



Voices of Scientists at FDA: Protecting Public Health Depends on Independent Science

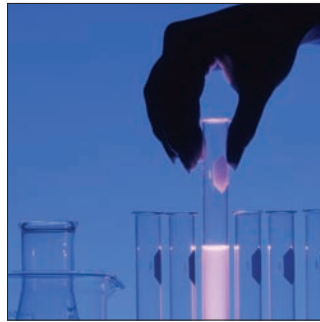
The U.S. Food and Drug Administration (FDA), now in its hundredth year, is responsible for protecting and advancing public health through the regulation of drugs, food, medical devices, cosmetics, and the blood supply—products that according to the FDA account for 25 cents of every American consumer dollar spent. The FDA mission statement calls for “helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.” Unfortunately, scientists at the agency are concerned that science no longer plays this crucial role in the FDA’s regulatory decisions.

In 2006, the Union of Concerned Scientists and Public Employees for Environmental Responsibility distributed a 38-question survey to 5,918 FDA scientists in order to

examine the state of science at the FDA. The results paint a picture of a troubled agency: hundreds of scientists reported significant interference with the FDA’s scientific work, compromising the agency’s ability to fulfill its mission of protecting public health and safety.

Independent science must be the driving force for decisions made by the FDA. Based on the survey responses from FDA scientists, it is clear that the agency needs to demonstrate a greater respect for independent science and improve both the transparency and accountability of its decisions. For this to occur, both the FDA leadership and Congress must act swiftly to pursue reforms. Without real leadership to defend impartial science, the FDA cannot do its job—with consequences for public health and safety.





Interference with Scientific Determinations at the FDA

Large numbers of agency scientists reported interference with their scientific work:

- Almost one in five (18 percent) responded, “I have been asked, for non-scientific reasons, to inappropriately exclude or alter technical information or my conclusions in an FDA scientific document.”
- More than three in five (61 percent) knew of cases in which “Department of Health and Human Services or FDA political appointees have inappropriately injected themselves into FDA determinations or actions.”
- Three in five (60 percent) also knew of cases “where commercial interests have inappropriately induced or attempted to induce the reversal, withdrawal or modification of FDA determinations or actions.” Fifty percent also felt that non-governmental interests (such as advocacy groups) had induced or attempted to induce such changes.

Negative Effect on Public Health

FDA scientists’ responses suggest that the agency’s ability to fulfill its mission—protecting public health—is being put at risk:

- Only half (51 percent) feel the “FDA is acting effectively to protect public health.”
- Less than half (47 percent) think that the “FDA routinely provides complete and accurate information to the public.”

- Less than half (49 percent) agree that “FDA leadership is as committed to product safety as it is to bringing products to the market.”

Chilling Effect on Scientific Candor

Agency scientists report being afraid to speak frankly about safety concerns and feel constrained in their roles as scientists:

- One-fifth (20 percent) say they “have been asked explicitly by FDA decision makers to provide incomplete, inaccurate or misleading information to the public, regulated industry, media, or elected/senior government officials.” In addition, more than a quarter (26 percent) feel that FDA decision makers implicitly expect them to “provide incomplete, inaccurate, or misleading information.”
- Two in five (40 percent) said they could not publicly express “concerns about public health without fear of retaliation.” More than a third (36 percent) did not feel they could do so even inside the confines of the agency.

FDA Scientists Face Immense Pressures

FDA scientists reported that they have inadequate resources to perform even the basic work of the agency. The lack of resources and other pressures have strained scientists’ morale:

- Nearly 70 percent do not believe the FDA has sufficient resources to effectively perform its mission of “protecting public health...and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.”



“Scientific discourse is strongly discouraged when it may jeopardize an approval... Whenever safety or efficacy concerns are raised on scientific grounds...these concerns are not taken seriously.”

A scientist from the Center for Drug Evaluation and Research

“The integrity of the scientific work produced by the FDA could best be improved by fostering a stronger scientific culture. Funds for research have dramatically declined in recent years...First class scientists are leaving the FDA, and recruiting new ones will be very difficult.”

“Most distressingly, there is no remaining support for or interest in SCIENCE.”

Scientists from the Center for Biologics Evaluation and Research

- Less than half (44 percent) say they “respect the integrity and professionalism of FDA leadership.”
- Two in five (40 percent) describe their morale as poor to extremely poor, while a mere four percent rate their morale as excellent.
- More than half (52 percent) say their personal job satisfaction has decreased over the past few years, while only 18 percent say their job satisfaction has increased.
- Less than a third (32 percent) think the agency “is moving in the right direction.”

Scientists Recommend Changes at the Agency

FDA scientists had strong opinions about reforms that would address some of their concerns:

- Nearly two in three (63 percent) said that the “laws and regulations that govern FDA, including the agency’s structure, need change for the agency to better serve the public.”
- More than four in five (81 percent) agreed that the “public would be better served if the independence and authority of FDA post-market safety systems were strengthened.”

