shield measure was written, had served as a congressional liaison at HHS and a special assistant to the HHS secretary.[70] In the run-up to Frist's covert insertion, Boyer served as an industry point of contact for the White House and the Hill, according to e-mails obtained by Public Citizen. He was furnished with an initial draft that the congressional leadership used as a jumping off point in drafting a liability shield. Boyer promptly forwarded this language to an undisclosed e-mail list and to employees of BIO. "Please send me your company's comments," he wrote. In the ensuing week, Boyer had a meeting at the White House and another, at the invitation of a Frist aide, with Frist's staff and representatives of the White House, the Justice Department and the Department of Health and Human Services. Both meetings were to "discuss liability," Boyer wrote in e-mails.

  Boyer continues to spin through the revolving door. The FDA announced on March 15, 2006 that Boyer had been named the agency's assistant commissioner for legislation. The press release announcing his appointment said, "Most recently, Boyer worked closely with members of Congress as the director of federal government relations for the Biotechnology Industry Organization."[71]

- **Tom DiLenge** may represent the ultimate revolving-door insider. In 2004, as policy director and chief counsel for the House Homeland Security Committee, DiLenge "was called upon … to lead the effort to draft and enact President Bush's signature initiative to combat bioterrorism, the Project BioShield Act," Rep. Peter T. King (R-N.Y.) said in an effusive tribute to DiLenge printed in the November 1, 2005 Congressional Record.[72]

DiLenge, a veteran of nine years on Capitol Hill, was leaving to become deputy general counsel of BIO, where he promptly got involved in helping Capitol Hill staffers draft the liability shield language that Frist inserted into the DoD Appropriations bill on Dec. 18 of that year.

Documents obtained by Public Citizen show that DiLenge was one of the BIO officials who received a copy of an early draft of the legislation that was sent to BIO for comment.[73] He was one of the BIO representatives at two key meetings in which the bill was discussed, a Nov. 15, 2005 session at the White House and a session with Frist staff members and administration officials on November 18.[74]

On the morning after Frist's covert insertion of the measure into the DoD conference report, DiLenge authored a three-page document titled "Key aspects of the final countermeasure liability and compensation program." The paper was circulated by Boyer less than 12 hours after Frist's insertion.[75]

## Former Frist Aides Who Turned Lobbyists

- **Dave Larson** was Frist's senior health policy advisor from 1995 to 2001, before the senator's ascent to majority leader. Larson advised Frist, then chairman of the Public Health Subcommittee, on a variety of issues including "food and drug law," according to the biography on his firm's Web site.[76]

  In 2005, Larson lobbied on vaccine issues for Sanofi Pasteur, Hollis Eden Pharmaceuticals and Genaco Biomedical.[77] Genaco says it offers a diagnostic test that can detect avian flu in four hours, while most tests take up to two days.[78]

  Larson also lobbies for other pharmaceutical companies, including Bayer Healthcare, Wyeth and the Pharmaceutical Research and Manufacturers of America, the trade group headed by former Rep. Billy Tauzin (R-La.)

- **Dean Rosen** left Frist's staff, where he was health policy director, late in 2005 to join the firm of Mehlman Vogel Castagenetti Inc., where, in November, he became a lobbyist for Merck, concerned about vaccines, among other issues.[79]

- **Lee Rawls** was Frist's chief of staff from March 2003 until March 2005. Rawls began lobbying for Schering-Plough on issues not related to vaccines and pandemics the month he left Frist's staff.[80]

## The Hastert Connection

- **The son of the Speaker.** While many members of Hastert's staff have graduated to K Street, the most significant connection between the speaker and the Washington influence peddling community is reflected in the work of his 30-year-old son, Joshua Hastert.

In the first half of 2005, Podesta Mattoon's Hastert lobbied on behalf of vaccine maker Chiron on "avian flu issues" and at least two vaccine-related bills. Each bill would have provided a liability shield for drug makers.[81]

"Josh has long-standing relationships with numerous offices on Capitol Hill and in the Administration as well as a unique understanding of the legislative process," Podesta Mattoon's Web site oozes about the younger Hastert.

