OMB WATCH

THE OBAMA APPROACH TO PUBLIC PROTECTION:
ENFORCEMENT

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ACKNOWLEDGEMENTS

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About OMB Watch
OMB Watch is a nonprofit research and advocacy organization dedicated to promoting government accountability, citizen participation in public policy decisions, and the use of fiscal and regulatory policy to serve the public interest.

Cover photo available at www.whitehouse.gov.

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INTRODUCTION

Nearly 30 years ago, President Ronald Reagan proclaimed in his first inaugural address, "[G]overnment is not the solution to our problem; government is the problem." Those words unleashed a sustained agenda of deregulation and relaxation of regulatory enforcement.

Increasingly, unscrupulous companies have been able to cut corners when it comes to issues such as environmental protection, worker safety, and consumer safeguards. In 2010, two such events captured national headlines. On April 5, an explosion at Massey Energy's Upper Big Branch mine killed 29 miners, the worst mining accident in 40 years. On April 20, 11 people died and 17 others were injured when BP's Deepwater Horizon rig exploded and spilled at least 185 million gallons of oil into the Gulf of Mexico, causing extensive damage to marine habitats, as well as the Gulf's fishing and tourism industries. While no one will ever know if a stronger regulatory enforcement system would have prevented these disasters, it is certain that the cozy relationship between government enforcer and business contributed to the problem.

President Barack Obama took office acknowledging weaknesses in regulation and arguing that special interests had taken control of the process. This report intends to determine whether the Obama administration has made progress in reinvigorating regulatory enforcement at the federal level. It covers health, safety, and environmental enforcement at federal agencies from January 2009 to October 2010.

This is the second of three OMB Watch reports evaluating the Obama administration's record on regulatory issues. The first report, released in September 2010, focused on rulemaking and will be occasionally referred to in this report. The third report will focus on the regulatory process, including issues of transparency, participation, regulatory analysis, and scientific integrity, and will more deeply examine the role of the White House, specifically the Office of Management and Budget (OMB), in shaping the administration's record. The third report will be released in the coming weeks.

Obama seemed to act quickly on regulatory enforcement during his first two years in office. He made financial regulatory reform a legislative priority. The reform initiative was predicated upon more effective oversight of financial institutions and enforcement of regulations. Obama also moved on other consumer enforcement initiatives, beginning with the Food and Drug Administration (FDA), which had fallen into a state of disrepair under President George W. Bush.[1] Early on, the administration signaled it would take action against violators of regulations. The chair of the Consumer Product Safety Commission (CPSC), Inez Tenenbaum, summed up the attitude of the new Obama team: "We are enforcing the law; that's what we do."

While it is unusual for the president to directly engage in regulatory enforcement issues, Obama has done so on several occasions. After the Upper Big Branch tragedy, Obama blamed management failures and loopholes in existing laws and regulations for the blast. Obama cited "a failure first and foremost of management, a failure of oversight and a failure of laws so riddled with loopholes" that companies can repeatedly violate safety regulations without penalty. He then ordered the immediate deployment of inspectors to all mines with similar poor safety records and called for the Department of Labor to

1 *The Washington Post* reported in 2009, "The new administration focused first on the FDA, which oversees a quarter of the U.S. economy and during George W. Bush's presidency had been faulted by consumer advocates and members of Congress for not blocking contaminated foods and drugs and faulty medical devices." See Lyndsey Layton, "A Vigorous Push From Federal Regulators," *The Washington Post*, Oct. 13, 2009, http://www.washingtonpost.com/wp-dyn/content/article/2009/10/12/AR2009101202554.html (accessed Nov.29, 2010).

determine whether existing laws and regulations could be made more effective. Obama recognized that enforcement actions face challenges: "Safety violators like Massey," he said, have used strategies such as "endless litigation" to jam the regulatory system.

In the aftermath of the BP-Deepwater Horizon oil spill, Obama said, "So one of the lessons we've learned from this spill is that we need better regulations, better safety standards, and better enforcement when it comes to offshore drilling."[2] The Obama administration continues to explore enforcement strategies in the aftermath of the disaster, with regard to both BP and its partners and all companies involved in offshore drilling and exploration.

As Obama suggested, a strong regulatory enforcement network is necessary to ensure that federal laws and regulations are successful in reducing risks to and expanding opportunity for consumers, workers, businesses, and the environment. If regulation is the engine that drives government, then enforcement is the fuel that powers the engine. In the absence of effective enforcement, disaster or tragedy can strike, often leaving the public to wonder why the incident was not prevented.

Several factors contribute to agencies' ability to administer successful enforcement programs. Translating strategy into action requires proper planning and sufficient resources, among other factors. A leadership team committed to achieving agency objectives through enforcement is also critical to success.[3]

The most effective administrations combine strategy and implementation by showing a willingness to hold violators accountable for their actions. Aggressive enforcement is the best way to make regulation an effective deterrent. Of course, enforcement is not just about violators: even application of regulation through enforcement ensures a level playing field for law-abiding citizens, organizations, and businesses.

This report focuses on three areas: worker safety and health, consumer safety and health, and environmental enforcement. The main regulatory agencies covered are the Occupational Safety and Health Administration (OSHA), the Mine Safety and Health Administration (MSHA), FDA, CPSC, the National Highway Traffic Safety Administration (NHTSA), and the U.S. Environmental Protection Agency (EPA). The report also touches upon other departments and agencies to the extent that their rulemaking activity has shaped the administration's record, including the Food Safety and Inspection Service in the Department of Agriculture, the Federal Trade Commission, and the Department of the Interior.

Each of the report's three sections begins with introductory remarks, followed by a detailed analysis of agency actions. The report includes various metrics of enforcement activity, such as numbers of inspections, numbers of violations, and amounts of penalties. The data can serve as a useful baseline for comparisons within or between administrations. However, because of the variety of metrics available, the potential variability among them, and the difficulty of determining the usefulness or virtue of the actions taken, the statistical evidence should be considered only a small component of an evaluation of agency performance.

More important than quantitative information is qualitative information. The three sections assess strategic shifts within agencies, both those that have been detailed in agency policy documents and those that have emerged, through examination of the evidence, as patterns. Assessing what the administration

2 Barack Obama, "Remarks by the President to the Nation on the BP Oil Spill," The White House, June 15, 2010, http://www.whitehouse.gov/the-press-office/remarks-president-nation-bp-oil-spill (accessed Nov. 29, 2010).
3 This report does not include profiles of agency leadership. Leadership is discussed in more detail in the first report in this series (see http://www.ombwatch.org/obamamidtermrulemakingreport).

has not done – where gaps in enforcement remain – is more difficult, but the sections discuss shortcomings where possible.

Key Findings

The agencies examined in this report appear to be exercising their enforcement authority more strenuously than they had in recent years. At OSHA, FDA, and EPA, for example, certain metrics of enforcement activity are rising, and the agencies appear to be reevaluating their regulatory enforcement strategies and focusing on specific problem areas in their respective domains:

- At OSHA, the number of safety and health violations cited by agency inspectors is increasing (see page 8), and officials are shifting the agency's attention toward high-risk sectors and repeat violators.

- The FDA has issued a greater number of warning letters to firms in violation of the agency's rules (see page 17) and has been a leader in the administration's efforts to crack down on misleading health claims promoted on product packaging.

- The EPA is moving more quickly to address violations of environmental laws (see pages 25-29) while agency leaders focus on new enforcement strategies for clean water.

The administration will need to accomplish more if it intends to truly reform the regulatory enforcement situation. One major challenge lies in the restoration of regulatory agency budgets. As a 2008 OMB Watch series shows,[4] many regulatory agencies have suffered from years, or even decades, of budget cuts and uncertainty. Even in those agencies where funding has not decreased, staffing has. Enforcement programs are often among the hardest hit, and several agencies have seen their inspectorate shrink over time.

The situation has improved somewhat in recent years. As this report details, Congress has approved significantly larger budgets for several key agencies and Obama has, for some agencies, taken his own steps to boost funding. (Budget information for major regulatory agencies is listed in the Appendix.) Still, for most agencies, progress has been modest in comparison to historical cuts. Resource levels must also be viewed in relation to the size of the regulated communities that agencies oversee, which are, in many cases, growing, causing agency workloads to grow commensurately. Moreover, absorbing and training staff hired under recent budget increases will take time, limiting progress in the short-term.

It is too early to determine whether Obama has or will transform the culture surrounding regulation. Unquestionably, Obama has dramatically changed course from the Bush years. The Bush administration took a hands-off approach to regulation, regularly failing to take a stand against repeat violators. As a result, uncertainty permeated regulatory agencies as staff approached their duties under the law tentatively. The Obama team has moved to change this culture by nominating people interested in regulatory enforcement, by increasing resources for regulatory activities, and by showing a greater willingness to use the regulatory tools at its disposal.

For the duration of the Obama administration, regulatory agencies are likely to face an increasingly hostile environment. Many conservatives and business leaders are already criticizing the Obama administration for what they perceive to be a rapid expansion of the regulatory state. This climate will require administration officials to show great resolve if they are to continue the task of rebuilding the regulatory enforcement machine.

4 Articles in the *Bankrupting Government* series are available at http://www.ombwatch.org/bankruptinggovernment.

WORKER HEALTH AND SAFETY ENFORCEMENT

Thus far, the Obama administration has viewed worker safety issues, including enforcement, predominantly through the lens of external crises.

When BP's Deepwater Horizon rig exploded, 11 workers on board were killed, prompting the administration to incorporate workplace safety issues into its response to a disaster that was predominantly characterized as environmental. The Department of Labor's Occupational Safety and Health Administration (OSHA) has been a key player in the administration-wide response to the explosion and subsequent spill. OSHA Administrator David Michaels has visited the region on multiple occasions to oversee cleanup workers and ensure their safety. As part of its policy response to the spill, the administration has also announced stricter oversight for rigs and their employees.

The April 5, 2010, explosion at the Upper Big Branch coal mine in West Virginia has dominated the Obama administration's strategy for mine safety enforcement. The Department's Mine Safety and Health Administration (MSHA), in cooperation with the White House, has begun to alter mine safety enforcement policy based largely on deficiencies exposed by the blast, which killed 29 miners.

When the disaster occurred, Joe Main, a mine safety and health expert who had worked for the United Mine Workers of America and President Obama's choice to lead MSHA, was already reviewing weaknesses in the enforcement system. However, the tragedy once again thrust mine safety into the national spotlight and commanded immediate attention. Obama met with Labor Secretary Hilda Solis, Main, and Kevin Stricklin, head of coal mine safety at MSHA, to receive a preliminary report on the disaster. In a speech following the meeting, Obama emphasized the need for stronger enforcement of mine safety rules, particularly in mines with poor safety records.[5] "Starting today, we'll go back and take another look at mines across this country with troubling safety records, and get inspectors into those mines immediately to ensure they aren't facing the same unsafe working conditions that led to this disaster," Obama said. He also indicated the administration would aggressively investigate the explosion and implied that the Justice Department would act against Massey Energy, the mine's owner.

At OSHA, Obama requested a significant budget increase for FY 2010, which Congress granted, and another increase for FY 2011. (Congress has yet to pass appropriations bills for FY 2011, which began Oct. 1, 2010.) Although the increases are not limited to enforcement issues, the agency is expected to devote more resources to enforcement. However, at MSHA, proposed increases have been more modest. (OSHA's and MSHA's budgets are discussed in more detail below.)

Occupational safety and health

Labor Department leaders appointed by Obama say they want to focus on employers most responsible for placing workers at risk. During an April 2010 event, Deputy Labor Secretary Seth Harris divided employers into three broad categories: those that view compliance with workplace laws and regulations as a necessity and a part of their business model; those that need and welcome the department's help to understand and comply with those laws and regulations; and those that are irresponsible and place workers at risk.[6] Harris suggested the department would reserve its toughest enforcement actions for the "chronic scofflaws" in the last category that violate worker health, safety, and rights.

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5 Barack Obama, "Remarks by the President on Mine Safety," The White House, April 15, 2010, http://www.whitehouse.gov/the-press-office/remarks-president-mine-safety (accessed Oct. 14, 2010).

6 "Labor Rules: The U.S. Department of Labor Spring 2010 Regulatory Agenda," Center for American Progress, April 29, 2010, http://www.americanprogress.org/events/2010/04/UnifiedAgenda.html (accessed Oct. 14, 2010).

