

WHITE **P**APER

Number 14 * August 2007

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Introduction: Private Industry Takes

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CORPORATE EMPOWERMENT AND THE DECLINE OF PUBLIC SAFETY

By Emily Gottlieb

INTRODUCTION: PRIVATE INDUSTRY TAKES HOLD

Wounded soldiers with traumatic brain injuries disappearing or sitting for weeks with no appointments or help from staff to arrange them. Suicide attempts and unintentional overdoses from prescription drugs and alcohol. Rooms with black mold, holes in the ceiling, stained carpets, mouse droppings and cockroaches. Staffing shortages, overworked case managers and disappearing paperwork.¹

Welcome to Walter Reed, the Army's top medical center, where physically and psychologically injured U.S. soldiers in need of outpatient care were left to languish after serving in Afghanistan and Iraq. While many have analyzed the reasons for this tragic turn of events, the White House's push for privatization has been in large part responsible, starkly showing what can happen when private, profitdriven industry is put in charge of health and safety decisions.²

Privatizing as many federal jobs as possible has been a major goal of the Bush administration.³ After taking office, the President mandated outsourcing 425,000 federal government jobs.⁴ In 2002, he launched a "competitive sourcing" initiative, allowing private companies to compete for nearly half of all federal jobs.⁵ This campaign accelerated previous Defense Department efforts to replace federal workers at Walter Reed with private companies, causing a mass

exodus of highly skilled and experienced personnel concerned about an impending takeover and anticipated job cuts.

According to an investigation by the House Committee on Oversight and Government Reform, a company called IAP Worldwide Services won a five-year, \$120 million contract in January 2006 to provide base operations services at Walter Reed. IAP had strong ties to the Bush administration – it was led by a former executive of KBR, a subsidiary of Halliburton, the Texas-based oil company once run by Vice President Cheney. In 2005, IAP had been subject to a congressional examination for problems it encountered delivering ice in the aftermath of Hurricane Katrina.⁶

IAP was awarded the contract although the Army had initially determined that Walter Reed's in-house federal workforce could perform support services more cheaply than IAP. After IAP protested that determination, the Army Audit Agency was directed to reevaluate the federal employees bid, withdrew its approval of that bid and unilaterally raised the employees' bid by \$7 million, making the employees' bid higher than IAP's.

During the one-year period between the award of the contract and IAP beginning work, federal employees – including skilled maintenance personnel and workers with specific knowledge of Walter Reed's systems and infrastructure – began leaving Walter Reed in droves. Government employee staff levels dropped from a high of over 300 in early 2006 to under 60 on February 3, 2007.8

When IAP took over operations on February 4, 2007, the company "reportedly began work with fewer than 50 workers, less than one-sixth the staff in the original workforce." This precipitous drop in staffing coincided with an increased workload due to the wars in Afghanistan and Iraq, creating an "under-lap" of personnel that was dangerous for patients, according to an internal Army memorandum. ¹⁰

Though top officials at Walter Reed and the U.S. Army Medical Command should have known of the dangers caused by privatization, they did nothing, leaving Walter Reed's base operations and patient care services "at risk of mission failure." It took a February 2007 investigative series by the *Washington Post* and the public outrage that followed for the White House to act. The result: a series of apologies, firings, investigations and calls for systemic reform all too little too late for the soldiers and their families who had already suffered.

Unfortunately, the terrible failures at Walter Reed are not an aberration. Since taking office, the Bush administration has continued to endanger the wellbeing of all Americans by empowering corporations at the expense of government institutions that were specifically established to protect citizens from harm.

Just look at today's federal regulatory agencies, which were created to safeguard the public from corporate abuses. These agencies have been captured and are controlled by the very industries they were intended to regulate. This transformation of mission and

management is primarily the result of the President's agenda to minimize the government's role in protecting its citizens.

The pattern of weakening and re-purposing federal agencies over the last six and a half years is both stark and chilling. During Bush's time in office, many of these agencies have been led by industry loyalists, who have undermined, and at times eliminated, critical health and safety protections. To make matters worse, President Bush recently amended a key executive order giving his administration, and by extension private industry, more power over agencies that enforce health, safety and environmental protections.

And finally, the Bush administration has been quietly attempting to wipe out or render meaningless the legal rights of consumers hurt by the very dangerous products and practices that the agencies themselves were created to safeguard against and have failed to prevent.

This was the finding of a June 2007 Center for Progressive Reform report. "Although executive-branch support of industry's claims of preemption of tort actions is not unprecedented, the systematic nature of this administration's backing of industry tort-preemption claims – involving multiple agencies charged with implementing health and safety protections – substantially exceeds anything done in prior administrations," explained the study's authors. "Prior to the Bush administration, agencies by and large took one of two positions. They either opposed preemption of state tort remedies or stayed on the sidelines and did not take a position."

The White House's campaign has an aggressive, targeted approach: push the courts away from preserving tort law's traditional role in protecting public health and safety while at the same time undermine federal health and safety standards and weaken the agencies responsible for enforcing these standards. Yet undercutting such regulatory protections and disempowering agencies only makes state tort law protections all the more vital.¹⁵

Over the past four election cycles, heavily regulated industries, such as oil and gas, transportation, agribusiness, manufacturing, pharmaceutical and construction, have given millions to Bush and his GOP allies. Heavily regulated industries have also spent millions lobbying Congress and agencies for deregulation of their activities since Bush took office. To

In this report, we examine how these investments have paid off. Our analysis is by no means exhaustive but merely an overview of the White House's campaign to undermine the critical role federal agencies play in safeguarding the public, all for the benefit of corporations. Part I looks at the administration's efforts to transform federal agencies into industry advocates. It discusses the industry-to-agency revolving door and Bush's new executive order, which together shift the agencies' focus away from the public interest and onto corporate interests. Part II explores how various agencies have strayed from their original mission, weakened by a White House that cares little for public health and safety. Here we take a closer look at the current state of five federal agencies: the

Consumer Product Safety Commission (CPSC), the Occupational Safety and Health Administration (OSHA), the National Highway Transportation Safety Administration (NHTSA), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA). This section also addresses the White House's aggressive push to use federal agencies to advance its "tort reform" agenda. By choosing to promulgate rules that seek to preempt state tort law while weakening health and safety standards and failing to police corporate malfeasance, such agencies have left Americans in a country with more risks and fewer protections.

PART I: TURNING REGULATORY AGENCIES INTO INDUSTRY ADVOCATES

THE REVOLVING DOOR

On March 1, 2007, President Bush nominated Michael Baroody to head the Consumer Product Safety Commission (CPSC), the federal agency charged with protecting the public, especially children, from serious injury or death from consumer products. For 13 years, Baroody had been chief lobbyist at the National Association of Manufacturers (NAM), an industry trade group representing the nation's largest manufacturing firms on Capitol Hill, before the executive branch and in the courts. While there, Baroody directed efforts to weaken the CPSC and undermine safety proposals pending before the agency on behalf of NAM's 14,000 corporate members. For example, during his tenure, NAM

- Opposed a CPSC proposal to improve safety standards for baby walkers;
- Opposed a petition from consumer organizations to improve the way the consumers find out about recalls of potentially dangerous children's products;
- Supported diluting guidelines companies used to determine whether they must report substantial product hazards; and
- Urged New York Governor George Pataki to veto legislation that mandated fire safe cigarettes.¹⁸

Despite calls from Senate Democrats and consumer groups to withdraw the nomination, President Bush refused.¹⁹ It wasn't until news broke of Baroody's \$150,000 severance package from NAM that Baroody removed his own name from consideration.²⁰

Unfortunately, Michael Baroody is the latest in a long line of industry insiders tapped by the White House to head health and safety agencies. As a result, federal agencies have been captured by the very industries they are supposed to regulate, led by a revolving door of industry figureheads. This endangers the health and safety of us all.

How? According to the Revolving Door Working Group – a broad-based coalition of organizations ranging from Public Citizen and Common Cause to Farm Aid and Public Employees for Environmental Responsibility – the appointment of corporate executives and business lobbyists to key posts in federal agencies "tends to create a pro-business bias in policy formulation and regulatory enforcement.... [A] corporate executive or lobbyist joining the government might not only tend to favor a previous private-sector employer but might also be ideologically inclined to shape policy to benefit business in general, as opposed to the broader public interest."²¹

The following examples illustrate the extent to which President Bush has let the fox guard the henhouse:

- Susan Dudley was director of the Mercatus Center, an industry-funded, antiregulatory advocacy organization, before heading the White House-controlled Office of Information and Regulatory Affairs (OIRA), the regulatory arm of the Office of Management and Budget (OMB). According to Public Citizen, while at Mercatus, Dudley attacked proposed regulations and orchestrated campaigns to strike down existing environmental, health and safety safeguards, including: the EPA's efforts to keep arsenic out of drinking water and lower levels of disease-causing smog; NHTSA's life-saving air bag regulations; and the Department of Transportation's rules to keep sleep-deprived truck drivers off the roads. President Bush had bypassed Congress and installed Dudley at OIRA through a recess appointment after her confirmation stalled in the Republican-controlled Senate amid concerns about her anti-regulatory agenda. Although the recess appointment allows Dudley to lead OIRA until Bush leaves office, the President was forced to resubmit her nomination to the Senate to ensure that she receives a salary. The outcome of that re-nomination has yet to be decided.²²
- Linda Fisher was a former top lobbyist and executive at pesticide producer Monsanto who had also practiced law at Latham & Watkins, a firm known for fighting tougher regulatory standards on behalf of powerful industry clients, before being named to fill the second-ranking position, Deputy Administrator, at the EPA. She left the agency in 2003, later taking a job at DuPont.²³
- Edwin Foulke was a partner at the union-busting law firm Jackson Lewis before being appointed to head OSHA. While there, according to the *New York Times* and OMB Watch, he headed the firm's OSHA compliance practice, defending companies accused of health and safety violations; opposed several workplace safety regulations, including the OSHA ergonomics standard promulgated by the Clinton Administration; advocated voluntary compliance standards over mandates before the Senate; and testified several times before Congress on behalf of the U.S. Chamber of Commerce, the nation's largest business trade association. As OSHA chief, Foulke has pushed a voluntary compliance agenda, ignored scientific evidence linking diacetyl to "popcorn worker's lung" and blamed many job-related injuries on worker carelessness, according to the *New York Times*.²⁴
- Jacqueline Glassman was a former DaimlerChrysler attorney before being tapped as chief counsel, Deputy Administrator and later Acting Administrator of NHTSA. According to the Revolving Door Working Group, while at DaimlerChrysler, Glassman helped defend the company against charges by California officials that it resold defective cars to consumers without their knowledge. At NHTSA she played a key role in the decision to block disclosure of "early warning" information such as detailed model-specific crash data.²⁵