In 2002, the *New York Times* wrote that this Hastert has "a pierced tongue, a goatee and owns a record label called 'Seven Dead Arson.'"[82]

- **Peter Jeffries**, a former senior adviser to and spokesman for Hastert, registered in November 2005 to lobby on behalf of BIO. He is employed by Hill and Knowlton.[83]

- **Darren Willcox,** a former senior policy advisor to Hastert, was the speaker's "point person on all health care and Social Security issues" for three-and-a-half years, according to his biography on the Dutko Worldwide Web site. Willcox lobbies for several pharmaceutical firms including GlaxoSmithKline.[84]

  In May 2002, while Willcox still worked on the Hill, Glaxo paid $2,817 for him to take a six-day "educational staff trip on vaccine issues" to Brussels, Belgium, according to a travel form Willcox filed with the House.[85]

- **David Thompson,** a former Hastert assistant on policy issues, works for Capitol Hill Consulting Group and has lobbied for Novartis, Abbott Laboratories, DFB Pharmaceuticals and Millennium Pharmaceuticals.[86]

- **Jack Howard** A former deputy chief of staff to Hastert and former Senate Majority Leader Trent Lott, Howard was also Deputy Assistant for Legislative Affairs to President George W. Bush for two years.[87] At Wexler and Walker Public Policy Associates, he lobbied on legislation that would have provided Medicare coverage for self-injected biologicals that replace drugs that cannot be self-administered.[88]

- **Amy Jensen Cuniffee** lobbies for Bristol-Myers, Aventis-Pasteur and Genentech at Quinn Gillespie and Associates.[89] Before joining Quinn Gillespie in May 2005, she worked at the White House legislative office. Earlier, she spent seven years as an aide to Hastert and former Majority Leader Tom DeLay (R-Texas.)[90]

# Section VI: BIO's Deceptive Reach

BIO underplays its link to giant pharmaceutical companies, preferring instead to emphasize its role in helping a fledgling industry. This is how the organization describes itself in press releases: "BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products"[91]

What BIO's biography doesn't say is that its membership is stacked with the nation's biggest pharmaceutical firms. Indeed, the top 10 firms in terms of U.S. pharmaceutical sales are members. Together, these companies control more than half of the U.S. pharmaceutical market. [See Figure 4]

**Figure 4: BIO's Biggest Members**

| Rank | Corporation | Total Sales 2005 (in billions) | Pct. Market Share |
|---|---|---|---|
| 1 | Pfizer | $27.2 | 10.8 |
| 2 | GlaxoSmithKline | $19.9 | 7.9 |
| 3 | Johnson and Johnson | $16.0 | 6.3 |
| 4 | Merck and Co. | $15.2 | 6.0 |
| 5 | AstraZeneca | $12.9 | 5.1 |
| 6 | Novartis | $12.3 | 4.9 |
| 7 | Amgen | $11.9 | 4.7 |
| 8 | Sanofi-Aventis | $11.0 | 4.4 |
| 9 | Lilly | $8.7 | 3.4 |
| 10 | Bristol-Myers Squibb | $8.4 | 3.3 |
| **Total** | | **$143.5** | **56.8** |

Sources: IMS Health Web site and BIO membership directory, as listed on its Web site.

It wasn't always thus.

BIO was formed in July 1993 from the merger of two small Washington-based biotech organizations, the Industrial Biotechnology Association (which mainly represented larger, established companies before Congress and federal agencies) and the Association of Biotechnology Companies (which represented emerging companies and universities). At its formation, BIO had 16 employees and a budget of $2.1 million.[92] Its first president was Carl Feldbaum, who had come to Washington in 1973 as an assistant Watergate special prosecutor and remained in the capital. He had served as an assistant secretary of energy, inspector general for defense intelligence at the Defense Department and chief of staff to Sen. Arlen Specter (R-Pa.)[93]

BIO had grown to almost 100 staffers with a $40 million budget by the time Feldbaum retired in 2004. Its membership roster had grown from 350 to more than 1,100.[94]

Feldbaum worked at making the organization a player in Washington's influence-peddling world. Between 1998, the earliest year for which lobbying disclosure forms are available online, and the end of 2004, BIO more than tripled its lobbying budget, from $1.7 million to $5.2 million.[95]

After Feldbaum retired at the end of 2004, BIO took another step toward making itself a force. The group hired a Capitol Hill veteran, former Rep. Jim Greenwood (R-Pa.), as its new president. Greenwood was a six-term congressman who had headed the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations.[96]

In Greenwood's first year, he presided over a 12.4 percent increase in the group's lobbying expenditures, to $5.8 million. Greenwood also used the Capitol's revolving door to increase BIO's firepower. On the same day in April 2005, for example, Greenwood announced that the group had filled four senior staff positions with veterans of Capitol Hill or the federal bureaucracy. They were:

- Scott Whitaker, BIO's chief of staff. He was formerly chief of staff and chief lobbyist for HHS and a staff member of former Senate Assistant Majority Leader Don Nickles (R-Okla.)[97]

