

Voices of FDA Scientists: Measuring Progress on Scientific Integrity Frequently Asked Questions

What is new about Voices of FDA Scientists?

This survey allows us – for the first time – to directly compare the responses of FDA scientists over time and across presidential administrations. Our previous survey allowed us to understand what FDA scientists experienced in 2006, and we wanted to understand if, and how, things have changed.

The study provides insight into the changes that have taken place at the FDA over the past five years. It is clear that overall leadership has changed markedly – scientists have more respect for agency leaders, they feel more support from senior management, and overall, they believe that the agency is moving in the right direction. All our data suggests that in this context, scientists feel more confident that FDA leadership is working to improve both the agency and public health.

How do the 2011 data compare to the 2012 data?

The survey demographics are remarkably similar to our 2006 survey of FDA scientists. As in 2006, many respondents were agency veterans, nearly half had worked at the Agency for 10 years or more and nearly two-thirds worked at a level of GS-10 or higher. By coincidence, in each survey, we received responses from 997 scientists.

The 2011 data suggest that for many questions, responses are slightly more positive than in 2006. This slight uptick is both encouraging and illuminating. While it is great to see improvements in scientist morale, there are still a concerning number of scientists who report inappropriate outside influences over the agency's scientific work. Scientists report that too much corporate and political pressure still influences FDA decisions, and they express a need for FDA to improve both the transparency and accountability of agency decision-making. This suggests there is still room for improvement at the FDA.

Why is the survey in the report not a random survey?

UCS designed this survey to allow as many FDA scientists as possible to voice their concerns about political interference at their agencies. Our first priority is also to ensure that individual scientists are not associated with individual responses. For these reasons, we cast a wide net and conducted a population survey, rather than a random survey.

We received responses from 997 scientists for a response rate of 14.2 percent, which is slightly lower than response rates for our previous surveys of this kind. We attribute the lower response rate to several factors. First, the survey was administered in July and August of 2011. This time period is traditionally a time when federal workers take vacations. Second, unlike previous

surveys, due to budgetary constraints, an advance letter was not sent to participants. Third, due to scheduling complications, the survey was administered and analyzed by UCS staff.

Unlike a random survey, the self-selection of respondents and other unknown selection effects make it difficult to extrapolate our survey findings to the entire group of scientists working at the FDA. Strong numbers for morale and job satisfaction give confidence that a broad cross-section of scientists responded to the survey – not just employees with grievances. In this report, we emphasize the raw numbers of responses to the survey questions and provide percentages as a tool for comparison. Percentages are drawn from the number of scientists who responded to a particular question, as not every scientist answered every question.

Comprehensive data and methodologies can be found at www.ucsusa.org/surveys.

Has corporate and political interference impacted human health?

Whenever drug and device reviews are inappropriately subject to corporate and political influence, and not based on the facts and the science, it is more likely that unsafe drugs and devices will be permitted to be marketed. Years later, flawed defibrillators, or painkillers like Vioxx are withdrawn from the market, after unnecessarily harming or even killing tens of thousands of patients.

Is this problem unique to the FDA?

The problem is by no means confined to any one agency. Science has been distorted, manipulated, and suppressed on dozens of issues, from prescription drugs to endangered species. Interference is most common in agencies with regulatory authority such as USDA, EPA, and FDA.

This interference can take many forms – from censorship and suppression of federal science to dissemination of inaccurate science-based information to the manipulation of scientific advice. The Union of Concerned Scientists has documented scores of examples of such abuses in our [online A to Z guide to political interference in science](#) and through our [surveys of scientists at nine federal agencies](#).

Is the FDA worse than the other agencies you have surveyed?

Thousands of scientists across nine agencies have expressed concerns for the health, safety, and environment of Americans as a result of the interference and the impact it has had on their work.