- **John Henshaw** oversaw environment, safety and health for Astaris LLC, a joint venture of chemical producers FMC and Solutia Inc. (a spinoff of Monsanto), and worked at Solutia and Monsanto before becoming head of OSHA. According to the Revolving Door Working Group, while at OSHA, Henshaw not only reduced the number of staffers devoted to developing new safety standards but also sharply curtailed the agency's rule-making powers, asking instead that companies voluntarily comply with safety standards. Henshaw resigned from his post in December 2004. ²⁶
- **David Lauriski** spent 30 years in the mining industry advocating looser coal dust standards before being named head of MSHA. According to the Revolving Door Working Group, the *New York Times* and Jack Spadaro, former head of the National Mine Health and Safety Academy (MSHA), a branch of the Department of Labor, during his tenure, Lauriski rejected a safety proposal targeting surface hauling, which was known to cause 30 percent of fatal, above-ground mine accidents; instituted a "compliance assistance" program that encouraged inspectors not to write up violations when operators failed to comply with the law; and attempted to institute new coal regulations that put miners at greater risk of black-lung disease. He left the agency in 2004 and took a position at a mine-industry consulting company.²⁷
- Richard Stickler worked 30 years as a coal industry executive before being appointed MSHA chief. According to the United Mine Workers, mines run by Stickler had accident rates twice the national average for six of eight years, including two fatal accidents at a mine Stickler managed for five years. During a Senate confirmation hearing just weeks after 15 coal miners had been killed in three separate underground incidents, Stickler refused to advocate new or more stringent regulations, saying, "generally I think the current laws are adequate." After Stickler's nomination was returned to the White House twice due to lack of Senate support, President Bush named Stickler MSHA head while the Senate was in recess. His term expires at the end of 2007.²⁸

Recent newspaper investigations have also exposed an unprecedented industry-to-agency revolving door under Bush. As reported in May 23, 2004's *Denver Post*, more than 100 high-level agency officials have regulated industries they once represented as lobbyists, lawyers or company advocates. "In at least 20 cases, those former advocates have helped their agencies write, shape or push for policy shifts that benefit their former industries," according to the *Post*.²⁹

Likewise, an analysis by *New York Newsday* in October 2004 uncovered excessive business influence over federal agency policymaking. The paper found that "[n]early half - 47 percent - of the Bush administration's 400 top-level Senate-confirmed appointees to cabinet departments came from corporations, law and lobbying firms, or business consulting," allowing representatives of the same companies that face regulation to hold key regulatory jobs.³⁰

A report issued by Representative George Miller (D-CA.) in February 2003 reached similar conclusions. The study, *A Sweetheart Deal: How Republicans have Turned the*

Government Over to Special Interests, catalogued 43 private sector lobbyists and corporate officers who attained high-level appointments in the Bush administration.³¹

"This Valentine's Day report documents how President Bush has put the special interest fox in charge of the public interest henhouse," said Miller in a press release. "The result is that critical laws and policies concerning clean air, pension security, health care, defense contracting, workplace safety, and other areas are now administered with an eye toward the special interests, not the public interest." ³²

EXECUTIVE ORDER 13422

On January 18, 2007, within weeks of Democrats taking control of Congress, President Bush quietly amended a Clinton-era executive order to give his administration greater control over agencies and their regulatory policies.³³ This new directive, Executive Order (E.O.) 13422, shifts regulatory power away from federal agencies – power Congress directly delegates to agencies through legislative enactments – and centralizes it in the White House-controlled Office of Information and Regulatory Affairs (OIRA), the regulatory arm of the Office of Management and Budget (OMB).

Closer examination of E.O. 13422, which is scheduled to take effect in late July 2007, reveals that the order could undermine a broad range of public health and safety protections, all to the benefit of corporate interests. Among the more alarming changes:

- Regulatory Policy Officer. Every agency will have a Regulatory Policy Officer (RPO) who oversees agency decisions about regulations and coordinates regulatory matters with OIRA. No rulemaking can commence or be included in an agency's regulatory plan without the approval of the RPO unless overruled by the agency head. The RPO is a presidential appointee, giving the White House a gatekeeper in each agency to ensure that the agency's regulatory agenda reflects the administration's priorities regardless of the need for public safeguards. Nothing in E.O. 13422 suggests that the RPO will be subject to Senate confirmation.
- Increased emphasis on "market failure" before regulating. Even if agencies identify threats to public health and safety that warrant regulation, OIRA can argue that private markets will correct the social problem on their own, making regulation unnecessary. This approach provides the White House with a pretext for rejecting crucial health and safety rules that clash with the administration's pro-business agenda.
- Cost-benefit analysis. No rulemaking can commence unless agencies estimate the combined aggregate costs and benefits of all planned regulations for the calendar year. Using economic analysis to assess the value of an agency's entire regulatory agenda and then allowing that analysis, rather than public need, to dictate regulatory decisions ignores the fact that: 1) many benefits of regulation, like health and safety, cannot be quantified in dollars and cents and are therefore likely to be underestimated; and 2) costs are often overestimated since the numbers are based on

industry estimates.

As Public Citizen recently put it, "This new requirement will make cost/benefit analysis the central factor in setting priorities for needed protections of the public interest. These cost/benefit analyses are notoriously biased against regulation, especially long-term goals such as preventing global warming or cancers that manifest years after exposure to toxic substances."³⁴

• Review of guidance documents. OIRA will have the authority to review and oversee agencies' development, issuance and use of guidance documents – informal, non-binding materials that tell regulated industries how agency rules will be enforced, which often cost businesses millions of dollars to comply with. Guidance documents subject to OIRA review include "interpretive memoranda, policy statements, guidances (sic), manuals, circulars, memoranda, bulletins, advisories, and the like."

Under the new order, OIRA's administrator can decide which guidance documents are "significant" (*i.e.*, are expected to cause an annual effect of \$100 million or more on the economy, raise novel legal or policy issues arising out of legal mandates, the President's priorities or principles set forth in E.O. 13422, among other criteria), a determination that automatically subjects the materials to a higher level of OIRA scrutiny. Once the documents are deemed "significant," agencies must give OIRA: 1) advanced notice of any "significant" guidance documents; 2) upon request, a draft of the proposed guidance with an explanation of the need for guidance and how it will meet that need; and 3) an opportunity to consult with the agency before final issuance of the guidance document.

Given that agencies issue thousands of guidance documents each year relating to hundreds of different types of activities, mandating OIRA oversight can lead to endless regulatory delays and greater White House control over the substantive work of federal agencies, making it more difficult for agencies to protect us from a variety of dangers.

Not surprisingly, public interest groups are extremely concerned that E.O. 13422 will prevent federal agencies from being able to develop, promulgate and enforce regulations that involve anything from warning labels on medicines to safety standards for construction worksites to environmental protections that keep cancer-causing chemicals out of the air and water.

"The new Executive Order that results from these amendments will further threaten public protections," said OMB Watch in its March 2007 report, *A Failure to Govern*. "It codified regulatory delay, further removes agency discretion over legislative implementation, and centralizes control over the regulatory process into a small executive office. It substitutes free market criteria for public values of health, safety, and environmental protections, and substitutes executive authority for legislative authority. In the process, it further tilts the regulatory playing field in favor of corporate interests." ³⁵

Sally Katzen, former OIRA Administrator during the Clinton Administration, echoed these sentiments in recent testimony before the House Subcommittee on Investigation and Oversight. "With its most recent actions, the Bush Administration has again restricted agency discretion and made it more difficult for them to do the job that Congress has delegated to the Federal agencies." According to Katzen, "[I]t will be even more difficult for agencies to do their jobs because regulations are disfavored in this Administration," adding that the new executive order was in essence "a codification of an anti-regulatory manifesto." "36"

The amendments have prompted similar concerns in Congress. "This order allows political appointees to dictate decisions out of the shadows on health and safety issues, even if impartial scientific experts decide otherwise," said Representative Brad Miller, chairman of the House Investigations and Oversight Subcommittee, who is spearheading congressional efforts to learn more about the creation of E.O. 13422 and its potential impact on regulatory procedures.³⁷ The directive is "another avenue for special interests to slow down and prevent agencies from protecting the public," explained Miller. "It is not good government when agency action is based on economic or political back room deals rather than environmental or public health consequences." "38"

On June 28, 2007, the House voted to block OIRA from implementing E.O. 13422. It is unclear whether this action will have any effect.³⁹