- Amit K. Sachdev, BIO's executive vice president for health, moved to BIO from the FDA, where he was deputy commissioner for policy. Sachdev also worked on Capitol Hill as majority counsel for the House Energy and Commerce Committee.[98]

- Brent A. Del Monte, who was named BIO vice president for federal government relations. Del Monte was formerly counsel to the House Energy and Commerce Committee and legislative director for former Rep. Tom Bliley (R-Va.) He worked for Washington Council Ernst and Young most recently before arriving at BIO.[99]

- Alan F. Eisenberg, who was named executive vice president, advocacy and operations, previously worked on Greenwood's congressional staff, and as a staffer for the Public Health Subcommittee of the Senate Health, Education, Labor and Pensions Committee, and as an aide to Rep John Shadegg (R-Ariz.)[100]

Greenwood has hired other veterans of the Hill and federal bureaucracy at other times, including two BIO officials who played key roles in crafting the liability shield to their organization's liking. In March 2006, the FDA announced Boyer's appointment as the agency's assistant commissioner for legislation.[101]

BIO also hired Tom DiLenge, who was credited by Rep. Peter T. King (R.-N.Y.) with being a major author of the BioShield Act of 2004, the predecessor to the liability shield.[102]

Greenwood seems fond of flattering members of Congress with "Legislator of the Year" awards. For example, over a two-day period in March 2005, BIO bestowed "BIO Legislator of the Year" honors to two senators and six House members. They were Sen. Richard Burr (R-N.C.), Sen. Mike Crapo (R-Idaho), Rep. Bobby Rush (D-Ill.), Rep John M. Shimkus (R-Ill.), Rep. Rush Holt

(D-N.J.) Rep. Sam Graves (R-Mo.), Rep. Diana DeGette (D-Colo.), and Rep. Melissa A. Hart (R-Pa.)[103]

But Greenwood wasn't finished.

A month later, he rounded out the BIO Baker's Dozen, by showering the award on five more lawmakers: Sen. Saxby Chambliss (R-Ga.), Sen. Mike Enzi (R-Wyo.), Sen. Blanche Lincoln (D-Ark.), Rep. Mike Castle (R-Del.) and Rep. Frank D. Lucas (R-Okla.).[104]

# Appendix A: Revolving Doors

## Figure 5: Former Members of Congress, Congressional Aides and Executive Branch Officials Who Lobbied Vaccines or Pandemic Issues, 2004-2005

| Lobbyist | Client Name(s) | Firm Name(s) | Revolving Door Connection(s) |
|---|---|---|---|
| Rebecca Anderson | Wyeth | Williams and Jensen | - Staff, Department of Energy;<br>- Legislative Affairs Office Transition Team, Bush-Cheney Transition Team;<br>- Administrative Assistant, White House Office of Legislative Affairs |
| Edward Baxter | Chiron Corporation | Parry, Romani, DeConcini and Symms | - Chief Counsel and Staff Director, Subcommittee on Patents, Copyrights, and Trademarks |
| Michael S. Berman | Chiron Corporation | Duberstein Group | - Aide, Office of Vice President Mondale, 1977-1981 |
| Roger Blauwet | Merck, Wyeth | Canfield and Associates | - Tax Counsel, Sen. Max Baucus (D-Mont.) |
| Kenneth Bowler | Pfizer | Pfizer | - Staff Director, House Ways and Means Committee |
| Dale Bumpers | Sanofi Pasteur | Arent Fox Kintner Plotkin and Kahn | - U.S. Sen. (D-Ark.), 1975-1998 |
| Brian Carey | Chiron Corporation | Foley, Hoag and Eliot | - Legislative Aide, Committee on Labor and Human Resources |
| Bertram Carp | Wyeth | Williams and Jensen | - Legislative Counsel, Sen. Walter Mondale (D-Minn.);<br>- Deputy Domestic Policy Adviser, White House Domestic Council |
| Steven M. Champlin | Chiron Corporation | Duberstein Group | - Executive Director, House Democratic Caucus;<br>- Executive Floor Assistant, House Majority Whip |
| Ronald Christie | Hoffmann-La Roche | Ruder Finn Global Public Affairs | - Deputy Director, USA Freedom Corps;<br>- Special Assistant, White House under President George W. Bush |
| Dack Dalrymple | Sanofi Pasteur | Dalrymple and Associates | - Counsel, Subcommittee on Health and the Environment, House Energy and Commerce Committee;<br>- Legislative Assistant, Rep. Paul Rogers (D-Fla.) |
| Dennis DeConcini | Chiron Corporation | Parry, Romani, DeConcini and Symms | - U.S. Sen. (D-Ariz.), 1977-1994 |
| Brent Del Monte | Biotechnology Industry Organization | Biotechnology Industry Organization | - Legislative Director, Rep. Tom Bliley (R-Va.);<br>- Senior Counsel, House Energy and Commerce Committee |
| Quin D. Dodd | Genaco Biomedical, Sanofi Pasteur, Hollis Eden Pharmaceuticals | Larson Dodd LLC | - Legislative Assistant, Sen. Kay Bailey Hutchison (R-Texas);<br>- Legislative Assistant and Counsel, Rep. Joe Skeen (R-N.M.) |