Evidence indicates that OSHA is moving in this direction, in part by creating a risk-based enforcement framework. The agency has employed strategies to target certain high-risk sectors or firms, including two initiatives focused on individual workplaces with historically poor health and safety records:

- In March 2010, OSHA sent letters to 15,000 workplaces with injury and illness rates exceeding the national average.[7] The OSHA letters highlighted frequently violated standards, tailored by industry sector, and offered the firms assistance in improving workplace conditions but also warned, "[Y]ou should be aware that OSHA may target up to 4500 general industry workplaces identified in the survey for inspection in the next year."[8] OSHA has sent similar letters every year as of late, but the 15,000 figure represents the most letters the agency has sent. Under the Obama administration, the letters mention union cooperation as means of mitigating workplace risks, a suggestion absent from letters sent during the Bush administration.

- In April 2010, OSHA announced its Severe Violator Enforcement Program, under which the agency will increase inspections at derelict workplaces, conduct mandatory follow-up inspections, and inspect other workplaces under the same ownership.[9] OSHA also says it will pursue higher penalty amounts for violators.

OSHA has also moved to increase oversight at inherently dangerous workplaces and strengthened enforcement efforts when necessary:

- In July 2009, OSHA launched a national emphasis pilot program for facilities that handle and may release hazardous chemicals. "The intent of the [program] is to conduct quick inspections at a large number of facilities that will be randomly selected from a list of worksites likely to have highly hazardous chemicals in quantities covered" by OSHA standards.[10]

- OSHA has increased its commitment to the Federal Agency Targeting Inspection Program, launched in 2008, which focuses on federal workers and contractors supervised by the federal government in high-risk areas. In FY 2009, agency inspectors uncovered 336 violations, "more than twice the number cited in 2008," according to OSHA.[11]

OSHA's focus on high-risk workplaces has been coupled with a decreasing emphasis on voluntary compliance and compliance assistance. For example, in June 2009, OSHA announced that it would reevaluate its Voluntary Protection Program, which is intended to provide certain advantages, including

7 "US Labor Department's OSHA notifies 15,000 workplaces nationwide of high injury and illness rates," U.S. Department of Labor, Occupational Safety and Health Administration, March 9, 2010, http://osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=17238 (accessed Oct. 14, 2010).
8 A sample letter is available at http://osha.gov/as/opa/foia/letter10.html (accessed Oct. 14, 2010).
9 "US Department of Labor's OSHA takes action to protect America's workers with severe violator program and increased penalties," U.S. Department of Labor, Occupational Safety and Health Administration, April 22, 2010, http://osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=17544 (accessed Oct. 14, 2010).
10 "U.S. Labor Department's OSHA national emphasis program targets workplaces that release highly hazardous chemicals," U.S. Department of Labor, Occupational Safety and Health Administration, July 28, 2009, http://osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=16119 (accessed Oct. 14, 2010).
11 "OSHA program protects federal workers," U.S. Department of Labor, Occupational Safety and Health Administration, April 1, 2010, http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=17340 (accessed Oct. 14, 2010).

less frequent inspections, to businesses with good safety records.[12] In 2004 and 2009, the Government Accountability Office (GAO) found that the program was dysfunctional and let too many delinquent employers fall through the cracks.[13,14] GAO's reports made several recommendations for reform, but the Bush administration largely ignored those in the first report. OSHA has yet to indicate next steps for its reevaluation.

OSHA's budget has grown under the Obama administration. In FY 2010, Obama's budget requested a $564 million appropriation for OSHA, more than $50 million more than the FY 2009 appropriation.[15] (Congress adjusted the request downward to $559 million.[16]) In the FY 2011 request, Obama called for a $573 million appropriation.[17]

A closer look at the budget underscores the shifts in enforcement strategy discussed above. In Obama's FY 2010 budget, almost $30 million of the $50 million requested increase was designated for federal enforcement.[18] Almost $14 million extra was requested for grants to states that administer their own occupational safety and health program.[19] Meanwhile, the budget called for only a $1 million increase for compliance assistance programs at the federal and state levels.[20] Hiring should follow suit, as OSHA has added or expects to add 160 inspectors and other employees to its enforcement division but projects no staff increases for compliance assistance activities.[21] The FY 2011 request calls for an overall increase to the federal and state enforcement budgets and an overall decrease for the state and federal compliance assistance budgets.[22]

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12 "U.S. Department of Labor's OSHA begins evaluation of Voluntary Protection Programs," U.S. Department of Labor, Occupational Safety and Health Administration, June 18, 2009, http://osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=18065 (accessed Oct. 14, 2010).

13 Robert E. Robertson, "Workplace Safety and Health: OSHA's Voluntary Compliance Strategies Show Promising Results, but Should Be Fully Evaluated before They Are Expanded," United States General Accounting Office, GAO-04-378, March 19, 2004, http://www.gao.gov/new.items/d04378.pdf (accessed Oct. 14, 2010).

14 Anne-Marie Lasowski, "OSHA's Voluntary Protection Programs: Improved Oversight and Controls Would Better Ensure Program Quality," United States Government Accountability Office, GAO-09-395, May 20, 2009, http://www.gao.gov/new.items/d09395.pdf (accessed Oct. 14, 2010).

15 "FY 2010 Congressional Budget Justification: Occupational Safety and Health Administration," U.S. Department of Labor, http://www.dol.gov/dol/budget/2010/PDF/CBJ-2010-V2-08.pdf, hereinafter "2010 OSHA budget request" (accessed Oct. 14, 2010).

16 "Consolidated Appropriations Act, 2010," P.L. 111-117, Dec. 16, 2009, http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ117.111.pdf (accessed Oct. 14, 2010).

17 "FY 2011 Congressional Budget Justification: Occupational Safety and Health Administration," U.S. Department of Labor, http://www.dol.gov/dol/budget/2011/PDF/CBJ-2011-V2-11.pdf, hereinafter "2011 OSHA budget request" (accessed Oct. 14, 2010). Figures do not include spending authorized under the American Recovery and Reinvestment Act of 2009.

18 2010 OSHA budget request.

19 Ibid.

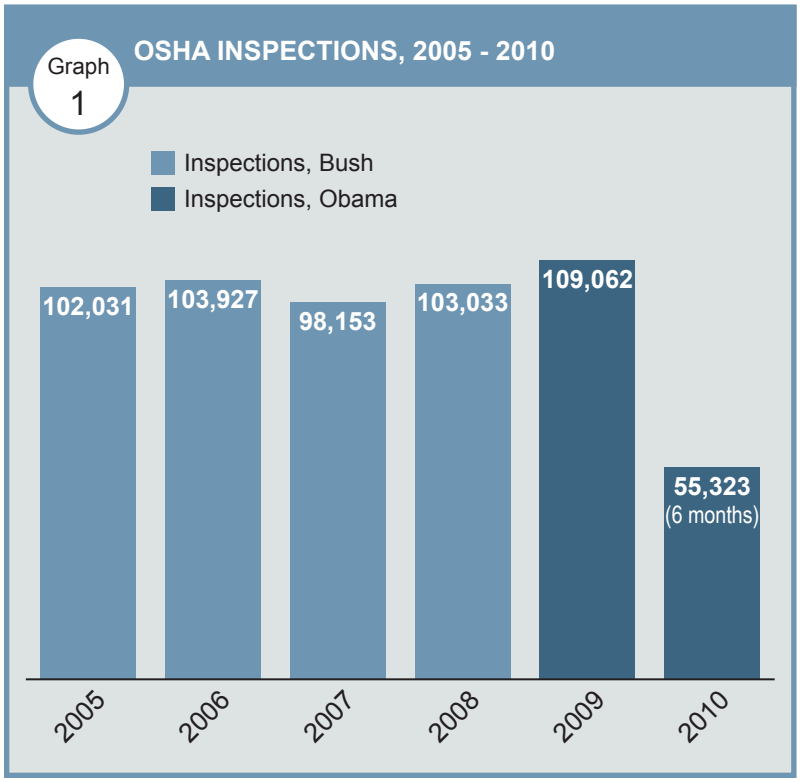
20 Ibid.

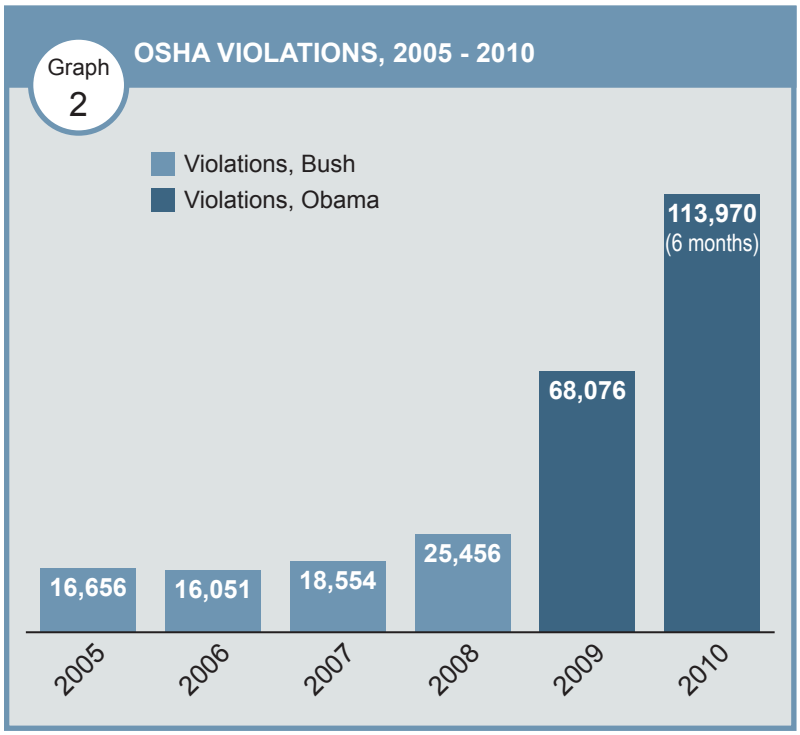
21 Ibid.

22 2011 OSHA budget request.

Currently, it is difficult to determine whether the strategic shifts are translating into on-the-ground results. Data provided by the Department of Labor do not show a significant change in the level of inspection activity from the Bush administration to the Obama administration. As Graph 1 shows, the number of workplace inspections conducted by OSHA and the states has increased, but not dramatically.[23]

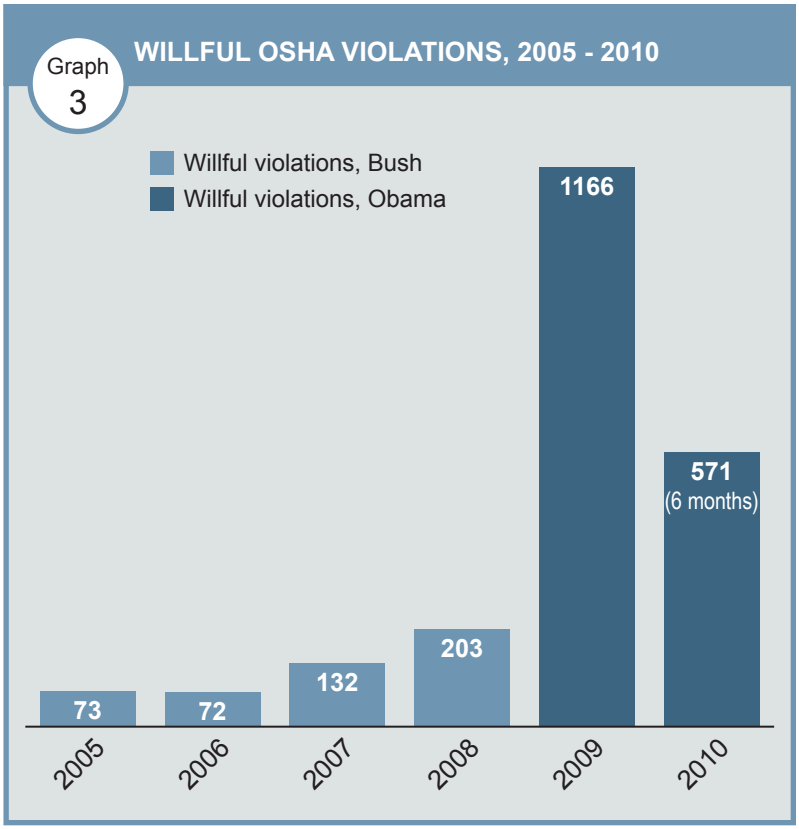
Data show, however, that OSHA has been citing workplaces for safety and health violations to a greater extent under the Obama administration. For example, from Jan. 20, 2009, through Jan. 19, 2010, Obama's first full year in office, federal and state OSHA programs handed out more than 68,000 citations for violations – a 167 percent increase from the previous year – and exceeded that total in the first half of 2010. (See Graph 2.) The number of citations for willful violations has increased as well. (See Graph 3.) Willful violations are those committed intentionally or as a result of plain indifference and generally lead to greater fines (up to $70,000) than other types of violations.





