

April 2008

## **UCS Backgrounder**

### **Federal Scientists Need Stronger Whistleblower Protections**

Contact: Celia Wexler, 202-331-6952

After an eight-year struggle, both the House and Senate passed bills last year to strengthen protections for federal whistleblowers, giving them the right to sue if they are fired or harassed after exposing waste, fraud or abuse at their agencies. House and Senate negotiators now are working to reconcile the two whistleblower bills, and Congress may vote on the final bill as soon as next month. According to the Union of Concerned Scientists (UCS), federal employees need a strong whistleblower protection law because a series of court decisions have eroded these protections.

The House version of the Whistleblower Protection Enhancement Act contains specific protections for federal scientists who expose the suppression or distortion of federal research or technical information. According to UCS, such provisions are critical to safeguard public health and safety and should be included in the final version of the bill.

Federal government scientists play a vital role in providing policymakers data and scientific analyses to ensure they can make the best, most informed decisions about our environment, health and national security. Whether it is toy safety, drug efficacy or air quality, we count on federal agencies to use independent and unbiased science to protect us from harm.

Recent UCS surveys have found that distortion and suppression of scientific data is a widespread problem in many federal agencies. More than 1,100 of the nearly 3,400 federal scientists at nine agencies who responded to UCS questionnaires reported that they fear retaliation for openly expressing concerns about their agency's work. Muzzling scientists has real-world implications. Consider, for example, the experience of scientists in the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC) and the Interior Department whose efforts to serve the public were stymied by agency supervisors.

### **The Public Was Harmed by Unsafe Drugs**

In 2006, UCS and Public Employees for Environmental Responsibility (PEER) jointly conducted a survey of FDA scientists. Nearly 1,000 of them responded to the 38-question survey. Nearly one-fifth (145) of the respondents said that they "have been asked, for non-scientific reasons, to inappropriately exclude or alter technical information or their conclusions in a FDA scientific document." (For the full survey results, go to: [www.ucsusa.org/surveys](http://www.ucsusa.org/surveys).)

- As associate director for science and medicine at FDA's Office of Drug Safety, Dr. David Graham, conducted an exhaustive study evaluating the impact of high doses of the painkiller Vioxx on the risk of heart attacks, and concluded that high doses sharply increased the risk. In late 2004, Graham testified before the Senate Finance Committee that he had been "pressured to change my conclusions and recommendations" by FDA senior management. One senior manager called his Vioxx study a "scientific rumor," Graham said. According to the New York Times, Graham estimated that, based on his and other studies, the FDA's decision to ignore warning signs about Vioxx may have resulted in as many as 55,000 deaths. Merck, Vioxx's manufacturer, withdrew the drug from the market in late September 2004.
- When Dr. David Ross, one of the lead FDA medical reviewers for the antibiotic Ketek, raised concerns about the drug's safety, agency management discouraged and muzzled him. The agency approved the antibiotic, Ross told the House Subcommittee on Oversight and Investigations, "knowing that it could kill people from liver damage and that tens of millions of people would be exposed to it; despite FDA knowing that the drugmaker submitted fabricated data; and despite knowing that Ketek is not better than

other antibiotics and may not work.” Dr. Ross was so angered by the FDA’s actions that he left the agency. In 2007, the FDA withdrew its approval for Ketek to treat acute bacterial sinusitis and acute chronic bronchitis.

- As deputy director of the FDA’s division of Drug Risk Evaluation, Dr. Rosemary Johann-Liang recommended in February 2006 that the diabetes drug Avandia get a “black box” warning about possible heart problems related to the drug. FDA managers reprimanded Dr. Johann-Liang and not only failed to act on her recommendation, they shifted the supervision of the Avandia safety review to her boss. “They decided to act like the review never happened,” Dr. Johann-Liang told the New York Times. The FDA asked for a black box warning only after being embarrassed by a May 21, 2007, article in the New England Journal of Medicine raised similar concerns about Avandia potentially increasing the risk of heart attacks in diabetics.