| | | | |
|---|---|---|---|
| Agnes Dover | Biotechnology Industry Organization | Hogan and Hartson | - Deputy General Counsel, Department of Energy |
| Raissa H. Downs | Tarplin, Downs, Young | Biotechnology Industry Organization | - Principal Deputy Assistant Secretary for Legislation, Department of Health and Human Services |
| Kenneth M. Duberstein | Chiron Corporation | Duberstein Group | - Deputy Undersecretary, Department of Labor;<br>- Deputy Chief and Chief of Staff, White House, Reagan administration;<br>- Assistant to the President for Legislative Affairs, White House Office of Legislative Affairs |
| Vic Fazio | Chiron Corporation | Clark and Weinstock | - U.S. Rep. (D-Calif.), 1979-1998 |
| Carl Feldbaum | Biotechnology Industry Organization | Biotechnology Industry Organization | - Inspector General, Defense Intelligence, Department of Defense;<br>- Chief of Staff, Sen. Arlen Specter (R-Pa.);<br>- Assistant to the Secretary, Department of Energy |
| Jack Fields | Sanofi Pasteur | Twenty-First Century Group | - U.S. Rep. (R-Texas), 1981-1996 |
| Henry Gandy | Chiron Corporation | Duberstein Group | - White House Liaison Officer, Reagan Administration;<br>- Aide, Rep. Tom Loeffler (R-Texas);<br>- Aide, Rep. Trent Lott (R-Miss.) |
| John Haddow | Chiron Corporation | Parry, Romani, DeConcini and Symms | - Aide, Sen. Orrin Hatch (R-Utah) |
| Ilisa Halpern | Sanofi Pasteur | Arent Fox Kintner Plotkin and Kahn | - Legislative Aide, Sen. Dianne Feinstein (D-Calif.) |
| J. Steven Hart | Wyeth | Williams and Jensen | - Assistant to the Chair, President's Task Force on ERISA Reorganization, White House Office of Management and Budget (OMB);<br>- Special Assistant, Assistant Attorney General for Legal Policy, Department of Justice;<br>- Staff, Department of Labor |
| Shannon Hembree | Biotechnology Industry Organization | PodestaMattoon | - White House, Deputy Director of Correspondence and Presidential Messages |
| Susan B. Hirschmann | Wyeth | Williams and Jensen | - Chief of Staff, Rep. Tom DeLay (R-Texas);<br>- Chief of Staff, Rep. Van Hilleary (R-Tenn.) |
| Claudia James | Chiron Corporation | PodestaMattoon | - Legislative Assistant, Rep. Chris Dodd (D-Conn.);<br>- Senior Legislative Assistant, Rep. Peter Peyser (D-N.Y.) |
| Courtney Johnson | MedImmune Inc. | Alpine Group | - Staff Research Assistant, House Energy and Commerce Committee |
| Michael S. Johnson | Biotechnology Industry Organization | OB-C Group | - Chief of Staff and Press Secretary for the House Minority Leader, Rep. Robert Michel (R-Ill.) |
| Bronwen Kaye | Wyeth | Wyeth | - Legislative Assistant, Sen. Evan Bayh (D-Ind.) |
| David Keaney | Chiron Corporation | Chiron Corporation | - Counsel, House Energy and Commerce Committee;<br>- Executive Assistant, Sen. James L. Buckley (R-N.Y.) |