23 OSHA enforcement data in this report were downloaded from the Department of Labor Enforcement Data website, http://ogesdw.dol.gov/search.php, in August 2010. Data were downloaded by state. Because OSHA updates inspection and enforcement information, data in this report will not be identical to data downloaded on future dates. Numbers are presented to provide the reader with an approximation of inspection and violation statistics. In text and in graphs 1, 2, and 3, years run from Jan. 20 through Jan. 19, to account for presidential inauguration, and data for 2010 are through July 20, 2010.

OSHA has struggled to secure adequate protection for whistleblowers, a key weakness in its overall enforcement approach. OSHA is responsible for whistleblower protections under 18 laws, but its program has long been criticized as inadequate. Those inadequacies have continued under the Obama administration. In an August 2010 report, GAO found that OSHA does not ensure that program staff complete mandatory trainings on whistleblower protections.[24] The report also said that the national office does not have access to data and case files to adequately monitor the regional offices for compliance with agency procedures. GAO recommended reforms to OSHA's whistleblower program while also criticizing the agency for failing to implement recommendations from past GAO reports. In September 2010, the Department of Labor Inspector General found that OSHA investigations into whistleblower complaints frequently deviate from the agency's own stated procedures and recommended that Michaels more closely oversee the program.[25]



Mine safety and health

In February 2010, just before the Upper Big Branch explosion, MSHA launched a fatality prevention program intended to help mines improve working conditions and focus the agency's enforcement activities.[26] Phase one of the program was outreach: MSHA identified the conditions and practices associated with mining fatalities and communicated its finding to mine owners and operators. In phase two, which began in mid-March, inspectors began giving greater scrutiny to factors associated with fatalities.

But the Upper Big Branch tragedy highlighted problems with mine safety enforcement severe enough that the agency was forced to change its course. Massey-owned mines, including Upper Big Branch, had a history of mine safety violations, but MSHA could not add Upper Big Branch to its pattern-of-violations

24 George A. Scott, "Whistleblower Protection: Sustained Management Attention Needed to Address Long-standing Program Weaknesses," United States Government Accountability Office, GAO-10-722, Aug. 17, 2010, http://www.gao.gov/new.items/d10722.pdf (accessed Oct. 26, 2010).
25 Elliot P. Lewis, "Complainants Did Not Always Receive Appropriate Investigations Under The Whistleblower Protection Program," U.S. Department of Labor, Office of Inspector General, Office of Audit, Sept. 30, 2010, http://www.oig.dol.gov/public/reports/oa/2010/02-10-202-10-105.pdf (accessed Oct. 26, 2010).
26 "MSHA fatality prevention program will include outreach, enforcement," U.S. Department of Labor, Mine Safety and Health Administration, Feb. 2, 2010, http://www.msha.gov/MEDIA/PRESS/2010/NR100202.asp (accessed Oct. 14, 2010).

list, which identifies the worst mining companies and invokes enhanced MSHA enforcement efforts. Massey fixed enough of the 515 citations the mine received in 2009 to stay off the list.[27] Massey and other owners and operators also have a history of keeping unsafe mines off the pattern-of-violations list by appealing citations to the Federal Mine Safety and Health Review Commission (FMSHRC) (which has an 18,000-case backlog[28]) in order to delay judgment and tie up the system. MSHA has never added a mine to the pattern-of-violations list in the program's 32-year history.

MSHA has altered its enforcement strategy in response to the Upper Big Branch tragedy. In April 2010, at Obama's urging, MSHA began a four-month inspection blitz focused on mines with questionable safety records.[29] MSHA chose to conduct "impact assessments," as the agency is calling them, at 111 coal, metal, and nonmetal mines based on factors that indicate safety problems, including frequent complaints to regulators, high injury and illness rates, and fatalities.

MSHA found "significant and substantial" violations at all but three of the 111 mines.[30] In all, "enforcement personnel issued 2,660 violations, 45 percent of which were classified as significant and substantial." MSHA said that, at some mines, inspectors found that conditions had actually deteriorated when they returned for follow-up inspections, naming two mines, one of which the agency shut down.

Evidence indicates MSHA is also cracking down on improper advanced notification of MSHA inspections, an illegal practice. During the inspection blitz, the agency seized surface phones to prevent advanced notification, varied the times of their visits, and drove unmarked vehicles.[31] On Aug. 26, 2010, the agency stressed the illegality of advanced notification by issuing a new Program Information Bulletin for inspectors and mine operators.[32] Under the Federal Mine Safety and Health Act of 1977, MSHA can fine or even imprison individuals who provide advanced notice of an inspection, the Bulletin says.

The Upper Big Branch disaster occurred after Obama submitted his FY 2011 budget request, which called for approximately a $3.5 million, or one percent, increase in appropriations for MSHA.[33] Obama's FY 2010 budget requested an overall budget increase of approximately $7 million,[34] to which Congress added

27 "Briefing by Department of Labor, Mine Safety and Health Administration on Disaster at Massey Energy's Upper Big Branch Mine-South," U.S. Department of Labor, Mine Safety and Health Administration, http://www.msha.gov/PerformanceCoal/DOL-MSHA_president_report.pdf (accessed Oct. 14, 2010).
28 "Federal Mine Safety and Health Review Commission Activity: Review Commission Decisions and Orders," *Mine Safety and Health News*, Oct. 15, 2010, Vol. 17, No. 19, 479.
29 "MSHA announces results of 5 months of impact inspections," U.S. Department of Labor, Mine Safety and Health Administration, Sept. 20, 2010, http://www.msha.gov/MEDIA/PRESS/2010/NR100920.asp (accessed Oct. 14, 2010).
30 Detailed results of the inspections are available at http://www.msha.gov/MEDIA/PRESS/2010/NR100920attach.pdf (accessed Oct. 14, 2010).
31 Kimberly Kindy, "Safety officials issue more than 2,600 citations in surprise mine inspections," *The Washington Post*, Sept. 20, 2010, http://www.washingtonpost.com/wp-dyn/content/article/2010/09/20/AR2010092005324.html (accessed Oct. 14, 2010).
32 Kevin G. Stricklin and Neal H. Merrifield, "Program Information Bulletin No. P10-15: Prohibition of Advance Notice of § 103(a) Inspections," U.S. Department of Labor, Mine Safety and Health Administration, Aug. 26, 2010, http://www.msha.gov/REGS/COMPLIAN/Pib/2010/pib10-15.asp (accessed Oct. 14, 2010).
33 "FY 2011 Congressional Budget Justification: Mine Safety and Health Administration," U.S. Department of Labor, http://www.dol.gov/dol/budget/2011/PDF/CBJ-2011-V2-12.pdf, hereinafter "2011 MSHA budget request" (accessed Oct. 14, 2010).
34 "FY 2010 Congressional Budget Justification: Mine Safety and Health Administration," U.S. Department of Labor, http://www.dol.gov/dol/budget/2010/PDF/CBJ-2010-V2-09.pdf (accessed Oct. 14, 2010).

an additional $3.5 million.[35] According to the Department of Labor, the increase helped MSHA add 21 employee's to the agency's coal, metal, and nonmetal enforcement programs and seven employees to its Office of Assessments, which handles civil penalties.[36]

Conclusions: Worker safety and health enforcement

OSHA appears to be developing an enforcement regime that focuses on industries and workplaces where employees are at greater risk for injury and illness. Department of Labor statistics reflect this shift in strategy, as agency inspectors appear more vigilant, citing more workplace safety and health violations than in any other time in recent years. Given this information and comments Harris has made in April 2010, it is reasonable to hypothesize that the leash has been taken off the OSHA inspectorate under the Obama administration.

Although data shows the upward trend in number of citations issued began in 2008, it accelerated dramatically in 2009 and 2010 under Michaels. (See Graph 2.) The fact that the number of willful violations has increased as well shows that OSHA's inspection presence is necessary to root out problems and protect workers.

The agency also appears to be placing less emphasis on voluntary compliance and compliance assistance, strategies preferred under the Bush administration. OSHA may be shifting its approach as it realizes voluntary compliance or compliance assistance programs do not adequately protect workers.

Changes at MSHA must be viewed through the lens of the Upper Big Branch mine explosion. The agency has publicized its enforcement efforts since the disaster and, like OSHA, appears to be targeting mines with historically poor safety records. However, the backlog at FMSHRC remains, and MSHA's approach is unlikely to translate into improved conditions for miners in the near term; MSHA must continue to be vigilant to help improve the safety culture in the mining industry.

35 "Consolidated Appropriations Act, 2010," P.L. 111-117, Dec. 16, 2009, http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ117.111.pdf (accessed Oct. 14, 2010).
36 2011 MSHA budget request.

CONSUMER HEALTH AND SAFETY ENFORCEMENT

On March 14, 2009, President Obama announced the formation of a Food Safety Working Group, an inter-governmental task force assigned with crafting recommendations to improve food safety.[37] Obama said, "Protecting the safety of our food and drugs is one of the most fundamental responsibilities of government."

When the working group released its recommendations in July 2009, it placed an emphasis on the role of data and analysis in food safety enforcement and recommended the creation of a food safety traceback system to help investigators quickly identify the source of foodborne illness outbreaks.[38]

At the Food and Drug Administration (FDA), more significant reforms require legislative action. The agency has been awaiting enhanced enforcement authority provided for in the FDA Food Safety Modernization Act currently pending in Congress. The bill would give FDA the authority to order the recall of dangerous or potentially dangerous food, a power the agency does not currently possess, and allow the agency to conduct more frequent inspections at food facilities. Obama publicly renewed his support for the bill as recently as July 2010 and commented that it "would complement the work already undertaken by the Food Safety Working Group."[39]

Obama's comments were aimed at the Senate. Although the House of Representatives passed its version of the legislation on July 30, 2009, the Senate did not take up the bill until November 2010, after the midterm elections. The Senate passed the bill on Nov. 30, 2010. Because the House and Senate passed different versions of the bill, the legislative process continues, with the end of the congressional session rapidly approaching.[40] Some of the bill's provisions, including a traceback requirement, are consistent with the recommendations of the working group.

At the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS), the enforcement agenda was likely impacted by a lack of leadership. Obama did not announce his nominee for USDA undersecretary for food safety, Elisabeth Hagen, until January 2010. The Senate Agriculture Committee did not approve the nomination until June 30. The full Senate did not take up the nomination before leaving for its 2010 summer recess. Finally, Obama installed Hagen through a recess appointment on Aug. 19.[41]

The Consumer Product Safety Commission (CPSC) continues to implement the Consumer Product Safety Improvement Act, the landmark 2008 law that overhauled product safety, and to explore the enhanced enforcement and penalty authority the bill granted the agency. Enforcement at the National Highway Traffic Safety Administration (NHTSA) has been dominated by its investigation of the recalls of millions of Toyota cars and trucks after the vehicles were linked to crashes caused by sudden, unintended acceleration.

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37 Barack Obama, "Weekly Address: President Barack Obama Announces Key FDA Appointments and Tougher Food Safety Measures," The White House, March 14, 2009, http://www.whitehouse.gov/the_press_office/Weekly-Address-President-Barack-Obama-Announces-Key-FDA-Appointments-and-Tougher-F/ (accessed Sept. 2, 2010).
38 "Obama Administration Delivers on Commitment to Upgrade U.S. Food Safety System," The White House, July 7, 2009, http://www.whitehouse.gov/the_press_office/Obama-Administration-Delivers-on-Commitment-to-Upgrade-US-Food-Safety-System/ (accessed Sept. 2, 2010).
39 Barack Obama, "Statement by the President on Food Safety," The White House, July 7, 2010, http://www.whitehouse.gov/the-press-office/statement-president-food-safety (accessed Oct. 28, 2010).
40 Because the Senate bill contains a revenue-raising provision, it has run into procedural concerns under the U.S. Constitution, which requires that revenue and tax bills originate in the House. The Senate may hold another vote.
41 Hagen has since been confirmed by the Senate, rendering the recess appointment moot.

Obama's budget requests for consumer protection agencies have been inconsistent. While the president has proved successful in significantly expanding resources at the FDA, budget requests for FSIS, another critical food safety agency, have been less aggressive. Obama has also shown moderation with the budgets of CPSC and NHTSA. Agency budgets are discussed in more detail below.

Food, drug, and medical device safety

Administration officials have indicated a desire to emphasize prevention in food safety enforcement. At the FDA, prevention has also characterized strategic shifts in drug and device safety enforcement.

In February, FDA commissioner Margaret Hamburg announced the launch of a new program that will help inspectors oversee the importation of food and drugs. The risk-based evaluation program (with the acronym PREDICT) is a shift toward a preventive approach rather than reacting to crises.[42] The program allows inspectors to target higher-risk products to maximize the effectiveness of inspections. Lower-risk products will receive quicker import approval based on the compliance records of the importers and shippers, according to Hamburg.

