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Voices of Scientists at the FDA

Measuring Progress on Scientific Integrity

The U.S. Food and Drug Administration (FDA) is responsible for protecting and advancing public health and safety through the regulation of drugs, food, medical devices, cosmetics, vaccines, veterinary products, and the blood supply—items that account for some 25 percent of American consumer spending, according to the agency. To protect the public from dangerous products and to ensure access to products that can improve or save lives, the FDA is required to rely on scientific evidence demonstrating safety and effectiveness.

In 2011, the Union of Concerned Scientists (UCS) distributed a 33-question survey to 7,043 FDA scientists in order to examine the state of science at the FDA. The survey asked many of the same questions as a 2006 UCS survey of FDA scientific staff, in which hundreds of respondents reported significant interference with the agency's scientific work.

In comparing the 2011 results with those of 2006, it is clear that the FDA has made progress toward restoring scien-

tific integrity to agency decision making, as more FDA scientists now believe that the agency is fulfilling its mission of protecting and advancing public health and safety. In 2011, 743 respondents agreed that “the FDA is acting effectively to protect public health”—an improvement of 25 percent over 2006.

However, there is room for significant improvement. For example, FDA scientists remain unsure of their right to publish research and to communicate with the press and the public. They also report a high and inappropriate level of political and commercial influence on regulatory decisions that are supposed to be exclusively evidence-based. And they cite a need for the FDA to do more to improve both the transparency and accountability of its decision making in general.

These findings suggest that systemic changes are necessary if robust science is to fully inform FDA decisions and sufficiently protect and advance public health and safety. Toward that end, both the agency's leadership and Congress should swiftly pursue reforms.



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Citizens and Scientists for Environmental Solutions



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Leadership at the FDA Is Stronger

- **FDA scientists are more confident in the agency’s future.** In the 2011 survey, 652 respondents—more than double the number in 2006—agreed that “the FDA is moving in the right direction.”
- **Scientists have more respect for overall agency leadership.** In 2011, 679 respondents agreed that they “respect the integrity and professionalism of overall FDA leadership”—a 25 percent increase over 2006.
- **Scientists also have respect for supervisors.** In 2011, 699 respondents agreed that they “respect the integrity and professionalism of the leadership at my center/office” (this question was not asked in 2006).
- **Scientists believe product safety is important to FDA leadership.** In 2011, 694 respondents agreed that “FDA leadership is as committed to product safety as it is to bringing products to the market”—a 22 percent increase over 2006.
- **Supervisors show more support for scientists pursuing potentially contentious research.** In 2011, 582 respondents agreed that their “direct supervisor stands behind scientists who put forth positions that may be controversial”—a 21 percent increase over 2006.
- **Scientists feel better supported in pursuing professional development.** In 2011, 536 respondents agreed that they are “provided appropriate time and resources to keep up with advances in [their] own profession”—an 18 percent increase over 2006.

Communication Is Discouraged or Unclear

- **Many scientists still fear retribution for sharing concerns about the FDA.** In 2011, 244 respondents felt they could not “openly express any concerns about the mission-driven work of [their] agency without fear of retaliation”—a 10 percent decrease over 2006.

- **Scientists still don’t know if they can publish work that might be considered contentious.** When asked if they were “allowed to publish work in peer-reviewed scientific journals regardless of the level of controversy of the subject,” 443 respondents answered they did not know, suggesting that the FDA should better clarify the right of scientists to publish their research—a 4 percent decrease over 2006.
- **Scientists are similarly unaware of their right to talk to the press.** 398 respondents didn’t know if they were “allowed to speak to the public and the news media about [their] scientific research findings, regardless of the level of controversy of the topic,” suggesting the need for the FDA to develop and implement a policy that enables scientists to more effectively share their expertise with a wide range of audiences.