| | | | |
|---|---|---|---|
| Thomas Keating | Biotechnology Industry Organization | OB-C Group | - Director of Policy Services and House Sergeant, Arms Control Bureau, Department of Defense;<br>- Professional Staff, Office of the House Sergeant At Arms |
| Paul Kim | Chiron Corporation | Foley, Hoag and Eliot | - Counsel, Sen. David Pryor (D-Ark.);<br>- Counsel, Rep. Henry Waxman (D-Calif.);<br>- Deputy Staff Director for Health on the Democratic side, Senate Health, Education, Labor and Pensions Committee |
| Bruce Kuhlik | Pharmaceutical Research and Manufacturers of America (PhRMA) | Pharmaceutical Research and Manufacturers of America (PhRMA) | - Assistant to the Solicitor General |
| Ed Kutler | Chiron Corporation | Clark and Weinstock | - Senior Advisor, Rep. Newt Gingrich (R-Ga.) |
| Dave Larson | Genaco Biomedical, Sanofi Pasteur, Hollis Eden Pharmaceuticals | Larson Dodd LLC | - Health Policy Adviser, Sen. Bill Frist (R-Tenn.);<br>- Aide, Rep. Harris Fawell (R-Ill.) |
| Steve Lawton | Biotechnology Industry Organization | Biotechnology Industry Organization | - Chairman, Advisory Commission on Childhood Vaccines, Department of Health and Human Services;<br>- Chief Counsel, House Subcommittee on Health and the Environment |
| Dirksen Lehman | Chiron Corporation | Clark and Weinstock | - Health Counsel, Senate Health, Education, Labor and Pensions Committee;<br>- Special Assistant to the President for Legislative Affairs, Senate, White House Office of Legislative Affairs |
| Nick Littlefield | Chiron Corporation | Foley, Hoag and Eliot | - Democratic Chief Counsel and Staff Director, Senate Labor and Human Relations Committee |
| Drew Littman | Chiron Corporation | PodestaMattoon | - Policy Director, Sen. Barbara Boxer (D-Calif.) |
| Ann-Marie Lynch | Wyeth | Williams and Jensen | - Deputy Assistant Secretary in the Office of Policy, Department of Health and Human Services;<br>- Staff Director, Subcommittee on Health |
| Karina Lynch | Wyeth | Williams and Jensen | - Counsel, Senate Governmental Affairs Committee;<br>- Investigative Counsel, Senate Aging Committee;<br>- Investigative Counsel, Sen. Charles Grassley (R-Iowa) |
| Robert Marsh | Biotechnology Industry Organization | OB-C Group | - Aide, Transportation Secretary Andrew Card, Department of Transportation;<br>- Aide, Rep. Peter Blute (R-Mass.);<br>- Special Assistant to the President for Legislative Affairs, House, White House Office of Legislative Affairs, George W. Bush Administration |
| Daniel J. Mattoon | Chiron Corporation | PodestaMattoon | - Administrative Assistant and Legislative Director, Rep. Thomas Corcoran (R-Ill.);<br>- Administrative Assistant and Legislative Director, Rep. John Grotberg (R-Ill.) |

| | | | |
|---|---|---|---|
| Patrick McLain | GlaxoSmithKline | GlaxoSmithKline | - Counsel, House Energy and Commerce Committee |
| Charles J. Mellody | Biotechnology Industry Organization | OB-C Group | - Aide, House Ways and Means Committee |
| Daniel Meyer | Chiron Corporation | Duberstein Group | - Chief of Staff, Rep. Newt Gingrich (R-Ga.);<br>- Administrative Assistant, Rep. Vin Weber (R-Minn.);<br>- Legislative Director, Sen. Rudy Boschwitz (R-Minn.) |
| Elizabeth Morra | Chiron Corporation | PodestaMattoon | - Press Secretary, Sen. Thad Cochran (R-Miss.);<br>- Press Secretary, House Appropriations Committee |
| Evan Morris | Hoffmann-La Roche | Hoffmann-La Roche | - Staff, Office of Presidential Advance and Communications Office, White House |
| Chris Myrick | Genaco Biomedical, Sanofi Pasteur, Hollis Eden Pharmaceuticals | Larson Dodd LLC | - Legislative Director, Rep. David Sweeney (R-Texas) |
| Patricia A. Nelson | Biotechnology Industry Organization | OB-C Group | - Staff member, House Ways and Means Committee |
| Lawrence O'Brien III | Biotechnology Industry Organization | OB-C Group | - Deputy for Tax Legislation to the Assistant Secretary for Legislative Affairs, Department of the Treasury |
| Eric Olsen | Wyeth | Williams and Jensen | - Chief of Staff and Counsel for Domestic Policy, Department of Agriculture |
| Jonathan Orloff | Sanofi Pasteur | Capitol Partners | - Legislative Assistant, Sen. Edward Kennedy (D-Mass.) |
| Geoffrey Peterson | Sanofi Pasteur | Sanofi Pasteur | - Aide, Sen. Abraham Ribicoff (D-Conn.) |
| Anthony Podesta | Biotechnology Industry Organization | PodestaMattoon | - Counsel, Sen. Edward Kennedy (D-Mass.);<br>- Assistant U.S. Attorney for the District of Columbia, Department of Justice |
| Julie Rabinowitz | Wyeth | Wyeth | - Tax Counsel, Sen. Charles Grassley (R-Iowa) |
| Helen Rhee | Pharmaceutical Research and Manufacturers of America (PhRMA) | Pharmaceutical Research and Manufacturers of America (PhRMA) | - Policy Health Subcommittee, Senior Policy Counsel |
| James Rock | Chiron Corporation | Parry, Romani, DeConcini and Symms | - Tax Legislative Assistant, Rep. Edgar Jenkins (D-Ga.);<br>- Tax Legislative Assistant, Rep. Kent Hance (D-Texas) |
| Paul Grant Rogers | Biotechnology Industry Organization | Hogan and Hartson | - U.S. Rep. (D-Fla.), 1955-1978 |
| Romano Romani | Chiron Corporation | Parry, Romani, DeConcini and Symms | - Legislative Director and Staff Director, Sen. Vance Hartke (D-Ind.);<br>- Chief of Staff, Sen. Dennis DeConcini (D-Ariz.) |
| Dean Rosen | Merck | Mehlman Vogel Castagnetti. | - Health Policy Aide, Sen. Bill Frist (R-Tenn.) |