In Hagen's first speech as USDA's undersecretary for food safety, she identified challenges the agency faces and placed two enforcement challenges, traceback and humane handling, in a prevention context.[43]

Past foodborne illness outbreaks have proved difficult to pinpoint, as an increasingly complex and global supply chain complicate efforts to trace the path of contaminated products. Hagen said the agency needs to respond to contamination crises more quickly and effectively but also acknowledged that FSIS "need[s] a more effective traceback policy for contamination that we find through our regulatory sampling programs, if we want to have a truly preventive system."

FSIS is responsible for enforcing the Humane Methods of Slaughter Act (HMSA), which requires livestock to be unable to feel pain before slaughter. Persistent public concern, and subsequent congressional concern, has led to several Government Accountability Office (GAO) reports about how well FSIS has been enforcing HMSA over the last decade. In March, GAO testified before a subcommittee of the House Committee on Oversight and Government Reform and highlighted problems with inconsistent enforcement, internal management, the lack of clear guidance, and not enough training.[44] Hagen acknowledged that "inconsistency" has plagued FSIS enforcement of the law in recent years.

While prevention is on the agenda for both FDA and FSIS, day-to-day functions are still dictated by external events to which the agencies must respond, including foodborne illness outbreaks and medical product problems.

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42 Margaret A. Hamburg, "FDA and the American Public: The Safety of Foods and Medical Products in the Global Age, Remarks of Margaret A. Hamburg, M.D., Commissioner of Food And Drugs, at the Center for Strategic and International Studies," U.S. Department of Health and Human Services, U.S. Food and Drug Administration, Feb. 4, 2010, http://www.fda.gov/NewsEvents/Speeches/ucm199926.htm (accessed Oct. 28, 2010).

43 Elisabeth Hagen, "Building a Stronger National Food Safety System, Remarks prepared for delivery by Dr. Elisabeth Hagen, Under Secretary for Food Safety, at the 2010 National Food Policy Conference, September 23, 2010, in Washington, DC," United States Department of Agriculture, Food Safety and Inspection Service, Sept. 23, 2010, http://www.fsis.usda.gov/News_&_Events/Speech_092310_Hagen/index.asp (accessed Oct. 28, 2010).

44 Lisa Shames, "Humane Methods of Slaughter Act: Weaknesses in USDA Enforcement," United States Government Accountability Office, GAO-10-487T, March 4, 2010, http://www.gao.gov/new.items/d10487t.pdf (accessed Oct. 28, 2010).

The recall of 550 million eggs contaminated with salmonella has been the most significant food-related crisis the Obama administration has confronted thus far. The eggs sickened at least 1,800 people in the U.S.[45] Investigators traced the outbreak back to two Iowa farms, and the FDA worked with the companies involved to initiate a voluntary recall. (The recall began Aug. 13; however, officials believe most of the contaminated eggs had already been consumed or disposed of, because they had been distributed and sold months earlier.[46]) FDA has since sent a warning letter to one of the companies, Wright County Egg, concerning unsanitary conditions that contributed to the salmonella contamination.[47]

E. coli contamination in beef continues to sicken consumers and vex FSIS. For example, in October 2009, a New York farm recalled half of a million pounds of ground beef due to *E. coli* contamination. The beef was linked to 26 illnesses and two deaths.[48] In August 2010, a California company recalled approximately one million pounds of ground beef for *E. coli* contamination after the beef was linked to seven illnesses.[49]

With regard to drug safety, FDA has spent much of 2010 chasing after health care product giant Johnson & Johnson. The company's problems made headlines at the end of 2009 when Tylenol, Motrin, and Benadryl products had to be recalled due to a "moldy, musty, or mildew-like odor."[50] Since then, FDA has discovered significant problems at the facility that manufactured the products, as well as two other Johnson & Johnson plants. The problems ranged from inadequate recordkeeping to bottles of medicine containing other products to contamination of drugs that made consumers ill.[51] According to reports, FDA inspectors found that a Lancaster, PA, plant could not guarantee that its drugs were manufactured to appropriate standards and that the company did not provide basic paperwork to inspectors in a timely manner. One of the plants was closed and is unlikely to reopen until 2011.[52]

On May 3, 2010, FDA recalled a brand of medical infusion pumps used in hospitals and other medical facilities to control the amount of fluids dispensed to patients. FDA issued the recall to Baxter Healthcare Corporation for its Colleague infusion pumps "based on a longstanding failure to correct many serious

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45 "Investigation Update: Multistate Outbreak of Human Salmonella Enteritidis Infections Associated with Shell Eggs," Department of Health and Human Services, Centers for Disease Control and Prevention, Oct. 19, 2010, http://www.cdc.gov/salmonella/enteritidis/ (accessed Oct. 28, 2010).

46 "Urgent Nationwide Egg Recall: Eggs in Their Shells May Put Consumers at Risk for Salmonella," U.S. Department of Health and Human Services, U.S. Food and Drug Administration, Aug. 19, 2010, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm223248.htm (accessed Oct. 28, 2010).

47 John W. Thorsky, "Warning letter: Ref. KAN 2011-01," U.S. Department of Health and Human Services, U.S. Food and Drug Administration, Oct. 15, 2010, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm229805.htm (accessed Oct. 28, 2010).

48 "Multistate Outbreak of E. coli O157:H7 Infections Associated with Beef from Fairbank Farms," Department of Health and Human Services, Centers for Disease Control and Prevention, Nov. 24, 2010, http://www.cdc.gov/ecoli/2009/1124.html (accessed Oct. 28, 2010).

49 "California Firm Recalls Frozen Ground Beef Products Due To Possible E. Coli O157: H7 Contamination," United States Department of Agriculture, Food Safety and Inspection Service, Aug. 6, 2010, http://www.fsis.usda.gov/News_&_Events/Recall_048_2010_Release/index.asp (accessed Oct. 28, 2010).

50 "Mcneil Consumer Healthcare Announces A Voluntary Nationwide Recall Of All Lots Of Tylenol® Arthritis Pain 100 Count With Ez-Open Cap," U.S. Department of Health and Human Services, U.S. Food and Drug Administration, Dec. 18, 2009, http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2009/ucm195690.htm (accessed Oct. 28, 2010).

51 Lyndsey Layton, "FDA reports slew of problems at Johnson & Johnson plant," *The Washington Post*, July 22, 2010, http://www.washingtonpost.com/wp-dyn/content/article/2010/07/22/AR2010072206169.html (accessed Oct. 28, 2010).

52 Ibid.

problems with the pumps," according to FDA's press release.[53] FDA had been working with Baxter since 1999 to correct flaws in the pumps, and in April 2010, Baxter submitted a revised schedule for fixing the pumps that would not have corrected the problem until 2013. FDA rejected the plan and issued the recall (a power the agency had under a 2006 consent decree) because "Baxter has failed to adequately correct, within a reasonable timeframe, the deficiencies in the Colleague infusion pumps still in use," according to the statement. FDA received more than 56,000 adverse event reports related to infusion pumps over the last five years, including more than 500 deaths. Other companies had also stopped selling brands of pumps due to defects.[54]

FDA has also taken regulatory action against the marketing of Avandia, a controversial diabetes drug that researchers have linked to an increased risk of heart disease and stroke. In September 2010, FDA announced it would require the drug's maker, GlaxoSmithKline, to limit access to the drug to patients truly in need of it and unable to take alternative drugs.[55] Some public health advocates criticized FDA's decision, saying it did not go far enough and pointing to the European Union's decision to remove Avandia from the market. Avandia has been on the market in the U.S. since FDA approved it in 1999.

The Avandia scandal underscores the challenges FDA faces in its drug and medical device approval programs. The agency has an expedited drug approval process designed to prevent companies from incurring long and costly drug trials. FDA may provide approval for drugs on the condition that companies do post-market studies on the effectiveness of drugs.[56] A 2009 GAO investigation of this process concluded that FDA has not adequately tracked post-marketing studies and does not have clear procedures for defining the circumstances in which drugs should be pulled from the market, thus undermining an important safeguard.[57]

FDA has started to improve some aspects of its internal tracking system since the GAO report and has an internal task force reviewing polices, but the agency has indicated it does not plan to be more assertive regarding the removal of drugs that have not proven to be effective.[58]

A similar expedited approval process exists at FDA for medical devices. The agency has different approval processes for devices depending on the level of risk of each device. Highest-risk devices normally undergo a premarket approval process but can be approved under a lower-risk category, called a 501(k) exemption, if the device is deemed to be the "substantial equivalent" of a device already on the market.[59] This 501(k) process has garnered criticism after devices like heart defibrillators and pacemakers have failed due to defects.

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53 "FDA Issues Statement on Baxter's Recall of Colleague Infusion Pumps," U.S. Food and Drug Administration, May 3, 2010, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm210664.htm (accessed Oct. 28, 2010).

54 Bruce Japsen, "FDA orders Baxter International to recall and destroy faulty hospital pumps," *Los Angeles Times*, May 5, 2010, http://articles.latimes.com/2010/may/05/business/la-fi-pumps-20100505 (accessed Oct. 28, 2010).

55 "FDA significantly restricts access to the diabetes drug Avandia," U.S. Department of Health and Human Services, U.S. Food and Drug Administration, Sept. 23, 2010, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm226975.htm (accessed Oct. 28, 2010).

56 Marcia Crosse, "New Drug Approval: FDA Needs to Enhance Its Oversight of Drugs Approved on the Basis of Surrogate Endpoints," United States Government Accountability Office, GAO-09-866, Sept. 23, 2009, http://www.gao.gov/new.items/d09866.pdf (accessed Oct. 28, 2010).

57 Ibid.

58 Matthew Perrone, "GAO: FDA Fails to Follow Up on Unproven Drugs," *The Seattle Times*, Oct. 25, 2009, http://seattletimes.nwsource.com/html/health/2010136268_apusfdaunprovendrugs.html (accessed Oct. 28, 2010).

59 Alan M Garber, "Modernizing Device Regulation," *New England Journal of Medicine*, April 1, 2010, N Engl J Med 2010; 362:1161-1163, http://www.nejm.org/doi/full/10.1056/NEJMp1000447 (accessed Oct. 28, 2010).

The Center for Devices and Radiological Health (CDRH), the FDA office with responsibility for assuring device safety, committed in 2010 to revise its premarket approval process based on recommendations from an internal working group.[60]

The administration's most proactive food and medical product enforcement efforts have occurred around product labeling. The Federal Trade Commission (FTC) filed a complaint against Pom Wonderful pomegranate juice in September 2010 in an attempt to stop the company from making claims that the juice can help reduce the risk of heart disease or result in other positive health effects. FTC says the claims are unsubstantiated, mislead consumers, and have not been approved by the FDA.[61] FTC has also proposed rules aimed at restricting companies that advertise products as environmentally friendly.[62]

Hamburg has also made labeling a high priority for FDA. In March 2010, the agency announced it had sent warning letters to 17 companies (including Pom Wonderful) telling them that they were in violation of federal law by making misleading or false claims on product labels that could make consumers believe the foods were healthier than they really are.[63] The foods covered by the warning letters include juices and teas, nuts, baked goods, ice cream, frozen fish, cereals, olive oil, and salad dressings. The letters asked the companies to report to FDA how they intended to fix the mislabeling and warned that further action could result if companies did not respond.[64] In May 2009, FDA sent a warning letter to General Mills that states the health claims for Cheerios cereal violate federal law. General Mills' claims that Cheerios can lower cholesterol or reduce the risk of heart disease make the product subject to pharmaceutical regulations under the Federal Food, Drug, and Cosmetic Act, FDA said.[65]

The increased use of warning letters is part of a broader effort to improve enforcement at FDA. Shortly after her May 2009 confirmation, Hamburg spoke of the "steep decline" and "unreasonable delays" in the agency's enforcement efforts.[66] She outlined several ways in which internal enforcement steps will improve, including issuing warning letters or taking enforcement actions quickly if companies deemed out of compliance do not remedy problems promptly. The agency will no longer issue multiple warning letters to violators but will proceed directly to other enforcement actions. FDA also plans to rely on its partnerships with state, local, and international enforcement agencies to address problems more quickly than FDA can when public health is at risk.

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60 "Center for Devices and Radiological Health: CDRH FY 2010 Strategic Priorities," U.S. Department of Health and Human Services, U.S. Food and Drug Administration, http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHVisionandMission/UCM197648.pdf (accessed Oct. 28, 2010).

61 Edward Wyatt, "Regulators Call Health Claims in Pom Juice Ads Deceptive," *The New York Times*, Sept. 27, 2010, http://www.nytimes.com/2010/09/28/business/28pom.html (accessed Oct. 28, 2010).