### **Product Safety Information Isn’t Getting to American Families**

Last summer, the CPSC’s overdue recall of millions of toys left parents with serious concerns about the agency’s ability to protect their families from harmful products. One reason for the agency’s tardiness was its lack of staff and resources. But former and current employees also complained about the agency’s propensity to impede their scientific work. UCS interviews with current and former CPSC staff revealed the following problems:

- After trying unsuccessfully to intimidate agency hazard statisticians to change their statistical findings and conclusions, a CPSC senior manager delayed by several months the release of crucial data on injuries and fatalities caused by all terrain vehicles, data that could have helped inform parents about ATV dangers.
- The problem predates the current administration. Regardless of who is in the White House, agency employees said their research had to conform to their supervisors’ views.
- If CPSC staff research does not reflect their supervisors’ views, it is either buried on the agency Web site or left off of it altogether.
- CPSC managers often will not communicate the conclusions of individual multidisciplinary teams fully and accurately to commissioners to help them make policy decisions.
- The agency has tight restrictions on who CPSC scientific, technical and research staff can contact. Often experts working outside federal agencies, such as professors at academic institutions, are off-limits.
- It is very difficult for CPSC staff to publish their research or make their research available on the agency’s Web site. CPSC managers can take months, even years, to respond to staff requests for publishing clearance.
- Employees must sign nondisclosure agreements before leaving the agency, making them reluctant to discuss the problems they experienced, even with Congress.

### **Our Environmental Heritage is Being Compromised**

The federal government should use objective scientific information and methods to determine whether a species should be considered endangered. Losing a species not only means losing a whole class of animals or plants, it also means losing the potential to solve some of humanity’s most intractable problems, including hunger and disease. The Endangered Species Act is more than just a law -- it is the ultimate safety net in our life support system.

Last year an Interior Department inspector general investigation found numerous examples of where Julie MacDonald, then deputy assistant secretary for fish and wildlife and parks, interfered with and manipulated scientific research on species proposed for listing under the Endangered Species Act. This interference has tainted many as 50 decisions. MacDonald resigned in May 2007.

MacDonald's meddling, unfortunately, was not exceptional. A 2005 UCS survey of U.S. Fish and Wildlife Service (FWS) scientists found that pressure to alter scientific reports for political reasons had become pervasive even before MacDonald's actions came to light.

- Twenty percent of the more than 400 respondents said they have been instructed to compromise their scientific integrity, reporting that they have been "directed to inappropriately exclude or alter technical information from a FWS scientific document," such as a biological opinion.
- More than a third (42 percent) of the respondents said they could not openly express "concerns about the biological needs of species and habitats without fear of retaliation," while nearly a third (30 percent) did not feel they could do so even inside the confines of the agency.
- Nearly a third (32 percent) felt they were not allowed to do their jobs as scientists, and a significant minority (19 percent) reported they were "directed by FWS decisionmakers to provide incomplete, inaccurate or misleading information to the public, media or elected officials."

### **Why We Need Stronger Protections for Federal Scientists**

Survey results from the FDA, CPSC and FWS all indicate that we need much stronger protections for federal scientists. Currently whistleblower laws protect federal employees who report waste, fraud and "abuse of authority," but that phrase does not clearly address attempts by agency managers to distort, censor or suppress the work of federal scientists.

It should be noted that specific whistleblower protections in the House version of the pending bill would not give federal scientists the right to usurp legitimate political appointee or senior manager supervisory oversight. The provisions would protect a federal scientist whose work has been suppressed or distorted from reprisal if the scientist publicly reported such tampering.

At a time when Congress has serious concerns about an aging federal workforce, federal agencies must do all they can to retain their most experienced and skilled employees. Whistleblower protections for scientists and researchers would improve morale at federal agencies and help to retain and recruit dedicated civil servants.

Finally, unbiased fact-based data benefit far more than federal scientists and the integrity of their work. The public at large also benefits. Federally funded fact-based scientific data serves as the basis for public policy decisions and must be publicly available. When that data is kept hidden or distorted, public health and safety are at risk.

###

Formed in 1969, the Union of Concerned Scientists is the leading science-based nonprofit organization working for a healthy environment and a safer world. UCS has offices in Cambridge, Massachusetts; Berkeley, California; and Washington, D.C. For more information, go to [www.ucsusa.org](http://www.ucsusa.org).