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| Andrew Rosenberg | Hoffmann-La Roche | Ruder Finn Global Public Affairs | - Legislative Assistant, Sen. Edward Kennedy (D-Mass.) |
| Amit Sachdev | Biotechnology Industry Organization | Biotechnology Industry Organization | - Deputy Commissioner for Policy, Food and Drug Administration |
| Shannon Salmon | Johnson and Johnson | Johnson and Johnson | - Staff, Senate Finance Committee |
| Victor Schwartz | Shook, Hardy and Bacon | Pharmaceutical Research and Manufacturers of America (PhRMA) | - Chairman, Federal Interagency Task Force on Product Liability;<br>- Executive Director, Federal Interagency Counsel on Insurance |
| Jen Siciliano | Biotechnology Industry Organization | PodestaMattoon | - Communications Aide, Senate Appropriations Committee |
| Amy Smith | Sanofi Pasteur | Sanofi Pasteur | - Aide, Sen. Bob Dole (R-Kansas);<br>- Assistant Secretary for Legislative Affairs, Department of Treasury |
| Peter Stein | Pharmaceutical Research and Manufacturers of America (PhRMA) | Pharmaceutical Research and Manufacturers of America (PhRMA) | - Aide, Sen. Rick Santorum (R-Pa.) |
| Tim Stewart | Genaco Biomedical, Sanofi Pasteur, Hollis Eden Pharmaceuticals | Larson Dodd LLC | - Chief of Staff, House Resources Committee |
| Thaddeus Strom | Chiron Corporation | Parry, Romani, DeConcini and Symms | - Chief Counsel and Staff Director, Sen. Strom Thurmond (R-S.C.);<br>- Republican Chief Counsel and Staff Director, Senate Judiciary Committee |
| Sandy Stuart | Chiron Corporation | Clark and Weinstock | - Assistant Secretary for Legislative Affairs, Department of Defense |
| Steve Symms | Chiron Corporation | Parry, Romani, DeConcini and Symms | - U.S. Rep., (R-Idaho) 1973-1980;<br>- U.S. Sen. (R-Idaho), 1981-1992 |
| Linda Tarplin | Tarplin, Downs, Young | Biotechnology Industry Organization | - Special Assistant for Legislative Affairs, - Senate, White House Office of Legislative Affairs |
| Gordon Taylor | Sanofi Pasteur | Arent Fox Kintner Plotkin and Kahn | - Chief of Staff, Rep. Chris John (D-La.) |
| Carl Thorsen | Hoffmann- La Roche | American Continental Group | - Senior Adviser for Border Enforcement, Department of Defense;<br>- Deputy Assistant Attorney General for Legislative Affairs, Department of Justice;<br>- Aide to Subcommittee on Crime, House Judiciary Committee;<br>- General Counsel, Rep. Tom DeLay (R-Texas);<br>- Aide, Sen. Arlen Specter (R-Pa.) |
| David Urban | Hoffmann- La Roche | American Continental Group | - Chief of Staff, Sen. Arlen Specter (R-Pa.) |