62 Tanzina Vega, "Agency Seeks to Tighten Rules for 'Green' Labeling," *The New York Times*, Oct. 6, 2010, http://www.nytimes.com/2010/10/07/business/energy-environment/07green.html (accessed Oct. 28, 2010).

63 Lyndsey Layton, "FDA Warns 17 Food Companies of Misleading Claims on Labels," *The Washington Post,* March 4, 2010, http://www.washingtonpost.com/wp-dyn/content/article/2010/03/03/AR2010030303119.html (accessed Oct. 28, 2010).

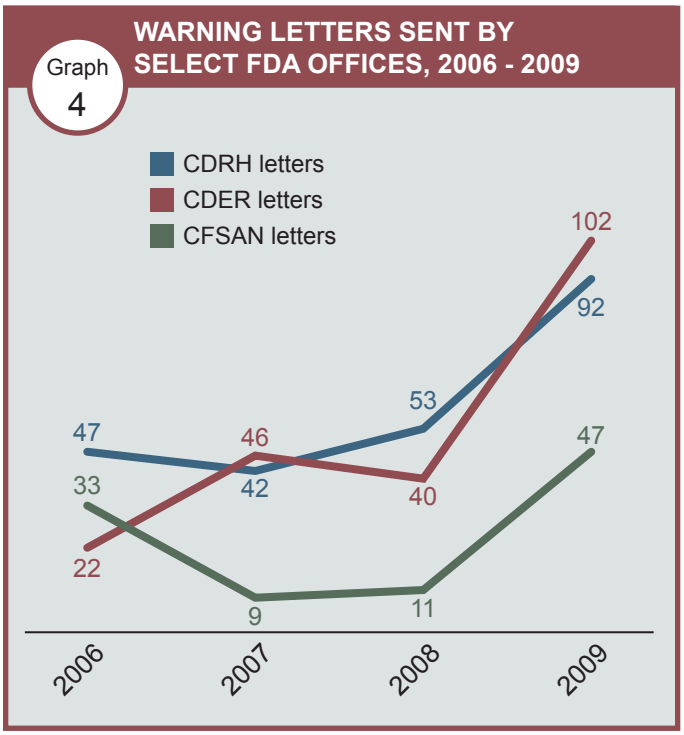
64 FDA, Warning Letters, available at http://www.fda.gov/Food/LabelingNutrition/ucm202859.htm.

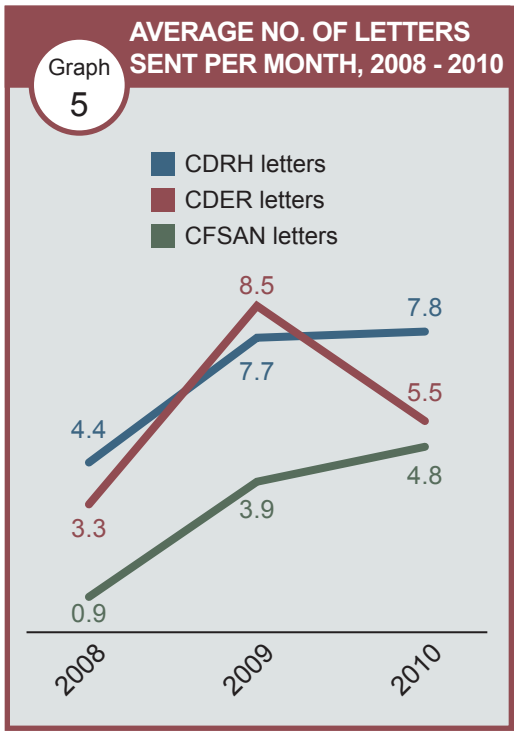
65 W. Charles Becoat, "Warning letter: Refer to MIN 09-18," U.S. Department of Health and Human Services, U.S. Food and Drug Administration, May 5, 2009, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm162943.htm (accessed Oct. 28, 2010).

66 Margaret A. Hamburg, "Effective Enforcement and Benefits to Public Health, Remarks by Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, at the Food and Drug Law Institute," U.S. Department of Health and Human Services, U.S. Food and Drug Administration, Aug. 6, 2009, http://www.fda.gov/NewsEvents/Speeches/ucm175983.htm (accessed Oct. 28, 2010).

Data indicate that FDA is using warning letters with increasing frequency. The number of warning letters issued by three FDA offices – the Center for Devices and Radiological Health (CDRH), the Center for Drug Evaluation and Research (CDER), and the Center for Food Safety and Nutrition (CFSAN) – spiked in 2009 under Hamburg and her team. (See Graph 4.) For two of those offices, CDRH and CFSAN, the trend continued through the first half of 2010, and, for the third, CDER, the number of letters issued still stands above 2008 levels. (See Graph 5.) FDA's Division of Drug Marketing, Advertising, and Communications has also increased its use of warning letters, issuing five in 2009 and seven in the first half of 2010 while issuing three, zero, and one in 2006, 2007, and 2008, respectively.[67]

FDA headquarters divisions have seen their budgets increased dramatically in recent years. Though the resource increases are not devoted solely to enforcement, they have likely assisted the agency in fulfilling enforcement responsibilities and contributed to the advances and policy shifts discussed above.





67 Warning letters are available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm. In text and in graphs 4 and 5, years run from Jan. 20 through Jan. 19, to account for presidentaial inauguration, and data for 2010 are through July 20, 2010.

Consumer product safety

CPSC continues to be challenged with implementation of the Consumer Product Safety Improvement Act (CPSIA), the landmark 2008 law that overhauled product safety, described in the first report in this series.[68] The law required CPSC to implement tough new standards for lead and phthalates in children's products, among other requirements.

Both industry and consumer protection groups have recognized the difficult position the Obama CPSC faces in implementing the law even with the additional resources Congress granted.[69] It is likely to take several years to fully implement the law.

Among the most significant challenges is the development of a public, searchable database on the safety of products that will allow the public to report unsafe products. Consumer groups support the database, arguing that it will allow outside parties and regulators to identify product defects more quickly. Many manufacturers are opposed, fearing that isolated or erroneous reports will unfairly besmirch their products.[70] The database is expected to be operational in early 2011.[71]

Where possible, the agency has taken advantage of enhanced enforcement tools provided by the CPSIA. For example, in March 2010, CPSC levied a $2 million fine against a children's products importer, Daiso, for violations of lead standards. CPSC also halted the company from importing products until it complied with court-imposed requirements.[72]

Outside of the CPSIA, the agency has been forced to deal with the fallout over contaminated drywall manufactured in China that was used in the construction of U.S. homes. The drywall has caused damage in homes, corroding metal and damaging ventilation systems, and has been linked to skin irritation and respiratory illnesses. CPSC has received thousands of complaints from consumers and continues to investigate. "To date, this has been the largest compliance investigation in agency history," according to CPSC.[73]

The drywall is only the latest in a string of contaminated products originating in China. Cognizant of the challenges posed by the rise in Chinese-made products and the heightened anxiety among consumers, CPSC has taken two significant steps to strengthen enforcement tools for imported products.

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68 Matt Madia, "The Obama Approach to Public Protection: Rulemaking," OMB Watch, September 2010, http://www.ombwatch.org/obamamidtermrulemakingreport (accessed Oct. 28, 2010).
69 Ed O'Keefe, "CPSC Making Safety Reforms During Busy Month for Recalls," *The Washington Post,* Dec. 23, 2009, http://www.washingtonpost.com/wp-dyn/content/article/2009/12/22/AR2009122203338.html (accessed Oct. 28, 2010).
70 Lorraine Gilbert, "Proposed Database 'Deficient,' Some Say; Consumer Group Comments More Favorable," Daily Report for Executives, The Bureau of National Affairs, Oct. 14, 2010, http://news.bna.com/drln/DRLNWB/split_display.adp?fedfid=18002066&vname=dernotallissues (accessed Oct. 28, 2010).
71 Inez M. Tenenbaum, "Statement of Chairman Inez M. Tenenbaum on the Commission Decision Regarding the Notice of Proposed Rulemaking on the Establishment of a Public Available Consumer Product Safety Information Database," U.S. Consumer Product Safety Commission, April 15, 2010, http://www.cpsc.gov/PR/tenenbaum04152010.pdf (accessed Oct. 28, 2010).
72 Inez M. Tenenbaum, "Consumer Federation of America Keynote Address, March 11, 2010 – Washington, DC," U.S. Consumer Product Safety Commission, March 11, 2010, http://www.cpsc.gov/pr/tenenbaum03112010.html (accessed Oct. 28, 2010).
73 "Investigation of Imported Drywall: Status Update, September 2010," U.S. Consumer Product Safety Commission, September 2010, http://cpsc.gov/info/drywall/sep2010status.pdf (accessed Oct. 28, 2010).

In April 2010, CPSC signed a memorandum of understanding with U.S. Customs and Border Protection (CBP) that will allow inspectors to better target imported products. Under the memo, CPSC has access to CBP-kept automated safety assessments of import shipments. The coordination will allow both agencies to identify risks earlier, according to CPSC Chair Inez Tenenbaum.[74]

CPSC announced in July 2009 plans to open an office in China in order to establish a more forceful overseas presence.[75] CPSC staff are working out of the U.S. Embassy in Beijing. The agency has also continued to meet with high-level Chinese regulators; Tenenbaum attended the third U.S.-China product safety summit in October 2009.[76]

The agency is trying to find new ways to reach consumers and the regulated community by expanding its use of social networking and building partnerships to help CPSC more effectively regulate more than 15,000 products. For example, in a Sept. 23 speech, Tenenbaum announced the creation of a new office of Education, Global Outreach, and Small Business Ombudsman. The office will "coordinate and provide education and outreach activities to domestic and international stakeholders, including manufacturers, retailers, resellers, small businesses, foreign governments, and consumers," according to Tenenbaum.[77] She gave no timeline for when the new office will be operational.

While CPSC has enjoyed significant budget increases starting in FY 2008, resource constraints remain a concern. In FY 2010, Obama requested a $107 million appropriation for CPSC, only about $1.6 million more than FY 2009. Congress chose to grant the agency a greater increase, to $118.2 million. In FY 2011, Obama requested another paltry increase – only $400,000. The agency plans to add 46 new full-time employees in FY 2011, bringing the staffing level to 576.[78] In FY 1976, CPSC employed 1,076 people, its historic high.[79]

Auto safety

The enforcement agenda at NHTSA has been dominated by the recalls of millions of Toyota vehicles for sudden, unintended acceleration problems. In November 2009, Toyota recalled 3.8 million vehicles, saying the accelerator pedals in the vehicles could become trapped under floor mats. (The recall was later expanded to cover more than 5 million vehicles.) Then, in January 2010, the company recalled another 2.3 million vehicles because of an internal malfunction that could cause accelerator pedals to stick. In

74 Inez M. Tenenbaum, "Memorandum of Understanding (MOU) Signing With U.S. Customs and Border Protection Commissioner Alan Bersin, Washington, DC. - April 26, 2010," U.S. Consumer Product Safety Commission, April 26, 2010, http://www.cpsc.gov/PR/tenenbaum04262010.html (accessed Oct. 28, 2010).
75 "U.S. to Monitor Product Safety in China," Associated Press, July 30, 2010, http://www.cbsnews.com/stories/2009/07/30/world/main5197405.shtml (accessed Oct. 28, 2010).
76 "3rd Biennial United States - China Consumer Product Safety Summit 2009 Wuxi, Shanghai, and Beijing China, October 21 – 26, 2009," U.S. Consumer Product Safety Commission, http://www.cpsc.gov/businfo/intl/chinasummit.html (accessed Oct. 28, 2010).
77 Inez M. Tenenbaum, "Consumer Specialty Products Association Conference Keynote Address Bethesda, MD, September 23, 2010," U.S. Consumer Product Safety Commission, Sept. 23, 2010, http://www.cpsc.gov/pr/tenenbaum09232010.html (accessed Oct. 28, 2010).
78 For budget and staffing information, see the Consumer Product Safety Commission section in "Appendix: Budget of the United States Government" for fiscal years 2010 and 2011. Final budget and staffing figures are published in volumes two years after the fiscal year. For example, final figures for FY 2009 are found in the FY 2011 budget. FY 2010 figures are estimates contained in the FY 2011 budget. Past volumes are available online at http://www.gpoaccess.gov/usbudget/browse.html.
79 For more information, see, "Product Safety Regulator Hobbled by Decades of Negligence," OMB Watch, Feb. 5, 2008, http://www.ombwatch.org/node/3599 (accessed Sept. 2, 2010).

February 2010, Toyota initiated a third recall, this time for braking problems, covering almost half of a million hybrid vehicles.