PART II: WEAKENED AGENCIES

A. CONSUMER PRODUCT SAFETY COMMISSION (CPSC)

Congress created the CPSC in 1972. Its stated mission is "to save lives and keep families safe by reducing the risk of injuries and deaths associated with consumer products." The agency regulates over 15,000 different consumer products, including many used by children such as strollers, swings, cribs, high chairs, baby walkers and toys. Every year there are more than 27,000 deaths and 33 million injuries associated with products under the CPSC's jurisdiction. The Commission has the authority to set safety standards, require labeling, order recalls, ban products, collect death and injury data, inform the public about consumer product safety and contribute to the voluntary standards setting process. 42

• Regulation at a standstill. The CPSC has struggled to do its job under the current administration. The three-person commission has been without a chairperson for over a year. Since January 2007, the agency has lacked a quorum because of a commissioner vacancy, meaning it cannot vote on rulemakings, set civil and criminal penalties, sue manufacturers or hold public hearings. Bush's failure to fill the opening with an appropriate, pro-consumer nominee has made it impossible for the Commission to regulate for consumer safety. As Rachel Weintraub, Director of Product Safety and Senior Counsel at the Consumer Federation of America (CFA), recently told a congressional committee:

The lack of a quorum is severely hindering the Commission's ability to protect the public from unreasonable risks associated with consumer products and signals to all of the industries that CPSC regulates, that it does not have its full power. This must affect CPSC's bargaining power as well as manufacturer or retailer decisions regarding CPSC compliance, rulemakings and other issues before the Commission."⁴³

• Inadequate budget. CPSC salaries and rent currently consume almost 90 percent of the agency's budget, with the remaining 10 percent dedicated to operation and maintenance of facilities and equipment, communications and utility charges, supplies and other functions. Insufficient funding has also forced significant staff cuts at the Commission, and the President's 2008 budget promises to do more of the same. The proposed budget would fund only 401 full-time employees (FTEs), the lowest number in the CPSC's history, and provide only \$63,250,000 million to operate the agency, a modest increase from the previous budget that does not account for inflation, maintain current CPSC programming or subsidize CPSC investment in research resources and infrastructure. High staff turnover and the departure of many experienced employees have added to the Commission's problems.

"This is an agency in distress," said Senator Mark Pryor (D-Ark.), chairman of the Senate Subcommittee on Consumer Affairs, Insurance & Automotive Safety. "The

budget has been cut, the number of positions has been cut. The testing facilities are antiquated. The CPSC resources and capabilities are not in step with the 21st century, yet this agency's oversight is critical to every family."⁴⁷

In late March 2007, the Senate agreed, passing a fiscal 2008 budget amendment from Pryor that calls for an additional \$10 million annually to maintain current CPSC staff levels, improve antiquated testing facilities and increase Commission agents at major U.S. ports of entry. This additional funding is a 16 percent increase to Bush's proposed CPSC budget for 2008. The amendment now goes to conference between the House and Senate after both chambers pass their 2008 budget resolutions.⁴⁸

- **No real oversight.** The CPSC does not issue safety standards for every product, have pre-market jurisdiction over any products it regulates, inspect manufacturing facilities or police products once they're on the on the market. Instead, the agency relies on pledges from manufacturers that their products meet relevant safety standards. ⁴⁹
- Communication stifled. The agency cannot alert the public to product dangers without prior industry approval. If an industry chooses to withhold crucial health and safety information, the CPSC has no choice but to remain silent as more consumers suffer avoidable injuries. 50
- Ineffective recalls. The CPSC is doing a poor job communicating recall information to consumers. Under the current system, the public must rely on the media to convey news of unsafe products. Requiring manufacturers to provide a product registration card or establish a similar electronic system would make it easier for consumers to send manufacturers their contact information and for manufacturers to directly notify consumers about a product recall. The Commission's proposed 2008 budget does not allocate any funds for the agency to study or improve recall effectiveness.⁵¹
- Weakening the duty to report. On July 13, 2006, the Commission proposed watering down the Substantial Product Hazard reporting guidelines. According to Public Citizen, this proposal would add "additional criteria to the test for determining if a product is both defective and potentially dangerous, and allowed companies new wiggle room in deciding whether to report unsafe products to the CPSC. The new guidelines will likely benefit manufacturers and reduce public notice of safety risks." CFA's Weintraub agreed, telling Congress, "We fear that this guidance may jeopardize the Commission's ability to receive important product safety information that is critical for CPSC's consumer protection function." Si
- **Discontinuing programs and activities.** The Commission has no plans to conduct in-depth studies on playgrounds or ATVs, depriving staff of vital data about the way injuries and deaths occur, which could then be used to help safeguard children from future harm. Similarly, even though drowning is a leading cause of death among children, limited funding has made it impossible for the agency to make reducing child drowning deaths a priority issue.⁵⁴

• Issues of particular concern – furniture tip-overs and lead exposure. Each year an estimated 8,000 to 10,000 people suffer severe injuries from furniture or appliances that tip over. Although these accidents have been serious enough to require emergency room treatment and result in an average of six deaths per year – with children accounting for the majority of such injuries and deaths -- the CPSC has not promulgated any mandatory safety standards for products that tend to tip over. 55

The agency has also not done enough to protect the public from products containing lead. This is especially troublesome in light of the fact that many children's products (*e.g.*, lunchboxes, jewelry, bibs and cribs) have been found to contain dangerous levels of lead.⁵⁶

• Products of particular concern – ATVs, magnet toys and yo-yo water balls. According to the most recent data available, in 2005, an estimated 700 people died in All-Terrain Vehicle (ATV) accidents. Of those 700, at least 120 were children younger than 16. Between 1985 and 2005, children under 16 accounted for 31 percent of all fatalities. At least 18 people died, five of them children, in ATV crashes over Memorial Day weekend 2007 alone.

Regarding injuries, there has been a 24 percent increase in serious ATV-related injuries since 2001. In 2005, nearly 137,000 people went to the emergency room for serious injuries from ATVs. Nearly one-third of the injured were children under 16. The CPSC estimates that 90 percent of those injured under 16 were riding adult-size ATVs. Since 2001, the number of children under 16 seriously hurt by ATVs has increased by 18 percent. Between 1985 and 2005, children younger than 16 accounted for 36 percent of all injuries.⁵⁷

ATVs cost more than lives, they also cost the nation lots and lots of money. As CFA's Weintraub told Congress on May 9, 2007, "Costs associated with ATV deaths of children increased from \$493 million in 1999 to \$723 million in 2003. Costs associated with ATV deaths of adults increased from \$1,706 million in 1999 to \$2,517 million in 2003." ⁵⁸

Despite these statistics, the CPSC has failed to take action to protect the public, especially children. Instead, the Commission, among other things,

Continues to allow the ATV industry to regulate itself, which has led to more dangerous ATVs, more children being killed and injured and dramatic increases in the number of ATV-related deaths and injuries each year. For example, there is no mechanism in place to ensure that children under 16 not operate or ride adult-size ATVs, an omission heavily criticized by the American Academy of Pediatrics. "The academy feels strongly that children aren't developmentally ready until about age 16 to operate a complex machine such as an ATV," said Dr. Gary Smith, chairman of the AAP Committee on Injury, Violence and Poison Prevention. "It has to do with maturity, with judgment, with coordination,

with strength."59

▶ Proposes to re-categorize ATVs from a system based on engine size to a system based on speed without evidence that children can safely operate ATVs at the new suggested speed limits (30 mph for 12-15 year olds; 15 mph for 9-11 year olds; and 10 mph for 6-8 year olds). This new rule would allow children to operate ATVs that have higher maximum speeds than what is currently suggested. ⁶⁰

The CPSC's poor safety record with respect to ATVs also applies to magnet toys. The agency has issued five recalls of toys with strong, small magnets since March 2006. These magnets can link together after being swallowed and siphon off the intestines, creating a life-threatening perforation and/or blockage that can kill or seriously injure children. Despite such dangers, the recalls have been unclear and unacceptably weak.⁶¹

- ▶ For example, a January 18, 2007 recall of Geometix International's MagneBlocks stated that the "CPSC recommends children under 6 years of age not play with toys containing magnets. If a magnet comes out of one of the blocks in these sets, immediately remove the block from the set and send it to Geometix International for a free replacement block." This reactive approach endangers children by saying that action should be taken only after it is visibly clear that the harm may have occurred. Also, it does not give consumers the opportunity to safeguard children from a known danger. 62
- ▶ Similarly, on April 17, 2007, the agency issued a second, expanded recall of Magnetix Magnetic Building Sets after receiving additional reports of serious injuries. The toys had been allowed to stay on the market for more than a year because the first recall was ineffective a "replacement program" involving 3.8 million Magnetix sets that left consumers with no way of knowing whether they were buying a dangerous toy. ⁶³
- ▶ According to a May 2007 investigation by the *Chicago Tribune*, the second recall, affecting 4 million Magnetix sets, has proved equally confusing. The *Tribune* was able to purchase sets that should've been removed from shelves weeks before. In addition, some major retailers immediately halted sales of the toy as a result of the paper's investigation. ⁶⁴
- ▶ To date, there has been at least one death, one aspiration and 27 intestinal injuries after children ingested loose Magnetix magnets. Emergency surgical intervention was needed in all but one case. Moreover, at least 1,500 incidents of magnets separating from the building pieces have been reported. 65

As with ATVs and magnets, the CPSC has allowed yo-yo water balls to continue to endanger children. The toys – long stretchy cords with a ball of the same material – have caused over 400 injuries, nearly three-quarters of which involved suffocation or strangulation. While many countries, as well as the state of Illinois, have banned the sale of these toys, the CPSC has not taken steps to recall or ban them. ⁶⁶

Destroying civil justice remedies for those injured by consumer products

In March 2006, the Consumer Product Safety Commission sought to preempt tort liability in the preamble of its long-awaited mattress-flammability rule. ⁶⁷ CPSC's own data show that from 1999-2002 mattresses or mattress bedding was the first item to ignite in 15,300 residential fires, causing 350 deaths and 1,750 injuries and resulting in property loss of \$295 million. ⁶⁸

According to the Center for Progressive Reform, the CPSC never allowed the public to review, evaluate or comment on the preemption provision and never cited "any instances from its 33-year history in which tort liability interfered with the implementation of its statutory mandate," actions that did not sit well with CPSC Commissioner Thomas Moore.