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| John Van Fossen | MedImmune Inc. | Artemis Strategies | - Chief of Staff, Rep. Peter Hoekstra (R-Mich.) |
| Vin Weber | Chiron Corporation | Clark and Weinstock | - U.S. Rep. (R-Minn.), 1981-1992 |
| Larry Werner | Biotechnology Industry Organization | Biotechnology Industry Organization | - Aide, Sen. Harry Reid (D-Nev.) |
| Richard White | MedImmune Inc. | Alpine Group | - Legislative Coordinator, Sen. John Chafee (R-R.I.) |
| Andrea Wilkinson | Sanofi Pasteur | Venable, Baetjer, Howard and Civiletti LLP, Sanofi Pasteur | - Aide, Rep. W.J. "Billy" Tauzin (R-La.);<br>- Aide, Sen. John Breaux (D-La.) |
| Michael Wyatt | Biotechnology Industry Organization | Hogan and Hartson | - General Counsel, Small Business Administration |
| Jennifer Baxendell Young | Tarplin, Downs, Young | Biotechnology Industry Organization | - Deputy Assistant Secretary for health in the office of legislation, Department of Health and Human Services |

## Endnotes

[1] E-mail from Peggy Binzer, Senior FDA Health Counsel, Senate Budget Committee, to Dave W. Boyer, Nov. 12, 2005 2:54 p.m..
[2] E-mail from Dave Boyer transmitting BIO comments on the draft bill to unknown recipients and to Brent A. Del Monte, BIO Vice President for Federal Government Relations, Nov. 13, 2005, 16:32. Subject: "FW: BIO Comments on November 11 Draft Liability Proposal," with this message, "All – This afternoon we provided the attached document to the Hill in response to their request for comment on a bicameral majority pandemic/biodefense liability proposal."
[3] E-mail from Dave Boyer transmitting BIO comments on the draft bill to unknown recipients and to Brent A. Del Monte, BIO Vice President for Federal Government Relations, Nov. 13, 2005, 16:32. Subject: "FW: BIO Comments on Nov. 11 Draft Liability Proposal," with this message, "All – This afternoon we provided the attached document to the Hill in response to their request for comment on a bicameral majority pandemic/biodefense liability proposal."
[4] E-mail from Dave Boyer transmitting BIO comments on the draft bill to unknown recipients and to Brent A. Del Monte, BIO Vice President for Federal Government Relations, Nov. 13, 2005, 16:32. Subject: "FW: BIO Comments on November 11 Draft Liability Proposal," with this message, "All – This afternoon we provided the attached document to the Hill in response to their request for comment on a bicameral majority pandemic/biodefense liability proposal."
[5] E-mail from Dave Boyer transmitting BIO comments on the draft bill to unknown recipients and to Brent A. Del Monte, BIO Vice President for Federal Government Relations, Nov. 13, 2005, 16:32. Subject: "FW: BIO Comments on November 11 Draft Liability Proposal," with this message, "All – This afternoon we provided the attached document to the Hill in response to their request for comment on a bicameral majority pandemic/biodefense liability proposal."
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[7] Public Citizen analysis of lobbying disclosure records filed with the Secretary of the Senate (available at sopr.senate.gov.)
[8] E-mail from Dave Boyer to unknown recipients, Nov. 15 2005, 18:30:36.
[9] E-mail from Dave Boyer to unknown recipients, Nov. 18, 2005, 15:47:55.
[10] E-mail from Dave Boyer to unknown recipients, Nov. 18, 2005, 15:47:55.
[11] E-mail from Dave Boyer to unknown recipients, Nov. 18, 2005, 15:47:55.
[12] E-mail from Dave Boyer to unknown recipients, Dec. 1, 2005, 4:22 p.m.
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[16] *Congressional Record*, Dec. 22, 2005, p. H13181.
[17] *Congressional Record*, Dec. 22, 2005, p. H13181.
[18] Kennedy spoke Jan. 23, 2006 at a videotaped seminar for reporters on covering the federal budget sponsored by the Center on Congress at Indiana University, the National Press Foundation and the Regional Reporters Association.
[19] Interview between Public Citizen Senior Researcher John O'Donnell and Rep. Jim Moran (D-Va.), Feb. 15, 2006.
[20] Interview between Public Citizen Senior Researcher John O'Donnell and Rep. Jim Moran (D-Va.), Feb. 15, 2006.
[21] Interview between Public Citizen Senior Researcher John O'Donnell and Rep. Jim Moran (D-Va.), Feb. 15, 2006.
[22] *Congressional Record*, Dec.21, 2005, p. S14242.
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[27] Sheryl Gay Stolberg, "A Capitol Hill Mystery: Who Aided Drug Maker?" *New York Times*, Nov. 29, 2002. See also, text of Public Law 107-296, Sections 1714-1717.