In the wake of the recalls, NHTSA came under scrutiny. The agency had, since 2003, investigated at least six complaints about unintended acceleration in Toyota vehicles but did not come to firm conclusions or take action. Toyota began announcing the recalls voluntarily after several reports of crashes involving runaway Toyota vehicles, including one in California in which an off-duty state trooper and three of his family members were killed.[80]

On Feb. 16, 2010, NHTSA announced it was investigating whether Toyota knew of the vehicles' defects well before announcing the recalls but failed to alert regulators, a violation of federal law.[81] In March, the agency, with the help of the National Academy of Sciences, continued to investigate the causes of the unintended acceleration problem.[82] Meanwhile, Toyota continues to announce other vehicle recalls, including an October 2010 recall for braking fluid leaks that covers more than 1.5 million vehicles worldwide.[83]

NHTSA possesses the authority to conduct mandatory recalls, but the agency has not ordered a recall since 1979.[84] Instead, manufacturers conduct voluntary recalls. In many cases, the manufacturers' decision is made independent of NHTSA. Of the 492 recalls announced in 2009, 340 were conducted entirely at manufacturers' discretion.[85]

By law, the maximum penalty NHTSA has the authority to issue is $16.4 million. However, before the Toyota incident, the largest penalty in NHTSA history came in 2004 when the agency fined General Motors $1 million. For several years during the Bush administration, the agency did not impose a single penalty.[86] Transportation Secretary Ray LaHood announced on April 5, 2010, that NHTSA would seek the maximum, $16.4 million penalty against Toyota. On April 19, Toyota agreed to pay the fine.[87]

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80 Soyoung Kim and John Crawley, "Toyota plans huge U.S. recall for dangerous floormats," Reuters, Sept. 30, 2009, http://www.reuters.com/article/idUSTRE58S69820090930 (accessed Oct. 28, 2010).

81 "NHTSA Launches Probe into Timeliness of Three Toyota Recalls," National Highway Traffic Safety Administration, Feb. 16, 2010, http://www.nhtsa.gov/PR/DOT-29-10 (accessed Oct. 28, 2010).

82 "U.S. Transportation Secretary Ray LaHood Announces Major Investigations to Resolve Issue of Sudden Acceleration," National Highway Traffic Safety Administration, March 30, 2010, http://www.nhtsa.gov/PR/DOT-54-10 (accessed Oct. 28, 2010).

83 Peter Whoriskey, "Toyota recalls 1.5 million vehicles for brake fluid problem," *The Washington Post*, Oct. 21, 2010, http://www.washingtonpost.com/wp-dyn/content/article/2010/10/21/AR2010102100913.html (accessed Oct. 28, 2010).

84 Subcommittee on Commerce, Trade, and Consumer Protection Staff, "Memorandum: Hearing on NHTSA Oversight," Congress of the United States, House of Representatives, Committee on Energy and Commerce, March 9, 2010, http://energycommerce.house.gov/Press_111/20100309/Briefing.Memo.2010.3.9.pdf (accessed Oct. 28, 2010).

85 Dave McCurdy, "Statement of the Alliance of Automobile Manufacturers before the Subcommittee on Commerce, Trade and Consumer Protection," Alliance of Automobile Manufacturers, March 11, 2010, http://energycommerce.house.gov/Press_111/20100311/McCurdy.Testimony.pdf (accessed Oct. 28, 2010).

86 Joan Claybrook, "Statement of Joan Claybrook, President Emeritus, Public Citizen, and Former Administrator, National Highway Traffic Safety Administration Concerning the Performance of the National Highway Traffic Safety Administration and Recommendations for Legislative Improvements Before the Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce," March 11, 2010, http://energycommerce.house.gov/Press_111/20100311/Claybrook.Testimony.pdf, hereinafter "Claybrook testimony" (accessed Oct. 28, 2010).

87 Ray LaHood, "Statement from U.S. Transportation Secretary Ray LaHood on Toyota's Agreement to Pay Maximum Civil Penalty," National Highway Traffic Safety Administration, April 19, 2010, http://www.nhtsa.gov/PR/DOT-71-10 (accessed Oct. 28, 2010).

Deficiencies in NHTSA's enforcement capabilities have been linked, in part, to budget shortfalls. While NHTSA's overall budget has grown in recent years, resources for its vehicle safety program have not. For FY 2010, Obama requested a $129.8 million appropriation for vehicle safety at NHTSA, a $2.8 million increase over FY 2009. (Congress appropriated $140.4 million.) The FY 2011 request, released during the height of the Toyota controversy, called for a $7.6 million cut for vehicle safety programs.[88] While the budget situation affects all aspects of vehicle safety regulation, enforcement programs have been impacted. In 1979, 119 employees worked in the enforcement division. That number has dropped to 57.[89]

Conclusions: Consumer product safety and health enforcement

Under Hamburg, the FDA, as a consumer product safety agency, has been the most active in terms of regulatory enforcement. The agency has been a key player, along with the FTC and other agencies, in the administration's efforts to improve and expand consumer information disclosure and strengthen oversight of potentially misleading product labeling. In this and other areas, FDA has shown a propensity to issue a greater number of warning letters than it had during the Bush administration. The agency may be leveraging the letters as an enforcement tool while it attempts to craft a prevention-focused framework. However, absent legislative reform that expands the agency's regulatory authority, a truly aggressive FDA is unlikely to emerge.

Investigations and consumer product crises have continued to dictate many day-to-day activities during the Obama administration. At FDA and FSIS, foodborne illness outbreaks continue to require the agencies' attention and likely divert resources from more proactive or preventative initiatives. At CPSC, an investigation into contaminated drywall has spanned more than a year and has ballooned into the largest in agency history.

The most significant consumer product safety incident thus far during the Obama administration has been the recall of millions of Toyota vehicles. From a public perspective, the controversy seems to have subsumed NHTSA's agenda and has highlighted deficiencies in NHTSA's regulatory authority, as well as the agency's limited application of it.

88 For budget information, see the Department of Transportation section in "Appendix: Budget of the United States Government" for fiscal years 2010 and 2011, available online at http://www.gpoaccess.gov/usbudget/browse.html.
89 Claybrook testimony.

ENVIRONMENTAL ENFORCEMENT

Much of the Obama administration's commentary and activity regarding environmental enforcement has centered on the BP-Deepwater Horizon oil spill. The disaster, which spilled at least 185 million gallons of oil into the Gulf of Mexico, is widely considered to be the worst environmental disaster in U.S. history.

Prior to the spill, President Obama was a staunch proponent of offshore drilling. On March 31, 2010, the White House announced its "comprehensive strategy for energy security."[90] A major pillar of the strategy was offshore drilling: "President Obama and Secretary Salazar announced that the Administration will expand oil and gas development and exploration on the U.S. Outer Continental Shelf (OCS) to enhance our nation's energy independence while protecting fisheries, tourism, and places off U.S. coasts that are not appropriate for development."

But the explosion at the Deepwater Horizon rig and the ensuing spill highlighted deficiencies in the process by which drilling projects are approved, as well as problems at sea, where safety inspectors proved careless and ineffective. Many of these deficiencies were found in the Department of the Interior's Minerals Management Service (MMS). One month after the spill, Interior dismantled MMS,[91] and, shortly thereafter, Obama tapped Michael Bromwich, a lawyer with a track record of reforming troubled agencies, to lead a replacement agency dubbed the Bureau of Ocean Energy Management, Regulation and Enforcement.[92]

The Obama administration's primary policy response imposed a moratorium on deepwater drilling. After Obama ordered a 30-day safety and environmental review of drilling, Interior Secretary Ken Salazar said May 6, 2010, that Interior would not approve new drilling permits until the review was complete.[93] The moratorium was extended on May 27 when Obama and Salazar announced a six-month freeze[94] then formalized on May 30 as an Interior notice to lessees.[95,96] In October 2010, Interior announced an end to the moratorium for lease holders meeting new safety and environmental standards, several weeks before

90 "Obama Administration Announces Comprehensive Strategy for Energy Security," The White House, March 31, 2010, http://www.whitehouse.gov/the-press-office/obama-administration-announces-comprehensive-strategy-energy-security (accessed Oct. 28, 2010).
91 Ken Salazar, "Order No. 3299: Establishment of the Bureau of Ocean Energy Management, the Bureau of Safety and Environmental Enforcement, and the Office of Natural Resources Revenue," Department of the Interior, May 19, 2010, http://www.boemre.gov/ooc/pdfs/DOI_pressrelease/SecretaryOrder3299.pdf (accessed Oct. 28, 2010).
92 "President Obama Announces Bromwich to Fix Oil Industry Oversight," The White House, June 15, 2010, http://www.whitehouse.gov/the-press-office/president-obama-announces-bromwich-fix-oil-industry-oversight (accessed Oct. 28, 2010).
93 "Salazar Meets with BP Officials and Engineers at Houston Command Center to Review Response Efforts, Activities," U.S. Department of the Interior, May 6, 2010, http://www.doi.gov/news/pressreleases/Salazar-Meets-with-BP-Officials-and-Engineers-at-Houston-Command-Center-to-Review-Response-Efforts-Activities.cfm (accessed Oct. 28, 2010).
94 Barack Obama, "Remarks by the President on the Gulf Oil Spill," The White House, May 27, 2010, http://www.whitehouse.gov/the-press-office/remarks-president-gulf-oil-spill (accessed Oct. 28, 2010).
95 "Interior Issues Directive to Guide Safe, Six-Month Moratorium on Deepwater Drilling," U.S. Department of the Interior, May 30, 2010, http://www.doi.gov/news/pressreleases/Interior-Issues-Directive-to-Guide-Safe-Six-Month-Moratorium-on-Deepwater-Drilling.cfm (accessed Oct. 28, 2010).
96 The original May 6 moratorium was verbal and was applied unevenly. The ensuing steps needed to be taken to accomplish the administration's goal of temporarily halting deepwater drilling. See Ari Shapiro, "Freeze On Offshore Drilling Was Verbal Order," National Public Radio, May 25, 2010, http://www.npr.org/templates/story/story.php?storyId=127114044 (accessed Oct. 28, 2010).

the ban was scheduled to expire. However, in December 2010, the administration altered its position yet again, halting lease sales in the Atlantic Ocean and in the eastern portion of the Gulf of Mexico through 2017, but allowing sales elsewhere on the OCS.[97]

Obama also created a commission to determine the cause of the spill and develop recommendations to prevent future spills. "The commission will be focused on the necessary environmental and safety precautions we must build into our regulatory framework in order to ensure an accident like this never happens again," the White House said.[98] The commission's report is due in January 2011.

Other high-profile environmental enforcement initiatives have focused on discrete issues.

- In May 2009, in response to a congressional request, the White House Council on Environmental Quality (CEQ) led an effort to develop principles for determining Clean Water Act jurisdiction in the wake of controversial court rulings that have made it more difficult for the EPA to enforce the law (discussed later in this section). A letter signed by CEQ, the U.S. Environmental Protection Agency (EPA), the Army Corps of Engineers, the Department of Agriculture, and the Department of Interior signals support for legislation amending the Clean Water Act to clarify EPA's role and strengthen the agency's hand.[99]
- Also in May 2009, Obama signed an Executive Order on Chesapeake Bay Protection and Restoration. The E.O. started a process in which states in the Chesapeake Bay watershed are developing pollution prevention plans and the EPA is exploring regulatory options.[100]
- In July 2010, Obama signed an executive order establishing a National Ocean Council. The council will implement a zoning-like approach to oceans management, taking into account ecology, commerce, and other factors to determine appropriate uses for different areas. The council will address issues affecting oceans, coasts, and the Great Lakes.[101]
- The White House linked toxic waste cleanup to its economic stimulus plans. The American Recovery and Reinvestment Act of 2009, better known as the Recovery Act, included $600 million for cleanup of sites in EPA's Superfund program, which manages dangerous hazardous waste sites.[102] In several op-eds, Vice President Biden touted the Superfund funding as an "investment."[103]

Since taking office, Obama has sent mixed messages on EPA's budget. In FY 2010, Obama proposed, and Congress approved, significant overall budget increases for the agency. However, in FY 2011, Obama proposed a minor cut to the agency's budget. (Information on agency budgets is located in the Appendix.)