In opposing the agency's preemption assertion, Moore argued that the release of the preemption language "at the twelfth hour, buried in the tabs of the briefing package on our web site, did not give it the public exposure it deserved." Added Moore, "[I]t makes no sense to risk eliminating sources of new information that might come from private litigation. Just as litigation informs our compliance activities, so should we allow it to inform our regulatory process."

Rachel Weintraub of CFA voiced similar concerns before Congress. "The U.S. Consumer Product Safety Commission's main duty to Congress and the public is to protect the public from unreasonable risks of injury associated with consumer products," Weintraub testified. "Since liability law enhances safety by providing continual incentives to improve product design, the inclusion of a preemption provision in a final rule would violate the CPSC's core mission.⁷¹

B. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)

OSHA is an agency of the U.S. Department of Labor. It was created by Congress under the Occupational Safety and Health Act of 1970 (OSH Act). OSHA's stated mission is "to assure the safety and health of America's workers by setting and enforcing standards; providing training, outreach, and education; establishing partnerships; and encouraging continual improvement in workplace safety and health." It has the authority to issue standards and rules, conduct workplace inspections and investigations, impose penalties and respond to worker complaints.

Almost every worker and employer in the United States comes under OSHA's jurisdiction. Private-sector workers are covered by an OSHA regional office under federal OSHA or an OSHA program run by their state government. Public-sector workers are only covered in states that operate their own OSHA programs. Federal OSHA approves and monitors state plans and may subsidize up to 50 percent of an approved plan's operating costs. State OSHA programs must meet but can exceed the federal program's worker protection standards.

OSHA has a long way to go to achieve its safety objectives. On average, 16 workers were killed and more than 12,000 were injured or made ill each day of 2005, according to the most recent government statistics available. These numbers do not include worker deaths from illnesses caused by occupational exposures, which cost an estimated 50,000 to 60,000 lives every year, nor do they accurately reflect the extent of workplace injuries and illnesses in the United States. United States.

The financial cost of workplace injuries and death is just as alarming. For example, a March 2007 report by Liberty Mutual, the nation's largest workers' compensation insurer, found that: occupational injuries cost U.S. employers \$48.6 billion in direct costs alone (*i.e.*, medical and lost wage payments); and businesses pay between \$145.8 billion and \$291.6 billion in direct and indirect (*i.e.*, overtime, training and lost productivity) workers' compensation losses each year. A subsequent analysis by the AFL-CIO revealed that Liberty Mutual significantly underestimated these costs. 2

- **Insufficient number of inspectors.** There are not enough OSHA inspectors to enforce worker-protection laws in the United States. This was the finding of *Death on the Job: The Toll of Neglect*, an annual report released by the AFL-CIO in April 2007. Among the study's more troubling data:
 - ▶ In fiscal year (FY) 2006, there were at most 2,112 federal and state OSHA inspectors responsible for enforcing the law at approximately eight million workplaces.
 - ▶ In 1975, federal OSHA had 2,405 staff (inspectors and all other OSHA staff) protecting the health and safety of 67.8 million workers at 3.9 million workplaces. In 2005, a smaller federal OSHA staff (2,208 people) was responsible for nearly double the number of workers (131.5 million) and workplaces (8.5 million).
 - ▶ In FY 2006, the 818 federal OSHA inspectors conducted 38,589 inspections and the 1,294 inspectors in state OSHA agencies combined conducted 58,367 inspections.
 - ▶ Today, it would take federal OSHA 133 years to inspect each workplace under its jurisdiction just once. In 1992, federal OSHA could inspect workplaces once every 84 years.

- ▶ In seven states (Florida, Delaware, Mississippi, Louisiana, Georgia, Maryland, and South Dakota), it would take more than 150 years for OSHA to pay a single visit to each workplace. In 18 states, it would take between 100 and 149 years to visit each workplace once.
- ▶ The current level of federal and state OSHA inspectors provides one inspector for every 63,670 workers.
- ▶ In nine states (Arkansas, Florida, Delaware, Nebraska, Georgia, Illinois, Louisiana, Mississippi and Texas), the ratio of inspectors to employees is greater than 1/100,000 workers.
- ▶ There were 300,000 fewer employees covered by federal OSHA inspections in FY 2006 than in FY 2005.
- ▶ Between FY 1999 and FY 2006, the number of employees covered by federal OSHA inspections decreased by 34 percent.
- ▶ The number of hours spent per inspection decreased between FY 1999 and FY 2006, from 22 hours to 18.8 hours per safety inspection and from 40 hours to 34.4 hours per health inspection.
- **Penalties too low, too infrequent.** The dollar amounts and number of federal and state OSHA penalties are trivial, giving employers no incentive to comply with health and safety rules. According to an analysis of government statistics by the AFL-CIO⁸⁴:
 - ▶ In FY 2005 and 2006, the average penalty per serious violation of the OSH Act totaled \$881 (\$873 for federal OSHA, \$890 for state OSHA plans). A violation is considered "serious" if it poses a substantial probability of death or serious physical harm to workers.
 - ▶ Federal OSHA issued 446 willful violations in FY 2006. The average penalty for a willful violation dropped substantially from \$43,294 in FY 2005 to \$32,158 in FY 2006.
 - ▶ In FY 2006, state-run OSHAs issued 153 willful violations, with an average penalty of \$23,519, and 2,482 repeat violations, with an average penalty of \$1,916 per violation.
 - ▶ There were 467 inspections involving persistent violators in FY 2006, a 21 percent decrease from the previous year. Persistent violators don't face enhanced penalties; they are usually subjected to increased oversight by OSHA or consultants.

- ▶ In FY 2006, the Department of Labor referred 11 persistent violator cases to the Justice Department for criminal prosecution. Employers may face criminal prosecution if a willful violation causes a worker's death.
- ▶ Though many workers die on the job or from occupational diseases because of employers' reckless disregard for worker safety, prosecutions are extremely rare.
- Voluntary compliance over standards and enforcement. At the behest of the Bush administration, OSHA has pursued a "voluntary compliance strategy," reaching agreements with businesses and industry associations to police themselves. Such voluntary programs often fail to address specific workplace hazards or have any enforcement power. As Peg Seminario, Director of Occupational Safety and Health at the AFL-CIO, told a Senate subcommittee on April 26, 2007: "With this approach, OSHA has abandoned its leadership role in safety and health, choosing to work with individual employers, rather than taking bold action to bring about broad and meaningful change in working conditions on an industry-wide and national level. Se

Moreover, only companies with strong safety records can participate in voluntary programs, leaving businesses with less than stellar records without an incentive to make their workplaces safer and healthier. "OSHA has been focusing on the best companies in their voluntary protection program while doing nothing in the area of standard setting," Seminario explained to the *New York Times*. "They've simply gotten out of the standard-setting business in favor of industry partnerships that have no teeth."⁸⁷

• **Regulatory inaction.** Rulemaking at OSHA has ground to a halt. Under Bush, OSHA has eliminated dozens of existing regulations, repeatedly delayed the adoption of others and pulled countless safety and health rules from its regulatory agenda. OSHA has also issued the fewest significant health and safety regulations in the agency's history. For example, it took OSHA five years to issue its first major rule – a standard on hexavalent chromium, a cancer-causing chemical – and that was done under court order. 88

As Dr. David Michaels, an occupational health expert at George Washington University, recently told the *New York Times*, "The people at OSHA have no interest in running a regulatory agency.... If they ever knew how to issue regulations, they've forgotten. The concern about protecting workers has gone out the window." 89

• Reliance on incomplete injury and illness data. OSHA has ignored evidence that the annual number of workplace injuries and illnesses is much higher than what's reported by employers. Instead, agency officials continue to rely on employer reports of workplace injuries as evidence that agency policies are effective. This has serious consequences for worker health and safety.