Each agency has unique patterns of interference. That said, UCS surveys of federal agencies have consistently found large numbers of scientists who:

- Fear retaliation for speaking concerns about their agency’s mission-driven work outside and even inside the agency;
- Are not free to communicate their research findings to the media or the public;
- Report their research findings have been changed by political appointees both within and outside of their agency; and

- Are disheartened by the level of interference at their agency.

Scientists feel that federal science agencies could be more effective:

- 285 U.S. Fish and Wildlife Service scientists could not agree that the USFWS was effective in recovering endangered species.
- 685 scientists at the Environmental Protection Agency could not agree that the agency was moving in the right direction.
- 182 climate scientists said the research environment at their agency for climate science was worse in 2006 than in 2001.

A 2010 survey of food safety scientists at FDA and USDA found a food safety system where special interests and public officials all too often inhibit the ability of government scientists and inspectors to protect the food supply. Among the more salient findings:

- 330 respondents (27 percent) had personally experienced, either frequently or occasionally, “instances where the public health has been harmed by businesses withholding food safety information from agency investigators.” Meanwhile, 621 respondents (38 percent) agreed or strongly agreed that “public health has been harmed by agency practices that defer to business interests.”
- 301 respondents (25 percent) had personally experienced, either frequently or occasionally, “situations where corporate interests have forced the withdrawal or significant modification of [an agency] policy or action designed to protect consumers or public health.”
- 266 respondents (24 percent) had personally experienced, either frequently or occasionally, “situations where members of Congress have forced the withdrawal or significant modification of [an agency] policy or action designed to protect consumers or public health.”
- 105 respondents (10 percent) had frequently or occasionally received requests from agency decision makers to “inappropriately exclude or alter technical information or conclusions in an agency scientific document.”

What does UCS recommend to restore scientific integrity to FDA science and policy making?

FDA should fully implement its recent [scientific integrity policy](#). The agency should also seek public comment on its policy to gather further input and ideas for improving it.

- It is crucial that the FDA strengthen transparency and accountability, and ensure that FDA scientists are free to do their work and speak the truth without fear of reprisal from FDA managers. FDA has begun a transparency initiative and needs to continue to fully embrace it.
- The agency must send a clear signal that safety is its highest priority, even if that means that drug and device approvals take longer than companies would like.

- The agency must quickly finish its media policy and it should make clear to FDA scientists that they have the right to express their views to the media, even when those views do not reflect the agency's, as long as they disclose that they are speaking as individuals and not as agency representatives.
- The FDA must find as many ways as possible to let its managers know that it will punish any agency manager who retaliates against an FDA scientist who raises concerns about the safety of a particular drug or device, or who asks a scientist to suppress or alter scientific data.
- The FDA must revamp its device approval process to ensure that high-risk devices receive adequate scrutiny, and do not qualify for a much less stringent review, as it often the case now.
- The FDA must do all it can to ensure that its advisory committees, whose recommendations about drug and device safety inform agency decisions, include only those experts who do not have financial ties to the drugs and devices under review.

Congress must vote against current legislative proposals that would elevate job creation and innovation over the FDA's core mission of ensuring that drugs and devices are effective and safe. Instead, Congress should strengthen the power of the FDA to recall unsafe devices, and to compel drug companies to report to the FDA all the results of their clinical trials. Congress must defeat current legislative proposals that would weaken conflict of interest rules at the FDA. Instead, Congress should build on current FDA policies and approve the following reforms:

- No longer permit conflicted experts to participate as voting members of FDA advisory panels. Instead the FDA could permit such experts to present before the panel, and to answer questions, but not to engage in either the discussion or the vote.
- Require members to disclose any financial ties over a longer period, at least three-years.
- Require the FDA to publicly disclose all requests by FDA scientists to make presentations of their research before an advisory panel. If the FDA declines to permit a request, it must publicly disclose its reasons for denying permission.
- Require that consumer reps that participate as leaders or officers of specific patient advocacy groups must disclose the groups' source of funding.
- Engage the public in the vetting process by asking for comments from the public on a potential slate of advisory panel candidates.

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