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97 John M. Broder and Clifford Krauss, "U.S. Halts Plan to Drill in Eastern Gulf," *The New York Times*, Dec. 1, 2010, http://www.nytimes.com/2010/12/02/us/02drill.html (accessed Dec. 7, 2010).
98 "Weekly Address: President Obama Establishes Bipartisan National Commission on the BP Deepwater Horizon Oil Spill and Offshore Drilling," The White House, May 22, 2010, http://www.whitehouse.gov/the-press-office/weekly-address-president-obama-establishes-bipartisan-national-commission-bp-deepwa (accessed Oct. 28, 2010).
99 Nancy Sutley, et al., "Letter to Representative James Oberstar," Executive Office of the President of the United States, et al., May 20, 2009, http://transportation.house.gov/Media/file/water/ACCWA/May%2020%202009%20CWA%20Letter%20Oberstar.pdf (accessed Oct. 28, 2010).
100 Barack Obama, "Executive Order: Chesapeake Bay Protection and Restoration," The White House, May 12, 2009, http://www.whitehouse.gov/the_press_office/Executive-Order-Chesapeake-Bay-Protection-and-Restoration/ (accessed Oct. 28, 2010).
101 Barack Obama, "Executive Order: Stewardship of the Ocean, Our Coasts, and the Great Lakes," The White House, July 19, 2010, http://www.whitehouse.gov/files/documents/2010stewardship-eo.pdf (accessed Oct. 28, 2010).
102 "Superfund Program Implements the Recovery Act," United States Environmental Protection Agency, http://www.epa.gov/superfund/eparecovery/index.html (accessed Oct. 28, 2010).
103 Joe Biden, "What You Might Not Know About the Recovery," *The New York Times*, July 26, 2009, http://www.nytimes.com/2009/07/26/opinion/26biden.html (accessed Oct. 28, 2010).

With regard to environmental enforcement, Obama's budgets have requested modest increases. Although there is no single line-item in the president's budget that encompasses enforcement activities at EPA, the "Compliance and Environmental Stewardship" line under the agency's program management budget shows that Obama requested a $24 million (4.3 percent) increase in FY 2010 and a $6 million (less than one percent) increase in FY 2011.[104]

Clean water

EPA has shown signs that it is employing different strategies for clean water enforcement under the Obama administration. Several of those strategies are outlined in the agency's Clean Water Act Action Plan (originally titled the Clean Water Act Enforcement Action Plan) released in October 2009.[105] EPA's enforcement office developed the plan in response to a July 2009 request from EPA Administrator Lisa Jackson.

In the plan, EPA pledged to focus on major threats to clean water and to target major violators, improve enforcement activity in states with EPA-approved clean water plans, and require electronic reporting and other transparency measures that allow the agency to more easily link incoming data to enforcement needs.

EPA also appears to be increasing its focus on "non-point" water pollution sources. The action plan acknowledges the increasing threat non-point sources, such as feedlots, stormwater runoffs, and construction sites, pose to clean water. Traditionally, EPA's Clean Water Act (CWA) enforcement efforts have focused on "point-source" pollution – pollution from industrial plants that evokes the well-known image of a drain pipe emptying waste into a river or lake. Monitoring and controlling non-point sources poses different challenges for the agency.

The action plan commits EPA in the near-term to a greater focus on one specific non-point source – concentrated animal feeding operations (CAFOs), a type of large feedlot. "CAFOs result in a large pollution load to the environment and have been cited as an environmental justice concern in some areas," the plan states.

Evidence indicates EPA is following through on its pledge. Since October 2009, the agency has taken enforcement action against several large feedlots, generally by forcing the feedlots to apply for pollution discharge permits so that EPA may better monitor their impact on local water quality.[106] EPA has also fined feedlots that violated the terms of existing permits.[107]

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104 For the "Compliance and Environmental Stewardship" line item under the "Environmental Programs and Management" account, the FY 2010 budget request shows $586 million in FY 2010 (requested) and $562 million in FY 2009 (estimated). The FY 2011 budget request shows $619 million in FY 2011 (requested), $613 million in FY 2010 (estimated), and $572 million in FY 2009 (actual). Because the documents are budget requests, the discrepancies may stem from differences in the amount of money appropriated by Congress and/or differences in the way the funds were allocated within the agency. See, "Appendix: Budget of the United States Government" for fiscal years 2010 and 2011.

105 "Clean Water Act Action Plan," U.S. Environmental Protection Agency, Office of Enforcement and Compliance Assurance, Oct. 15, 2009, http://www.epa.gov/oecaerth/resources/policies/civil/cwa/actionplan101409.pdf (accessed Oct. 28, 2010).

106 See, for example, "Eight Beef Feedlots in Northwest Iowa Face Enforcement Actions as EPA Emphasizes Compliance with Clean Water Act," United States Environmental Protection Agency, Aug. 12, 2010, http://yosemite.epa.gov/opa/admpress.nsf/ab2d81eb088f4a7e85257359003f5339/20380c11e7bca0718525777d005514f7!OpenDocument (accessed Oct. 28, 2010).

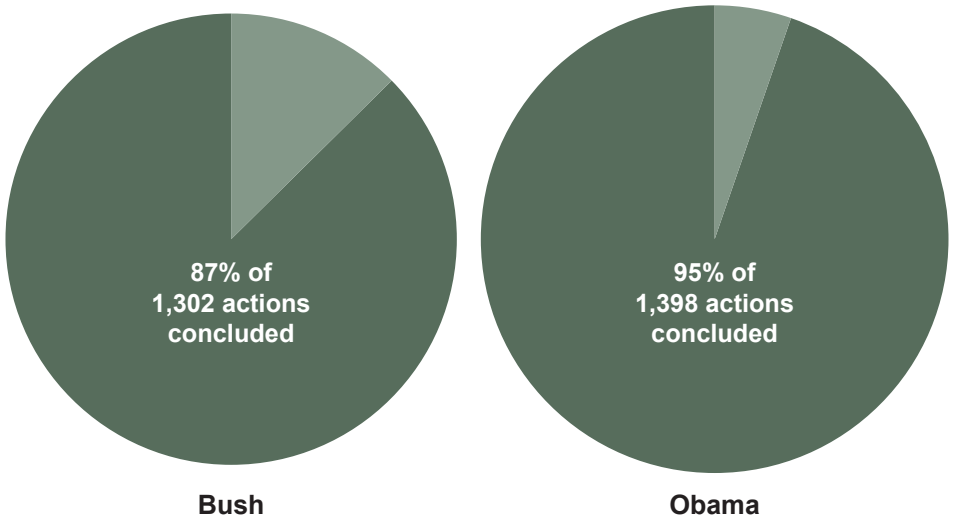
107 See, for example, the case of Bruce Feedlot at "Three Beef Feedlots in Iowa Face Civil Enforcement Actions as EPA Continues Emphasis on Compliance with Clean Water Act," United States Environmental Protection Agency, June 9, 2010, http://yosemite.epa.gov/opa/admpress.nsf/ab2d81eb088f4a7e85257359003f5339/f981d572b2a396058525773d006adef8!OpenDocument (accessed Oct. 28, 2010).

With regard to state oversight, EPA issued guidance in June 2010 to create unity among state and regional enforcement programs, ensure that water bodies in different regions receive the same level of protection, and provide all citizens with safe drinking water.[108]

While the Obama administration has opened roughly the same number of clean water enforcement actions as the Bush administration had early in its tenure, Obama's EPA has been more dogged in closing cases and penalizing CWA violators. During the first 18 months of Obama's presidency, EPA opened only slightly more formal administrative actions (an EPA order that a facility correct a violation, sometimes accompanied by a fine) against CWA violators than it had under Bush (1,398 to 1,302). However, Obama's EPA completed 95 percent of those actions, compared to Bush's 87 percent, during the 18-month period. (See Graph 6.) Obama's EPA took, on average, only nine days to complete each action, while Bush's EPA spent an average of 26 days to complete the administrative action.[109]

Graph 6

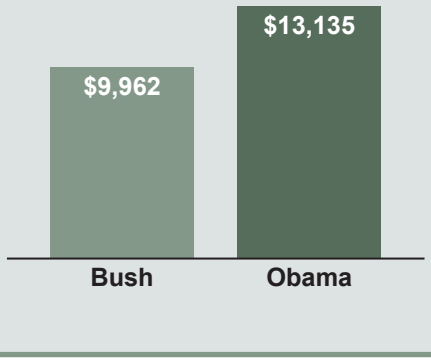
CLEAN WATER ACT VIOLATIONS IN THE FIRST 18 MONTHS OF THE ADMINISTRATION



Obama's EPA has issued penalties for serious violations at a slightly lower rate than Bush's EPA. Among those actions resolved in the first 18 months, Obama's EPA levied fines 43 percent of the time, compared to 46 percent for Bush. However, as Graph 7 shows, the average penalty has been greater under the Obama administration – $13,135 under Obama versus $9,962 under Bush, a 32 percent increase. (This includes only those cases where a penalty was assessed.)

AVERAGE PENALTY AMOUNT FOR CWA ENFORCEMENT ACTIONS IN THE FIRST 18 MONTHS OF AN ADMINISTRATION

Graph 7



108 Cynthia Giles and Peter Silva, "Memorandum: Interim Guidance to Strengthen Performance in the NPDES Program," United States Environmental Protection Agency, June 22, 2010, http://www.epa.gov/compliance/resources/policies/civil/cwa/interim-guid-npdes-062210.pdf (accessed Oct. 28, 2010).

109 Data taken from EPA's ECHO (Enforcement & Compliance History Online) Database, available at http://www.epa-echo.gov/echo/index.html. For graphs 6 and 7, 18-month periods run from Jan. 20 of the inauguration year through July 20 of the following year.

Other data show that criminal enforcement under the CWA continues to decrease under the Obama administration. According to the EPA, there were only 32 CWA convictions in FY 2010.[110] In FY 2009 (which spanned both the Bush and Obama administrations), there were 42 convictions. The number of convictions is down significantly from the late 1990s and early 2000s, when it topped 60 in multiple years.

EPA clean water enforcement efforts continue to be complicated by two U.S. Supreme Court cases, decided in 2001 and 2006. In 2001, the Court held in *Solid Waste Agency v. U.S. Army Corps of Engineers*[111] that Congress did not intend the CWA to protect "isolated ponds, some only seasonal" that were located wholly within one state, where the only asserted basis for jurisdiction was their use as habitat by migratory birds. Then in *Rapanos v. United States*,[112] decided in 2006, the Court ruled that the CWA does not apply to many wetlands, arguing that they are excluded from protection because CWA explicitly applies to "navigable" waters.

EPA has encountered numerous challenges in determining when a body of water is within its regulatory jurisdiction as a result of these decisions. One report by the Office of the Inspector General blamed the *Rapanos* ruling for a system-wide drain on resources that often forces EPA and the Army Corps of Engineers, which the ruling also impacts, to abandon enforcement actions that have a significant likelihood of facing a costly jurisdictional challenge.[113] According to the report, "CWA enforcement activities have decreased since the *Rapanos* ruling. An estimated total of 489 enforcement cases have been affected…"[114]

As a result, jurisdictional decisions have become a hot topic for the agency. For example, in July 2010, EPA claimed CWA jurisdiction over the Los Angeles River.[115] EPA's decision was hailed by community members who had been engaged in a years-long battle to obtain federal protection for the river.[116] The L.A. river designation could indicate a shift in the way that EPA determines jurisdiction over a particular water body. Rather than making its decision based purely on navigability, EPA considered other factors, like recreational and commercial uses and educational benefits to the public, among others.