“In my experience, it is never the ‘low level’ reviewers in the FDA who breach the integrity of our work. It is usually at much higher levels, such as center directors and above. Those higher levels are so far removed from the scientific work we do that politics has even more sway over their decisions....The people I work with are truly dedicated to serving the American public and doing whatever is in their power to ensure their safety.”

A scientist from the Center for Devices and Radiological Health

“The focus should truly be on protecting public health instead of catering to the interest of industry...FDA leadership should let FDA scientists do the jobs they were hired to do.”

A scientist from the Center for Veterinary Medicine

“We need more of a commitment by FDA management and the political establishment towards reversing the decline in the FDA science base...Morale is at the lowest point I’ve seen in 2+ years at the FDA. I am glad I will be eligible for retirement soon.”

A scientist from the National Center for Toxicological Research

FDA Survey Demographics

Surveys were sent to 5,918 scientists at all FDA centers, regional offices, and headquarters. Responses came from 997 scientists (17 percent), and 503 provided narrative responses. A significant majority (62 percent) were senior scientists at the General Schedule (GS) 13-15 level. Almost one-third of the scientists who responded had been with the FDA for more than 15 years, and nearly half had been with the agency for more than 11 years.

About the Survey

This survey is one in a series of surveys designed to explore the level of political interference in science at federal agencies. View full survey results, more detailed survey methodology, and excerpts from the survey essays at www.ucsusa.org/surveys.

Other Recent Reports on the FDA

Department of Health and Human Services, Office of the Inspector General, 2005. *OIG Oversight of FDA Activities; A Summary Report*.

Department of Health and Human Services, Office of the Inspector General, 2006. *FDA's Monitoring of Postmarketing Study Commitments*.

Institute of Medicine of the National Academies, in press (due out in 2006). *Assessment of the U.S. Drug Safety System*.

United States Government Accountability Office, 2006. *Improvement Needed in FDA's Postmarket Decision-making and Oversight Process*.

United States House of Representatives Committee on Government Reform, Minority Staff, 2006. *Prescription for Harm: The Decline in FDA Enforcement Activity*.

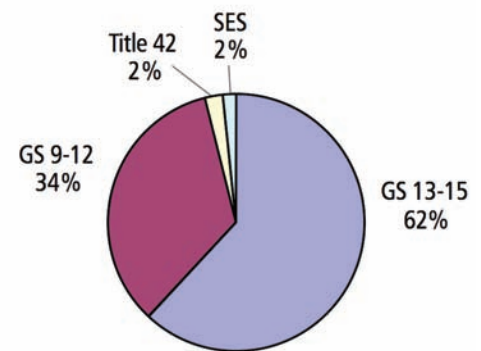
The Union of Concerned Scientists

The Union of Concerned Scientists (UCS) is a nonprofit partnership of scientists and citizens combining rigorous scientific analysis, innovative policy development, and effective citizen advocacy to achieve practical environmental and global security solutions.

The UCS Scientific Integrity Program

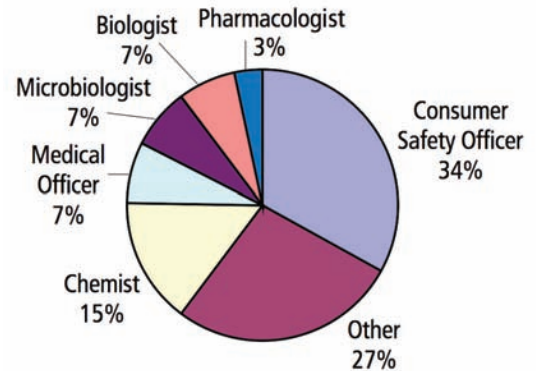
Policy makers depend on the results of independent research in order to make the informed decisions that keep us and our environment safe and healthy. The UCS Scientific Integrity Program mobilizes scientists and citizens alike to defend science from political interference and restore scientific integrity in federal policy making. To learn more, visit www.ucsusa.org/scientific_integrity.

Respondents' GS Grade Level

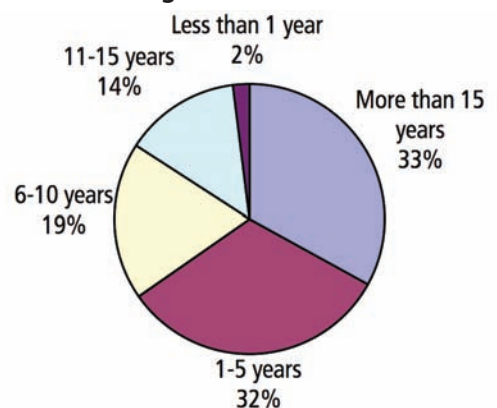


SES (Senior Executive Service): Scientists who serve in key positions just below the top presidential appointees
Title 42: Public health scientists
GS 13-15: Top-level federal employees
GS 9-12: Mid-level federal employees

Job Titles (Mailed Surveys)



Respondents' Length of FDA Service



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