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[32] Bureau of the Public Debt, Trust Fund Management Branch Vaccine Injury Compensation Trust Fund balance sheet as of Dec.31, 2005 and "Smallpox Vaccine Injury Compensation," Congressional Research Service, June 13 , 2003, p. 6.
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[36] Sheryl Gay Stolberg, "A Capitol Hill Mystery: Who aided Drug Maker?" *New York Times*, Nov. 29, 2002.
[37] Sheryl Gay Stolberg, "A Capitol Hill Mystery: Who aided Drug Maker?" *New York Times*, Nov. 29, 2002.
[38] Erwin Chemerinsky e-mail to Public Citizen Senior Researcher John O'Donnell, Mar.19, 2006
[39] Letter of Professor Erwin Chemerinsky to senators, Dec. 20, 2005, as inserted in the *Congressional Record*, Dec. 21, 2005, p. S14247.
[40] Interview between Public Citizen Senior Researcher John O'Donnell and Legislative Counsel Jillian Aldebron and Tom DiLenge, April 28, 2006.
[41] Interview between Public Citizen Senior Researcher John O'Donnell and Legislative Counsel Jillian Aldebron and Tom DiLenge, April 28, 2006.
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[43] Bob Evans, "Skillful Lobbying Leads Vaccine Maker to Lucrative Profits," *The Olympian*, Dec. 10, 2005.
[44] Nelson D. Schwartz, "Rumsfeld's Growing Stake in Tamiflu," CNNMoney.com, October 31, 2005.
[45] Tom DiLenge, BIO's deputy general counsel, in an analysis of the shield provision that was distributed via e-mail only hours after the vote.
[46] Letter from Michael O. Leavitt, Secretary of Health and Human Services to House Speaker Dennis J. Hastert, Nov. 1, 2005, with attached proposed legislation.
[47] Tom DiLenge, BIO's deputy general counsel, in an analysis of the shield provision that was distributed via e-mail only hours after the vote.
[48] Comments of Sen. Orrin Hatch (R-Utah), *Congressional Record*, Dec. 21, 2005, p. S14238.
[49] E-mail from Professor Erwin Chemerinsky to Public Citizen Senior Researcher John O'Donnell, Mar.19, 2006.
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[51] "Department of Health and Human Services, Office of the Secretary, Determination and Declaration Regarding Emergency Use of Anthrax Vaccine Absorbed for Prevention of Inhalation Anthrax," signed Jan. 14, 2005, published in the *Federal Register*, Feb. 2, 2005, p. 5450 and Barbara Loe Fisher letter to Col. Robert P. Kadlec, M.D., (USAF Ret.), Staff Director, Senate Subcommittee on Bioterrorism and Public Health Preparedness, Nov. 15, 2005.
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[65] 28 U.S.C. § 1346(b), § 1402(b), § 2401(b), §§ 2671-2680.
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[69] Public Citizen reviewed lobbying registration forms and semi-annual lobbying disclosure forms filed with the Secretary of the Senate by the 20 largest pharmaceutical manufacturers and the lobbying firms they hired in 2004 and 2005. Additional firms were reviewed if their names appeared in news reports as being involved in issues relating to vaccines or pandemic diseases, or if they were discovered in our canvass of lobbying disclosure to be involved in lobbying on vaccines, pandemic diseases, or related issues. If the lobbying disclosure report listed vaccines as an issue on which lobbying occurred (or listed related topics, such as pandemic diseases, avian flu or bioshield), the information in the form was included in this report. Because disclosure laws do not require a breakdown of lobbying expenditures by issue, the entire amount of lobbying expenditures reported on the form was counted, even though other issues may also have been listed in the report.
[70] HHS Assistant Secretary for Legislation office, roster of employees, as of May 2, 2001 and Lobbying disclosure reports filed with Secretary of the Senate (available at sopr.senate.gov.)
[71] "David W. Boyer Appointed New Head of FDA's Office of Legislation," FDA press release March 15, 2006.
[72] Rep. Peter T. King, speech in the House of Representatives Nov. 1, 2005, extension of remarks. *Congressional Record*, Nov. 1, 2005, p. E2237.
[73] E-mail from Dave W. Boyer to unknown recipients with copies to BIO officials Brent A. Del Monte, Grant Erdel, Tom DiLenge and Chris Colwell, Nov. 12, 2005, at 15:49:28.
[74] Dave. W. Boyer e-mail to unknown recipients with CC to Brent A. Del Monte at BIO, Nov. 15, 2005, at 18:30:36; Dave W. Boyer e-mail to unknown recipients with CC to Brent A. Del Monte at BIO, Nov. 18, 2005, at 5:47:55; and interview between Public Citizen Senior Researcher John O'Donnell and Legislative Counsel Jillian Aldebron and Tom DiLenge, April 28, 2006.
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