Outside of CWA enforcement, EPA has also taken a significant enforcement action under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), more commonly known as Superfund. On Dec. 10, 2009, EPA announced the largest environmental bankruptcy case in U.S. history. In a settlement, EPA, along with the departments of Justice, Interior, and Agriculture, obtained $1.79 billion in a bankruptcy reorganization of American Smelting and Refining Company LLC, a copper

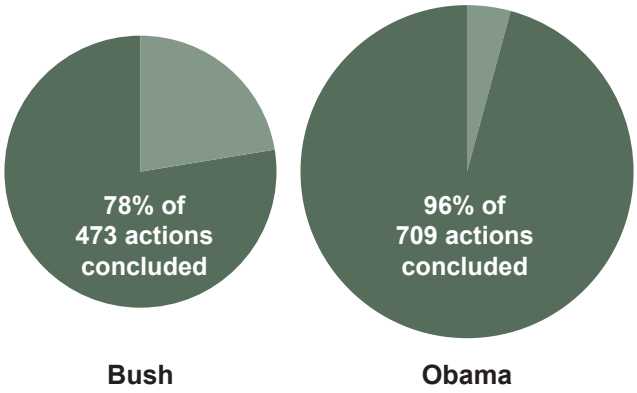
110 "Slide in EPA Clean Water Criminal Enforcement Continues Under Obama," Greenwire, Oct. 25, 2010, http://www.nytimes.com/gwire/2010/10/25/25greenwire-slide-in-epa-clean-water-criminal-enforcement-83471.html?ref=energy-environment (accessed Oct. 28, 2010).
111 *Solid Waste Agency v. Army Corps of Engineers*, 531 U.S. 159 (2001), http://www.oyez.org/cases/2000-2009/2000/2000_99_1178 (accessed Oct. 28, 2010).
112 *Rapanos v. United States*, 547 U.S. 715 (2006), http://www.oyez.org/cases/2000-2009/2005/2005_04_1034 (accessed Oct. 28, 2010).
113 Bill A. Roderick, "Congressionally Requested Report on Comments Related to Effects of Jurisdictional Uncertainty on Clean Water Act Implementation," U.S. Environmental Protection Agency, Office of Inspector General, Report No. 09-N-0149, April 30, 2009, http://www.epa.gov/oig/reports/2009/20090430-09-N-0149.pdf (accessed Oct. 28, 2010).
114 Ibid.
115 "EPA Takes Action to Strengthen Environmental and Public Health Protection for the L.A. River Basin," United States Environmental Protection Agency, July 7, 2010, http://yosemite.epa.gov/opa/admpress.nsf/0/B0963186A72DF31F85257759007150E9 (accessed Oct. 28, 2010).
116 Louis Sahagun, "L.A.'s River clears hurdle," *Los Angeles Times*, July 8, 2010, http://articles.latimes.com/2010/jul/08/local/la-me-Compton-Creek-20100708 (accessed Oct. 28, 2010).

mining giant based in Arizona. The money will fund environmental cleanup and restoration of "more than 80 sites contaminated by mining operations in 19 states," according to EPA.[117]

As with the CWA, information on enforcement cases brought under the Resource Conservation and Recovery Act (RCRA), the U.S.'s most significant waste management statute administered by EPA, shows that Obama has developed a strong record of enforcement compared to Bsuh. In its first 18 months, Obama's EPA opened a significantly higher number of enforcement cases under RCRA, 709, compared to Bush's EPA, 473, in its first 18 months. Obama's EPA completed 96 percent of those cases. Bush's EPA completed only 78 percent. (See Graph 8.) Obama's EPA took an average of six days to complete each action, compared to an average of 37 days for Bush's EPA to complete an action during the same time frame.[118]

Graph 8

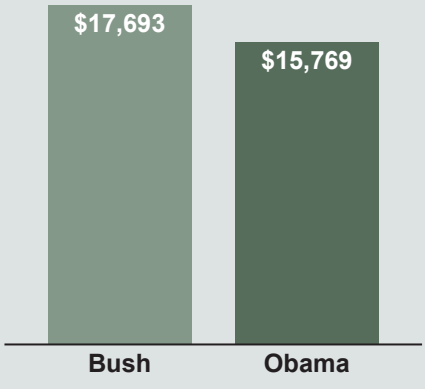
RCRA VIOLATIONS IN THE FIRST 18 MONTHS OF THE ADMINISTRATION



Under Obama, penalties issued to RCRA violators have been smaller than those issued during the Bush administration. Of the RCRA enforcement cases concluded during the first 18 months of the Obama presidency, approximately 83 percent resulted in penalties averaging $15,769 per action. During the first 18 months of Bush's first term, penalties were issued in about 75 percent of all RCRA administrative actions, averaging $17,693 per case. (See Graph 9.)

AVERAGE PENALTY AMOUNT FOR RCRA ENFORCEMENT ACTIONS IN THE FIRST 18 MONTHS OF AN ADMINISTRATION

Graph 9



117 "Largest Environmental Bankruptcy in U.S. History Will Result in Payment of $1.79 Billion towards Environmental Cleanup and Restoration / Largest recovery of money for hazardous waste clean up ever," United States Environmental Protection Agency, Dec. 10, 2009, http://yosemite.epa.gov/opa/admpress.nsf/ab2d81eb088f4a7e85257359003f5339/c40dd49b8eebe5ff85257688006c9c7f!OpenDocument (accessed Oct. 28, 2010).

118 Data taken from EPA's ECHO (Enforcement & Compliance History Online) Database, available at http://www.epa-echo.gov/echo/index.html. For graphs 8 and 9, 18-month periods run from Jan. 20 of the inauguration year through July 20 of the following year.

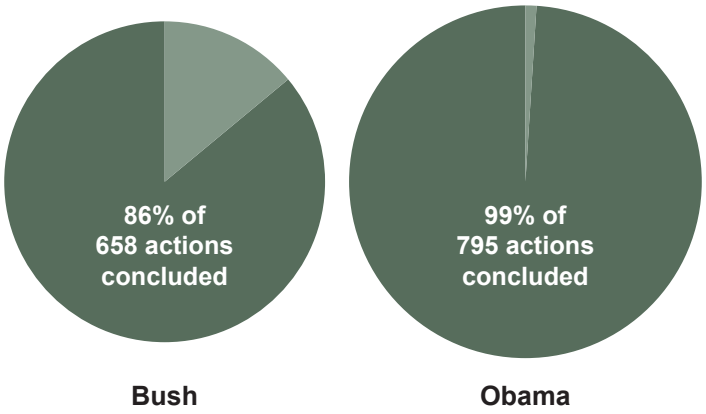
Clean air

EPA's clean air agenda has centered around rulemaking, as detailed in the first OMB Watch report in this series. However, several major enforcement actions, as well as enforcement data, should be noted.

In 2009, BP Products North America agreed in a settlement to pay $12 million for Clean Air Act (CAA) violations stemming from the 2005 explosion of a Texas refinery that killed 15 workers and injured 170 others.[119] In 2010, in a settlement with EPA, Pep Boys agreed to pay $5 million in civil penalties for importing and selling motorcycles, recreational vehicles, and generators manufactured in China that did not comply with the CAA.[120] Both fines are among the largest settlements in CAA history.

As with the Clean Water Act and RCRA, EPA has shown signs of aggressiveness in its enforcement of the Clean Air Act. Since taking office, Obama's EPA opened 795 formal administrative actions under CAA and concluded 99 percent of those actions. During Bush's first term, 658 actions were opened within the same time frame, and only 86 percent had been completed. (See Graph 10.) Obama's EPA took an average of five days to complete each action, compared to an average of 27 days spent by Bush's EPA over the same amount of time.[121]

Graph 10 **CLEAN AIR ACT VIOLATIONS IN THE FIRST 18 MONTHS OF THE ADMINISTRATION**

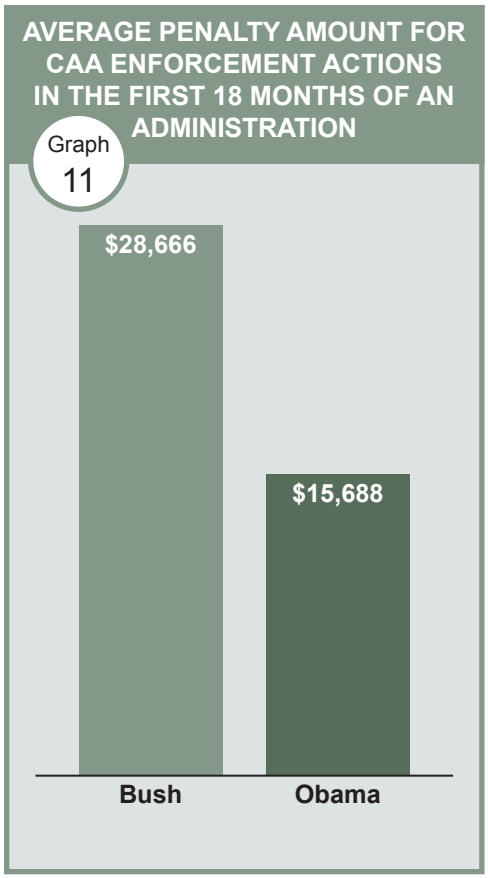


119 "BP Products to Pay Nearly $180 Million to Settle Clean Air Violations at Texas City Refinery," United States Environmental Protection Agency, Feb. 19, 2009, http://yosemite.epa.gov/opa/admpress.nsf/d985312f6895893b852574ac005f1e40/4cc2b0b1f0abd044852575620068783 7!OpenDocument (accessed Oct. 28, 2010).

120 "Pep Boys Agree to Pay $5 Million to Resolve Clean Air Act Violations Claims / Largest importation case in Clean Air Act history," United States Environmental Protection Agency, May 10, 2010, http://yosemite.epa.gov/opa/admpress.nsf/ab2d81eb088f4a7e85257359003f5339/b14a70e1f812ccb18525771f00598dd0!OpenDocument (accessed Oct. 28, 2010).

121 Data taken from EPA's ECHO (Enforcement & Compliance History Online) Database, available at http://www.epa-echo.gov/echo/index.html. For graphs 10 and 11, 18-month periods run from Jan. 20 of the inauguration year through July 20 of the following year.

Obama's EPA issued penalties in about 65 percent of all formal administrative actions under CAA in the administration's first 18 months. During the first 18 months of the Bush presidency, EPA only issued penalties in 30 percent of these actions. Although Obama's EPA issued penalties more frequently in CAA administrative actions, the average penalty amount is well below those penalties issued by Bush's EPA during the same time period – approximately $15,688 per action compared to Bush's $28,666. (See Graph 11.)



Conclusions: Environmental Enforcement

Thus far in the Obama administration, Jackson has centered much of EPA's environmental enforcement agenda on clean water issues. Of the major statutes EPA enforces, the agency has developed an enforcement action plan for only one – the Clean Water Act. While the agency has shown an increasing enthusiasm for monitoring non-point pollution sources, including large feedlots, a theme of the action plan, the plan is only in its earliest stages of implementation.

Statistics on civil enforcement actions taken under the Clean Water Act indicate that EPA has been more industrious under the Obama administration than under the Bush administration. Under Jackson, the agency has also handed out larger fines to violators. However, criminal enforcement remains stagnant.

The enforcement progress has occurred despite two Supreme Court rulings that have complicated the agency's ability to determine jurisdiction over U.S. waters. The *Rapanos* ruling has been particularly troubling, as the lack of clarity caused by the decision is diverting enforcement resources and has prevented EPA from pursuing certain cases.

Civil enforcement action data for other issues, including clean air and waste management, follow a similar course to clean water. Across the board, it appears the Obama administration is citing more environmental violators and doing so in less time than it had during the Bush administration. For clean air and waste management issues, the agency is also handing out more penalties. Increases in enforcement activity may be due in part to the infusion of resources, particularly in FY 2010.

APPENDIX

This table presents budget information for several major federal enforcement agencies. These figures represent budgets for the entire agency, with the exception of the U.S. Environmental Protection Agency, for which only the Programs Management budget line is presented. The funds are obligated for activities including but not limited to enforcement. This table is included to present the reader with a general sense of how regulatory agency budgets have fared during the Obama administration. All dollar figures are in millions. More information on the budget figures is explained on the following page.

	President Bush	President Obama		President Obama		
Agency	FY 2009, enacted	FY 2010, enacted	Change, FY '09 - '10	FY 2011, requested	Change, FY '10 - '11	Change, FY '09 - '11
Occupational Safety and Health Administration[1]	$521	$561	7.68%	$575	2.50%	10.36%
Mine Safety and Health Administration[2]	$348	$359	3.16%	$363	1.11%	4.31%
Food and Drug Administration[3]	$2,761	$3,233	17.10%	$3,743	15.77%	35.57%
Food Safety and Inspection Service[4]	$1,107	$1,140	2.98%	$1,158	1.58%	4.61%
Consumer Product Safety Commission[5]	$108	$122	12.96%	$123	0.82%	13.89%
National Highway Traffic Safety Administration[6]	$127	$140	10.24%	$133	-5.00%	4.72%
U.S. Environmental Protection Agency (programs)[7]	$2,575	$3,078	19.53%	$2,969	-3.54%	15.30%

Appendix Notes

[1] Budget authority (gross) for Salaries and Expenses account, Occupational Safety and Health Administration, Department of Labor.
[2] Budget authority (gross) for Salaries and Expenses account, Mine Safety and Health Administration, Department of Labor.
[3] Budget authority (gross) for Salaries and Expenses account, Food and Drug Administration, Department of Health and Human Services.
[4] Budget authority (gross) for Food Safety and Inspection Service account, Food Safety and Inspection Service, Department of Agriculture.
[5] Budget authority (gross) for Salaries and Expenses account, Consumer Product Safety Commission, Other Independent Agencies.
[6] Budget authority (gross) for Operations and Research account, National Highway Traffic Safety Administration, Department of Transportation.
[7] Budget authority (gross) for Environmental Programs Management account, Environmental Protection Agency.

All data is taken from "Appendix: Budget of the United States Government: Fiscal Year 2011," available online at http://www.whitehouse.gov/omb/budget/Appendix (accessed Sept. 3, 2010).

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