As the AFL-CIO recently put it, "Reliable data is needed to have an accurate picture

of the true nature and toll of workplace injuries and illnesses, to develop policies and initiatives to address identified problems and to assess the effectiveness of efforts to reduce this toll and address safety and health hazards."⁹¹

- **Budget problems.** Since FY 2001, OSHA's budget has been cut by \$25 million. The President's proposed 2008 budget for OSHA is \$490 million. Of that amount, 27 percent (\$134.1 million) is allocated to compliance assistance programs for employers. Since taking office, the Bush administration has increased the budget for such programs by nearly \$29 million. In contrast, every year the White House has tried to decrease or eliminate funding for OSHA worker safety and health training and education programs. As in FY 2006 and FY 2007, the Administration has not designated any funding for these programs in FY 2008.
- **Staffing problems.** Since 2001, OSHA has eliminated almost 200 full-time positions. The number of federal OSHA enforcement staff has been reduced by 8 percent, while staff levels for the development of safety and health standards have decreased by 17 percent. 94
- Health and safety issues of particular concern:
 - ▶ **Hispanic and immigrant workers** suffer more deaths and injuries than any other group of workers in the United States. For example, between 1992 and 2005, the overall number of workplace fatalities decreased while the number of fatalities among Hispanic and immigrant workers increased by 73 percent and 63 percent, respectively. OSHA has inadequate staff and funding to protect these more vulnerable segments of the workforce. ⁹⁵
 - ▶ Ergonomic injuries. It's been more than six years since Bush repealed the ergonomics standard OSHA created during the Clinton administration, and OSHA still hasn't taken concerted action to address ergonomic injuries. Such injuries are caused by repetitive job-related motions and lifting and account for one-third of workplace injuries and illnesses, making it the biggest health and safety problem American workers face. Since 2001, OSHA has issued only three final ergonomics guidelines and 17 general duty citations for ergonomics hazards. 96
 - ▶ Pandemic flu. OSHA has refused to issue a pandemic flu standard to protect millions of health care workers, firefighters, emergency medical services personnel and other responders who will be needed to care for the sick if a flu virus spreads through the entire population. Instead, OSHA has announced new pandemic flu guidelines, non-binding recommendations that leave employers with no obligation to develop and establish comprehensive infection control plans and measures before pandemic flu hits.⁹⁷

▶ Chemical exposure. Though job-related exposure to toxic substances endangers millions of workers, OSHA has not established chemical exposure limits and standards that protect workers from serious chemical hazards ⁹⁸

C. NATIONAL HIGHWAY TRANSPORTATION AND SAFETY ADMINISTRATION (NHTSA)

NHTSA is part of the U.S. Department of Transportation. It was established by Congress under the Highway Safety Act of 1970. NHTSA's stated mission is to "[s]ave lives, prevent injuries, reduce vehicle-related crashes." The agency has the power to establish and enforce mandatory safety standards, conduct investigations, issue penalties and recall defective vehicles.

Government statistics show NHTSA is not doing enough to protect the public. According to agency estimates, 43,300 people were killed on our nation's highways in 2006. That same year, there were more than 1.7 million injuries in motor vehicle crashes. Such crashes continue to be a leading cause of death in the U.S. and are the number one killer of children. During 2005, 1,451 children ages 14 years and younger died as occupants in motor vehicle crashes and approximately 203,000 were injured. As the Centers for Disease Control put it, "That's an average of 4 deaths and 556 injuries each day."

These crash-related deaths and injuries cost more than lives – highway crashes cost society an estimated \$230.6 billion a year, about \$820 per person. 105

Moreover, hundreds of children are killed or injured in non-traffic, non-crash-related incidents each year, with over 9,100 children being treated in emergency rooms. As of June 22, 2007, at least 101 children had died from non-traffic, non-crash-related incidents, which include being backed over by vehicles, inadvertently left in hot vehicles, strangled by power windows and setting cars in motion when left unattended in a vehicle. In 2006, at least 219 children were killed. These fatality statistics come from the Kids and Cars national database; NHTSA does not collect such information.

• Inadequate operations and research budget. For FY 2008, NHTSA is asking for a safety operations and research budget of \$230 million, only a \$3 million increase from the previous year's amount. In 2006, Public Citizen's Auto Safety Group warned that NHTSA needed triple the \$227 million allocated for its FY 2007 safety operations and research budget to do its job effectively. The agency is "really starving for funds particularly for its Fatality Analysis Reporting System (FARS), National Accident Sampling System (NASS) and other research," explained the Auto Safety Group. "NHTSA collects information of vehicle-related crashes, injuries, and fatalities. This information is essential for the agency to understand vehicle and highway safety and areas where remedial actions are necessary."

- Non-existent SAFETEA-LU standards. NHTSA has yet to issue vehicle safety standards mandated by the Safe, Accountable, Flexible and Efficient Transportation Equity Act A Legacy for Users (SAFETEA-LU), enacted by Congress in August 2005. SAFETEA-LU requires NHTSA to 112
 - ▶ Issue a stronger roof crush rule that helps prevent deaths and spinal cord injuries to vehicle occupants on both the driver and passenger side in a rollover crash. Rollover crashes cause one-third of all crash fatalities, over 10,000 deaths annually.
 - ▶ Issue a final rule to protect vehicle occupants from being completely or partially thrown from their vehicles during crashes.
 - ▶ Issue a rollover prevention standard for all vehicles to help prevent rollover crashes.
 - ▶ Issue roof crush, rollover prevention and ejection prevention standards for vehicles up to 10,000 pounds, which covers 15-passenger vans. Such vans have a "high rollover propensity," "weak roofs that crush in during rollover crashes, often leading to occupant death or paraplegia" and are often used to transport young people and the elderly." ¹¹³
 - ▶ Issue a side-impact protection rule that could significantly reduce the risk of occupant death in crashes by an estimated 1,000 lives every year. 114
 - ▶ Issue a stronger safety belt rule to ensure that vehicle occupants are properly protected from partial ejections in rollover crashes.

On June 15, 2007, 17 Democratic and Republican House sent a letter to NHTSA's chief, urging the agency to promulgate "strong and effective" vehicle safety standards authorized by SAFETEA-LU. The Members signing the letter explained that NHTSA should address the safety rules in a "comprehensive fashion" rather than as "stand-alone" and urged the agency to "base these rules on the best safety technologies available in order to maximize the number of lives saved and injuries prevented." 116

"A thoughtful and proper implementation of these life-saving safety standards is crucial to the health and safety of our nation's children, teens, and families," said California Representative Mary Bono (R-CA), who signed the bi-partisan letter. "I am hopeful that the NHTSA will recognize the importance of these long overdue standards which will allow for increased protections for America's drivers." 117

• Children in danger. NHTSA has failed to take the steps necessary to protect children from future vehicle-related deaths and injuries. Appearing before a Senate subcommittee in February 2007, Joan Claybrook, Public Citizen president and former

NHTSA Administrator, identified numerous areas where NHTSA needs to take action. ¹¹⁸ Among her concerns:

- ▶ NHTSA's failure to make information related to children -- such as the number of children killed in rear-impact crashes or potential defects in child safety seats readily available to the public;
- ▶ Significant gaps in NHTSA's existing and developing vehicle safety standards, which fail to adequate address the particular needs of children. Standards involving side-impact crash protection, rollover crashes and seat backs are especially problematic.
- ▶ The agency's failure to issue comprehensive standards for child restraints and adequately focus its safety and consumer information programs on child restraints.
- NHTSA's unwillingness to help states develop laws for school buses. "With states left to themselves to develop these regulations on a state by state basis," explained Claybrook, "the country will be left with an inconsistent hodgepodge of school bus restraint systems, which would hinder and confuse school bus safety developments."
- **Tire data kept secret.** NHTSA has refused to give the public access to data about deaths and injuries related to tire failures involving the Ford Explorer. Despite earlier recalls, such tire failures have continued, with the death toll in Ford Explorer, tire-related crashes rising in 2005 at the rate of about one death per week. 119

NHTSA's actions are in violation of the TREAD Act, which Congress passed in October 2000 in response to Ford Explorer-Firestone tire rollover deaths. When President Clinton signed the bill into law, he directed NHTSA "to implement the information disclosure requirements of the [TREAD] Act in a manner that assures maximum public availability of information." ¹²⁰

"It is truly outrageous that the Bush administration would move to seal such essential auto safety information from the public," said Joan Claybrook, president of Public Citizen and former NHTSA Administrator. "Public access to this type of data could mean the detection of problems like the deadly Ford Explorer/Firestone tire combination and could save lives." 121

A vehicle-safety research firm recently filed a Freedom of Information Act lawsuit against NHTSA over its refusal to release the Ford Explorer data. 122

• Other safety areas of concern. According to Public Citizen's Auto Safety Group, Americans' would be better protected on the nation's highways if NHTSA¹²³:

- ▶ Issued a compatibility standard to ensure that vehicles are compatible in crashes in order to minimize crash related injuries and decrease crash fatalities;
- ▶ Issued an improved seat structure rule to ensure that all vehicle occupants are adequately protected.
- Reissued a conspicuity standard so drivers can fully view the environment in which they operate their vehicles.
- ▶ Issued a strong rule on Tire Pressure Monitoring Systems (TPMS) that warns consumers when their tires are not properly inflated.
- ▶ Issued a rule to address the dangers posed to vehicle occupants by "new" tires that may have been languishing unsold in warehouses for years, degrading significantly in quality.
- ▶ Issued a rear seat belt reminder rule, requiring automakers to include such reminders in all new vehicles.

Destroying motorists' civil justice remedies

On August 19, 2005, the National Highway Transportation Safety Administration (NHTSA) proposed a new rule for vehicle roof strength to be adopted in 2006. ¹²⁴ Included in the "roof-crush" rule's preamble is a provision that bars injured consumers from suing automakers in state court if their vehicles' roofs meet minimum federal safety standards.

As a result, if courts agree, accident victims hurt in a rollover or similar crash would not be able to file product liability suits against manufacturers as long as they meet NHTSA's standards, regardless of how weak or obsolete such standards may be. The bar against lawsuits applies even if a car company knows of safety problems with its products and refuses to take actions to them reasonably safe.

To put this in perspective, rollover accidents cause 24,000 injuries and kill 10,000 people annually, accounting for one-third of all people killed in auto crashes. When promulgating the "roof-crush" rule, NHTSA estimated that the new regulation would save only 13 to 44 lives a year. Moreover, most automakers already meet the proposed standard.

Although NHTSA recently announced that it's still working on a final roof strength rule, there is no indication that the agency plans to remove the lawsuit preemption language. 127

In late December 2005, 26 state attorneys general urged the government to drop the lawsuit preemption provision, arguing that it would infringe on states' rights and shift injured motorists' medical costs to states. "State governments and the federal

government will have to cover millions of dollars in health care costs which they will pass along to taxpayers, costs that, by all rights, should be the responsibility of manufacturers," the attorneys general wrote. 128

That same month, the National Conference of State Legislatures weighed in on the issue, sending a letter to NHTSA that it opposed the proposal "in the strongest terms possible," citing worries about the litigation provision.¹²⁹

The policy prompted similar concerns in Congress. Senators Arlen Specter (R-PA), chairman of the Senate Judiciary Committee, and Patrick Leahy (D-VT), the ranking Democrat, questioned NHTSA about the preemption language. "We are interested to learn how NHTSA concluded that preemption of state law was the intent of Congress," the senators wrote in a letter dated November 17, 2005. 130

Public interest advocates also opposed this rule, stating that the new standards were weak and, when coupled with preemption, allowed manufacturers to place dangerous vehicles on the market with no accountability.

"This is a new doctrine, coming straight from the secretary of transportation and the White House," said Clarence Ditlow, executive director of the Center for Auto Safety. "I can't tell you how bad this is for consumers." According to Ditlow, "The primary purpose of this rule is to set a weak standard and to allow manufacturers to use it as a preemptive shield against product liability lawsuits." 132

The Rollover Safety Coalition, whose members include USAction, Public Citizen and CJ&D, echoed these sentiments in a November 2005 letter to Congress. "On the basis of vaguely formulated suppositions, NHTSA's August 2005 assertion of preemption would, by agency fiat, preempt civil justice laws in all 50 states. This would constitute an unprecedented incursion upon the states, upon Congress, and upon the constitutional rights of ordinary citizens, who will remain uncompensated for the needless deaths and injuries that occur due to the foreseeable negligence of manufacturers." ¹³³

D. FOOD AND DRUG ADMINISTRATION (FDA)

The FDA is an agency within the U.S. Department of Health and Human Services. Among other things, the FDA is responsible for ensuring the safety and efficacy of new prescription drugs; helping speed innovations that make medicines more effective, safer and more affordable; and making sure the public gets the information they need to use medicines effectively. 134

The FDA is not fulfilling this mission. Every year there are over 2 million serious adverse drug reactions (ADRs). Of this total, an estimated 100,000 people die from ADRs, making it one of the leading causes of death in the United States. 136

Americans agree that the FDA should do more to ensure the safety and efficacy of new prescription drugs. In a March 2007 Consumers Union poll, ¹³⁷ more than 60 percent agreed that the Food and Drug Administration and Congress have failed to adequately protect consumers from harmful prescription drugs.

- 84 percent agreed that drug companies have too much influence over the government officials who regulate them.
- More than two-thirds (67 percent) were concerned that much of the FDA's funding comes from the pharmaceutical industry, with more than half 54 percent "very concerned" about that funding situation.
- Six in 10 disapproved of allowing doctors and scientists with a conflicting financial interest to participate on advisory boards.
- 40 percent said they had experienced an adverse reaction to a medication.

A May 2007 Harris poll conducted for *The Wall Street Journal* reported a similar lack of confidence in the FDA's ability to protect Americans. Among the responses: 49 percent thought the FDA is doing a fair or poor job when it comes to ensuring the safety and efficacy of new prescription drugs; 57 percent agreed that the agency's reliance on drug industry funding could lead to less rigorous scrutiny when reviewing new prescription drugs.

• User fees. The FDA is too close to the industry it is supposed to regulate. The agency lost much of its independence in 1992 when Congress passed the Prescription Drug User Fee Act (PDUFA), which lays out the drug oversight and review process. The PDUFA, among other things, allows drug manufacturers to pay the FDA "user fees" to review their products.

These "user fees," paid to speed up the FDA's drug review process, constitute a huge portion of the agency's budget for regulating drugs, making the FDA financially beholden to the pharmaceutical industry. As a result, drug companies and their lobbyists have had a great deal of influence over FDA decision-making and policy. Last year, the agency collected over \$300 million in "user fees." ¹³⁹ To put this in perspective, "user fees" accounted for more than one-third of the entire budget for the Center for Drug Evaluation and Research, the FDA office that oversees drugs. ¹⁴⁰

On March 16, 2007, the FDA sent Congress its recommendations for a five-year reauthorization of the PDUFA, which is set to expire in September 2007 unless Congress reauthorizes it. ¹⁴¹ In describing its proposal, PDUFA IV, the FDA said: "These proposed recommendations were developed after discussions with regulated industry and consultation with appropriate scientific and academic experts, healthcare professionals, and representatives of patient and consumer advocacy groups." ¹⁴² It turns out the process was far from collaborative.

Data released by the House Appropriations Committee show that between October 2005 and December 2006:

- ▶ FDA officials held 112 meetings lasting 224 hours, or 28 business days, with pharmaceutical industry representatives to negotiate PDUFA IV before it was submitted to Congress. Agency officials met only five times with consumer and patient groups over the same 15-month period.
- ▶ Forty-nine drug industry representatives met with the FDA, combining for 2,116 hours, or 264.5 business days. Six of those 49 representatives attended at least 40 percent of the meetings.
- ▶ Seventy-two FDA staff members participated in the 112 meetings with industry, accruing a combined 1,852.5 hours of meeting time, or 231.5 business days.
- ▶ From the summaries provided of the FDA-industry meeting topics, it appears only a few meetings addressed the concerns of patients, consumers and the general public. 143

"The FDA has essentially become the government affairs office of the pharmaceutical industry," said Congressman Maurice Hinchey (D-NY), who spearheaded efforts to uncover information about how PDUFA IV was created. "The data surrounding the FDA's meetings on PDUFA IV make it clearer than ever that the agency and drug industry continue to have a relationship that is far too cozy and inappropriate. By treating the drug industry like a privileged client that deserves preferential treatment rather than a regulated industry, the FDA is jeopardizing the health and safety of the American public." ¹⁴⁴

On May 9, 2007, the Senate voted to reauthorize the PDUFA, which has the drug industry paying \$393 million in annual "user fees." The House is now considering a similar "user fees" measure, but unlike the Senate version, it allows consumer and patient advocates to participate in negotiations between the drug industry and the FDA on the next "user fee" proposal, scheduled for 2012. 146

Reauthorizing the PDUFA puts Americans at risk. "User fees may appear to save the taxpayers money, but at an unacceptable cost to public health," a group of 22 drug regulatory experts, including six former senior FDA staff and four authors of the Institute of Medicine's drug safety review, warned in a recent open letter to Congress. "Unlike other user fee programs in the federal government, PDUFA requires the FDA to negotiate with representatives of the users, in this case the Pharmaceutical Research and Manufacturers of America (PhRMA), about how the agency may allocate its resources," the group explained. "The negotiated arrangement finances the drug approval process but neglects the equally important task of risk management once these drugs are on the market. This negotiated arrangement, which has explicitly limited its ability to conduct post-marketing drug

safety surveillance and other critical activities, clearly diminishes the capacity of FDA to do its work on behalf of the nation."

• **Biased drug advisory panels.** FDA committees that recommend drugs for market often include several members with financial ties to the company whose drug is up for approval, creating clear conflicts of interest that jeopardize public health and safety. A recent case in point: the FDA advisory committee which recommended that Merck's Vioxx and Pfizer's Celebrex and Bextra be kept on the market, despite evidence that they all carried serious risks of heart attack and stroke. According to the February 25, 2005 *New York Times*, ten of the 32 panel members had consulted in recent years for Merck, Pfizer or Novartis, which was applying to sell a very similar pill discussed by the panel. ¹⁴⁸

As the *Times* reported, "If the 10 advisers had not cast their votes, the committee would have voted 12 to 8 that Bextra should be withdrawn and 14 to 8 that Vioxx should not return to the market. The 10 advisers with company ties voted 9 to 1 to keep Bextra on the market and 9 to 1 for Vioxx's return.... Of the 30 votes cast by the 10 panel members on whether Celebrex, Bextra and Vioxx should continue to be marketed, 28 favored the drugs. Among the 66 votes cast by the remaining 22 members of the panel, just 37 favored the drugs." 149

An April 2006 study conducted by Public Citizen and published in the Journal of the American Medical Association uncovered similar conflicts of interest. The report examined self-reported conflicts disclosed by outside advisory committee members and FDA-invited voting consultants from 2001 to 2004. Among the study's more troublesome findings:

- ▶ 28 percent of advisory committee members and voting consultants had a conflict, and at least one member or consultant had a conflict in 73 percent of the meetings. Despite this, only one percent of members were recused from attending the meeting.
- ▶ For advisory committee members and voting consultants present, 19 percent of consulting arrangements involved more than \$10,000, 30 percent of investments were worth more than \$25,000 and 23 percent of contracts or grants exceeded \$100,000.

"Conflicts of these magnitudes should result in automatic recusal from advisory committee meetings," said Dr. Peter Lurie, deputy director of Public Citizen's Health Research Group. "With as many highly qualified professionals as we have in this country, there should be little difficulty identifying members with more limited or, ideally, no conflicts of interest." ¹⁵¹

Congress is currently considering legislation that limits the FDA's ability to waive conflict of interest laws ¹⁵²

- Lack of leadership. The FDA has been without a permanent commissioner for nearly 70 percent of George W. Bush's presidency. ¹⁵³ As the Institute of Medicine recently pointed out, "Instability in the Office of the Commissioner has been a serious problem for FDA and CDER in particular. A large, complex, science-based regulatory agency cannot perform optimally in the absence of stable, capable leadership, and clear, consistent direction." ¹⁵⁴
- **Culture of secrecy.** Time and again, the FDA has failed to inform the public about the agency's drug review process, post-market safety concerns or a drug's effectiveness, making it difficult for Americans to make informed choices with their health care providers. ¹⁵⁵

Even more disturbing, however, is the fact that in recent years many FDA drug-safety officers have been punished or ignored after uncovering drug dangers. As reported in the June 11, 2007 *New York Times*, this happened to safety researchers reviewing the diabetes drug Avandia and a similar drug Actos, both of which were shown to cause heart failure; antidepressants that led some children to become suicidal; and the antibiotic Ketek which caused serious illness and death in certain patients. An FDA drug-safety official who discovered that Vioxx had a dangerous effect on the heart suffered the same fate, with FDA superiors delaying publication of a study that connected the painkiller to heart problems and even pressuring him to change the report's conclusions. 157

• **Weak oversight.** The FDA has no systematic way to monitor the safety of drugs once they've been approved. There are no regular public assessments or disclosures of post-market safety reviews, no clear timelines that force the FDA to act quickly on reports of drug problems and no requirements that the agency submit regular reports on its adherence to these goals. To put the FDA's priorities in perspective, for every seven employees who work on drug approval, only one works on post-market safety. As the *New York Times* found, "Questions about the safety of already-marketed drugs are increasingly seen as sand in the gears..." 160

Instead, today's FDA is more concerned with how quickly a drug is approved than whether it will kill or injure patients. It often takes voluntary reports of injuries or deaths from doctors and patients for the FDA to undertake post-market study of a drug. Moreover, the agency does not have the money and infrastructure to run or commission its own drug trials. And although there is an FDA office charged with post-market surveillance, it lacks the funding, independence and authority to do its job effectively.

Legislation pending in Congress gives the FDA more power to track post-approval safety, requires an advisory committee to meet twice a year to consider safety issues and compels the drug industry to provide funds for drug-safety monitoring programs.¹⁶¹

• **Virtually powerless after drugs approved.** The FDA cannot, with few exceptions, force a manufacturer to conduct safety studies once a drug is on the market. It also lacks the power to fine companies that fail to carry out promised post-approval safety studies, which allows drug companies to renege on such pledges without consequence. The result: "[M]ost post-market studies promised by drug companies have never been started, and, of those which have, nearly three-quarters remain incomplete," according the June 25, 2007 *New Yorker*. 163

In addition, the FDA has little control over how drugs are distributed and marketed to doctors and consumers, nor can it fine drug makers for false or misleading drug advertisements. The pharmaceutical industry also has a say in all drug label changes, which can take far too long, as was the case with Vioxx, where negotiations over language alerting physicians about the drug's heart risks lasted over a year. And as for taking drugs off the market, the FDA can only suspend drug sales under extraordinary circumstances and is slow to remove approved drugs from the shelves once evidence shows them to be unsafe.

"FDA was our country's first consumer protection agency and Americans have relied on FDA to ensure the safety of their food and drugs for 100 years," said Representative Henry A. Waxman (D-CA). "Under the Bush Administration, FDA has undermined enforcement and betrayed its consumer-first legacy. FDA must start enforcing the law and return to a culture that places public health concerns ahead of industry profits." ¹⁶⁵

Congress, equally concerned about the FDA's inability to protect public health and safety, is expected to pass legislation this summer that will, among other things, give the FDA greater authority to order label changes, require drug makers to conduct additional studies and levy substantial fines for non-compliance. ¹⁶⁶

Destroying civil justice remedies for those injured by drugs and medical devices

In 2006, the FDA included a new policy in the preamble of its long-awaited drug-labeling rule that prevents injured consumers from bringing state product liability suits against drug makers whose medication labels have been approved by the FDA. ¹⁶⁷

The FDA's justification? That it knows best when it comes to regulating drugs and therefore courts (specifically juries) should not be allowed to second-guess the agency by hearing injured consumers' tort claims. The FDA has made similar arguments in "friends of the court" or amicus briefs filed on behalf on drug companies being sued by patients, interventions that are a marked departure from what the agency has done in previous administrations. ¹⁶⁸

This is particularly troubling in light of numerous recent examples where the FDA either didn't know or chose not to investigate issues of safety with prescription drugs. Such was the case with its handling of selective serotonin reuptake inhibitors (SSRIs) like

Paxil and Zoloft, dietary herbs like ephedra and, more recently, the diabetes drug Avandia and the painkiller Vioxx.

While some judges have not adopted the "federal agencies know best" argument put forth in FDA and other agency briefs, other courts are deferring to this position. 169

State officials were outraged by the FDA's new preemption policy, which was only included in the preamble of the final drug-labeling rule, depriving most of the public, including state officials, of any chance to weigh in before the rule was finalized. ¹⁷⁰ In a January 13, 2006 letter to Health and Human Services Secretary Michael Leavitt, the National Conference of State Legislatures called the proposal a "thinly-veiled attempt on the part of the FDA to confer upon itself authority it does not have by statute" and an "abuse of agency process," adding that "[i]t is unacceptable that FDA would not permit the states to be heard on language that has a direct impact on state civil justice systems nationwide."

E. ENVIRONMENTAL PROTECTION AGENCY (EPA)

The EPA has been in existence since 1970. Part of its mission is to protect human health by working for a cleaner, healthier environment for all Americans. The agency has the power to develop and enforce regulations; set and enforce national standards under a variety of environmental laws in consultation with state, tribal, and local governments; and delegate the responsibility for issuing permits, monitoring and enforcing compliance to the states and Native American tribes. EPA enforcement powers include fines and sanctions. ¹⁷²

Under Bush, the EPA has aggressively pursued an anti-environmental agenda that exposes the public to greater risk of death and injury from environmental hazards. *Rewriting The Rules*, a 2005 report by the National Resources Defense Council (NRDC), bears this out. According to the study, the administration's "thorough and destructive campaign against America's environmental safeguards" in its first term led to more toxic releases, fewer hazardous waste cleanups, more mercury contamination warnings, less environmental enforcement, dirtier air and less refinery oversight, among other dangers, plus radical policy changes to core environmental laws. ¹⁷³

It turns out that Vice President Cheney is primarily responsible for the EPA's dangerous environmental policies. A June 2007 investigative series by the *Washington Post* reveals that Cheney, driven by "unwavering ideological positions," has taken on "a decisive role to undercut long-standing environmental regulations for the benefit of business." ¹⁷⁴

The EPA's blatant disregard for citizens' health and safety in the aftermath of the World Trade Center attacks also shows that this administration cares little for the public welfare. For example, within days of the 9/11 attacks then-EPA chief Christine Todd Whitman repeatedly told the public that the air in Lower Manhattan was "safe to breathe,"

statements that the EPA's Inspector General later found to be falsely reassuring, without a scientific basis and politically motivated. ¹⁷⁵

In a June 25, 2007 hearing, Representative Jerrold Nadler (D-NY), chair of the House Judiciary Subcommittee on the Constitution, Civil Rights and Civil Liberties, condemned the EPA's World Trade Center response¹⁷⁶:

These EPA statements, and a series of subsequent EPA misdeeds, lulled Americans affected by 9/11 into a dangerously false sense of safety, and gave other government decision-makers, businesses and employers the cover to take extremely perilous short cuts which did further harm.

. . .

Six years later, we are just beginning to see the enormous consequences of these actions. Our government has knowingly exposed thousands of American citizens unnecessarily to deadly hazardous materials. And because it has never admitted the truth, Americans remain at grave risk to this day. Thousands of first-responders, residents, area workers and students are sick, and some are dead, and that toll will continue to grow until we get the truth and take appropriate action.

Those false statements continue to the present. Ms. Whitman herself has rationalized the White House's soft peddling of risk in EPA statements, proclaiming to Newsweek in 2003 that she did not object to the White House changing her press releases and that, "the public wasn't harmed by the White House's decision to adopt the more reassuring analysis." Even now, they try to rewrite history, arguing, for example, that their reassuring statements were "only talking about air on the 'pile,' not in the surrounding neighborhoods" or that they were "only talking about outdoor, not indoor air" or that they had "always told residents to get their homes professionally cleaned." The IG reached a different conclusion, and the statements speak for themselves. Governor Whitman has even gone so far as to blame the victims themselves for their illnesses.

The EPA's indifference to public health and safety risks after Hurricane Katrina is equally disturbing. According to a recent GAO report, the EPA potentially exposed countless residents, workers and volunteers to asbestos fibers by failing to effectively monitor the contaminant during Hurricane Katrina cleanup efforts.¹⁷⁷

"EPA abdicated a legal and moral responsibility they had to protect returning residents from toxic contamination that was exacerbated by the flood," said Albert Huang, an

attorney with the Natural Resources Defense Council. "People have the right to return to an environment that is safe." ¹⁷⁸

"It's deja vu all over again," explained Hugh Kaufman, a senior policy analyst at EPA and longtime whistleblower within the agency. "Unfortunately, nobody has told the people of the risks, just like with 9/11 and the World Trade Center." 179

• **Inadequate budget.** The Bush administration's proposed FY 2008 budget for the EPA – which cuts the agency's budget by more than \$400 million from the 2006 enacted levels undermines critical EPA programs that safeguard Americans from future harm ¹⁸⁰

"Budgets are about priorities," explained Senator Barbara Boxer (D-CA), chair of the Committee on Environment and Public Works, during a Senate hearing on the EPA's FY 2008 budget. "By chopping hundreds of millions of dollars out of EPA's funding, this budget sends an unmistakable message to people who are concerned about our health and a clean environment: You are not a high priority." Among the areas impacted:

- ▶ The Clean Water Revolving Loan Fund, which provides grants to states to help cities and towns build water treatment plants and protect water quality. The President's budget would slash the fund by \$400 million, leaving the program nearly 37 percent below 2006 enacted funding levels.
- ▶ State and local programs that help keep air clean in cities and states. Under Bush's proposal, these programs would be cut by nearly \$35 million.
- ▶ Superfund sites, the nation's most heavily contaminated toxic waste sites in communities across the country. According to the Senate Committee on Environment and Public Works, "This year, the Bush Administration reduced their expected number of final cleanups from 40 to 24, a more than 70 percent decline from the pace of cleanups an average of 82 per year in the last six years of the prior administration." Efforts to remediate Superfund sites would be slowed down even further if \$7 million were stripped from the program's budget.
- ▶ The EPA's environmental justice program, which helps communities most at risk from pollution. The President's proposed budget cut of more than \$1.7 million will hamper the agency's efforts in this area.
- Army Corps of Engineers' construction programs, which include critical flood protection projects that save lives and property. If Bush's FY 2008 budget passes, this program would be slashed by roughly 35 percent, a cut of approximately \$800 million. 182

On June 27, 2007, the House stepped in, passing an amendment that increases the EPA's FY 2008 budget to \$8.1 billion, a \$361 million increase over current spending. It is also \$887 million more than President Bush's budget request, which may trigger a veto threat. 183

• **Job cuts at EPA's watchdog.** Since June 2006, Bill Roderick, acting Inspector General (IG) of the EPA, has undertaken efforts to lay off 60 of his 360 employees through buyouts or resignations. His rationale: Bush's proposed (*i.e.*, not-yet-approved by Congress) \$5.1 million cut in the IG Office's FY 2008 budget. Roderick's plan mostly affects auditors, criminal investigators and senior program analysts, who work to ensure that the EPA is enforcing the country's anti-pollution rules.

This premature buyout scheme does not sit well with Congress, especially since the EPA gave Roderick a \$15,000 bonus just before EPA chief Stephen Johnson approved Roderick's buyout/layoff plan. In an April 23, 2007 letter to Johnson, Representative John Dingell (D-MI), head of the House Energy and Commerce Committee, wrote that he and other subcommittee chairs were concerned by Roderick's "adventuresome and sweeping buyout approach" that was taken without much "fact finding or analysis to ensure" that the Inspector General's Office could still do its job effectively. "It is disturbing," added Dingell, "that EPA would give a \$15,000 bonus to an acting inspector general apparently intent on significantly undermining the ability of the office to detect waste, fraud and abuse." 184

• **Library closings.** The White House is seeking to shut down the EPA's network of technical libraries, which provide vital services to EPA staff and the general public, such as providing "important information regarding the health and environmental hazards of pollution in communities," "inding the most current information on health risks of chemical substances, providing documentation in enforcement cases against corporate polluters, and helping to prepare scientific support for new regulations." ¹⁸⁶

Why? The EPA claims it is because of proposed 2008 budget cuts. Yet an internal EPA study estimated that the library network saved the agency almost \$7.5 million annually in professional staff time – an amount three times greater than the agency library budget of \$2.5 million – which raises concerns that the agency's budget argument is simply a pretense to limit access to information. Thousands of EPA scientists, engineers, environmental protection specialists and support staff made that argument through their union representatives in a June 29, 2006 letter to Congress:

The proposed \$2 million budget cut for EPA libraries was initiated by EPA management, and approved by the Office of Management and Budget and the President, before being sent to Congress. We believe that this budget cut is just one of many Bush Administration initiatives to reduce the effectiveness of the U.S. Environmental Protection Agency, and to continue to demoralize its employees.

The sudden, draconian manner in which the EPA libraries are being closed, with little regard to protection of its unique collection of past technical reports and documents, is one more example of the Bush Administration's efforts to suppress information on environmental and public health-related topics while cloaking these actions under the guise of "fiscal responsibility." 188

The President of the American Library Association also questioned the White House's financial rationale in recent testimony before the Senate Environment and Public Works Committee:

The closing of these libraries initially took place under the guise of a proposed \$2 million budget cut – suggested by the EPA and included in President Bush's budget proposal for Fiscal Year (FY) 2007. Though recently, the EPA has backed away from the financial contention, instead casting the closures as a plan to digitize library collections (or convert library collections to digital formats) to reach a "broader audience" in providing access to these materials, as EPA spokespeople mentioned in a teleconference last December, but many scientists, EPA staff, and librarians continue to dispute this contention. ¹⁸⁹

The EPA has already closed libraries in Chicago, Washington, DC, Dallas and Kansas City and limited public access in four others. The agency's other 22 libraries only remain open because Congress has strongly objected. If all the libraries close, according to Public Employees for Environmental Responsibility, 191

- ▶ Tens of thousands of unique holdings will be boxed up and inaccessible for an unknown period;
- ▶ Public access to EPA holdings will cease; and
- ▶ EPA scientists, enforcement agents and other specialists will have a much harder time doing their jobs.

It is unclear whether the recently approved House amendment, allocating additional funds to the EPA's 2008 budget, will ultimately save the libraries from closure. ¹⁹²

• Lab closings. The EPA plans to cut laboratory staff and close or consolidate many of its research labs nationwide. According to an internal memo from EPA Administrator Stephen Johnson dated June 8, 2006, the agency hopes to shut down 10% of its laboratories and research centers where much of the EPA's work on pollution monitoring, toxicological effects and other public health issues is conducted. In addition, the agency will shrink the number of lab scientists by 20 percent by the year 2011. 193

In a recent petition calling for congressional intervention, representatives for thousands of EPA scientists and other technical specialists argued that these cuts will affect "the quality and quantity of work produced at U.S. EPA's laboratories." ¹⁹⁴

- **Rollbacks.** The EPA continues to weaken or eliminate existing agency rules and standards that were put in place to safeguard Americans from future injury. For example, in a February 6, 2007 oversight hearing, Senator Barbara Boxer (D-CA), chair of the Committee on Environment and Public Works, criticized a series of EPA rollbacks that "benefit polluters' bottom line" at the expense of public health and safety. Actions of particular concern:
 - Weakening the Community Right to Know rules for toxic chemicals used and released in communities across the country. According to Boxer, this will "quadruple the amount of toxic pollutants that companies can release before they have to tell the public and reduce the amount of public information on long-lasting toxins that can build up in the body, like lead."
 - No further testing of tap water for perchlorate, which interferes with the thyroid and is especially risky to pregnant women and newborns. Although the toxin has been found in millions of Americans' drinking water and pollutes 35 states, the EPA has not issued a health standard for perchlorate in tap water. As Boxer explained, "Americans will lack up-to-date information on whether their tap water is contaminated with this toxin."
 - Allowing EPA experts to set air quality standards without input from key scientists, a plan recommended by the American Petroleum Institute. "EPA's new approach is bad for American families," said Boxer, "because it will likely lead to more politics rather than science-based standards, making weaker air standards and more early deaths and illnesses more likely."
 - ▶ Weakening rules for controls on toxic air pollution, despite knowing that the change could lead to an increase in toxic air emissions. "Toxic air pollutants include some of the most dangerous cancer-causing and neurotoxic chemicals that pose a serious health threat to American families, especially pregnant women, infants and children," warned Boxer. "Increased levels of toxic air pollutants will only increase these risks."
- Cause-marketing for poisons. The EPA is allowing commercial manufacturers of bleach, pesticides and other toxic substances to display promotions for charitable causes and charities on their products' safety labels. Such "cause-marketing" takes up important label space traditionally devoted to consumer safety and usage information. The EPA's new policy "appears to violate the spirit, if not the letter, of its own consumer protection guidelines and risks drowning out critical safety

warnings with purely promotional visual clutter," explained Jeff Ruch, Executive Director of Public Employees for Environmental Responsibility. "EPA will be squandering its limited regulatory resources to referee promotional slogans rather than protecting consumer health." ¹⁹⁶

• **Human testing.** In 2006, the EPA finalized a human studies rule that allows companies to intentionally dose human beings with pesticides to justify weaker regulation. Studies show that people with high exposures to pesticides are far more likely to develop genetic mutations linked with cancers, birth defects and neurological disorders. Here

While the rule prohibits the EPA's use of data collected from pesticide testing on pregnant women, infants and children, it still allows the testing to continue. The rule is the product of a meeting between OMB staff, EPA officials and pesticide industry lobbyists, whose top objective was access to children for experiments. ¹⁹⁹

A coalition of U.S. senators, health and environmental advocates, farm workers and doctors are challenging the rule in court, arguing that it violates a 2005 congressional law that mandated strict ethical and scientific protections for pesticide testing on humans. Congress passed such legislation after learning of the EPA's "CHEERS" project, an industry-backed pesticide study that offered low-income families in Florida \$970, a camcorder and children's clothing if they would record "routine exposure" of their infants and toddlers to household pesticides.

CONCLUSION

For decades, Americans have relied on federal agencies as part of the framework that ensures the safety of, among other things, our environment, workplaces, food, drugs and consumer products. Such agencies were created because businesses were operating without oversight, leaving Americans without any protection.

The Bush administration has radically transformed the mission of these agencies from safeguarding citizens to safeguarding corporations. By installing industry loyalists in key agency management positions, by encouraging the departure of thousands of experienced agency professionals, by undermining agency authority through presidential flat, by minimizing congressional involvement and oversight, by weakening the rights of the injured to seek justice in the courts and by decreasing transparency, the White House has taken unprecedented steps that will have detrimental, long-term effects not only on the efficacy of federal agencies but also on the nation's collective wellbeing.

Given all the other news affecting our country, this drastic transformation has not received much attention even though the effects of the President's actions will be felt for years to come. The impact will be much more dramatic, however, unless Congress and the American people act to reclaim our federal agencies. As Senator Barbara Boxer

recently put it in an EPA oversight hearing, "EPA has gone too long without meaningful oversight. I want to send a clear signal to EPA and to this Administration. We are watching. The American public is watching."

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