Corporate and Political Interference Persist

- **Business interests frequently influence science-based regulatory decisions.** 214 scientists, or 25 percent of respondents, felt that business interests had “a lot of weight in the FDA’s final decisions” and 347 scientists (40 percent) thought that this influence was “too high.”
- **Political interests frequently and excessively influence science-based regulatory decisions.** 265 scientists, or 30 percent of respondents, felt that political interests had “a lot of weight in the FDA’s final decisions” and 485 scientists (55 percent) thought such influence was “too high.”
- **There is a significant revolving door.** 219 respondents had previously worked for a regulated industry or a group representing such an industry. In other words, nearly a quarter of respondents had worked for an industry they were tasked with regulating.
- **338 different scientists reported personally experiencing interference in their work at least once in the past year:**



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- 309 scientists said they “frequently” or “occasionally” experienced public health being harmed by businesses’ withholding of safety information from the agency.
- 253 scientists “frequently” or “occasionally” experienced members of Congress forcing the withdrawal or significant modification of an FDA policy or action designed to protect consumers or public health.
- 238 scientists “frequently” or “occasionally” experienced corporate interests forcing the withdrawal or significant modification of an FDA policy or action designed to protect consumers or public health.
- 196 scientists “frequently” or “occasionally” experienced nongovernmental interests (such as advocacy groups) forcing the withdrawal or significant modification of an FDA policy or action designed to protect consumers or public health.

Challenges to Science-based Decision Making Remain

- **Fewer scientists believe their expertise is fully utilized.** In 2011, 150 fewer respondents felt the FDA always, frequently, or occasionally “makes use of the best judgments of its scientific staff”—a 10 percent decrease over 2006.
- **Fewer scientists believe agency determinations are consistent with the science.** In 2011, 168 fewer respondents agreed that FDA determinations and actions are always, frequently, or occasionally “consistent with the scientific findings contained in agency documents and reports”—a 12 percent decrease over 2006.
- **Scientific uncertainty and complex issues lead to decision delays.** When asked to select the greatest barriers to timely FDA decisions, scientists most often cited scientific uncertainty or disagreement with the science, the complexity of the issue at hand, an inefficient decision-making process within the agency, and the influence of industry stakeholders.

FDA Scientists in Their Own Words

When asked what the FDA should include in a scientific integrity policy, scientists said:

“I personally believe the FDA is doing the best it can with the number of professionals it has currently. The greatest hindrance to the agency is Congress—by limiting our budget and other resources and by siding with industry on many issues.”

A scientist from the Center for Drug Evaluation and Research

“Currently I have found that managers have the last say on a subject even if they are not familiar with the subject but just because they are managers. This is ridiculous. I experience bad science decisions happening frequently and there is nothing I can do about it except leave the government.”

A scientist from the Center for Biologics Evaluation and Research

“There are a lot of good people at FDA (at all levels) but also a lot of well-meaning people who have been placed in the position of making decisions concerning matters that are outside of their experience. They do the best they can, but if the public wants an effective FDA, we need to be able to hire more people with in-depth knowledge and extensive experience.”

A scientist from the Center for Devices and Radiological Health

“Over my 40 years at FDA, science has been taking a greater and greater back seat to politics. It used to be that administrations would come and go and we could go about the business of protecting the public using scientific and legal principles. Now the lawyers and politicians seem to run the show and think they know better.”

A scientist from the Center for Food Safety and Applied Nutrition

“Overall I have been impressed with the integrity of FDA management and that is why I continue to work here.”

A scientist from the Center for Biologics Evaluation and Research

Response Rates and Demographics

In both surveys we received responses from 997 scientists, representing a 17 percent response rate in 2006 and a 14 percent response rate in 2011. The demographic and educational background distributions of respondents were nearly identical for the two surveys. The level of participation by managers was 15 percent in 2006 and 13 percent in 2011.

About the Survey

The 2011 UCS survey is the seventh in a series designed to assess the level of political interference in science at federal agencies. Past surveys in this series have polled scientists at the FDA, U.S. Department of Agriculture, U.S. Environmental Protection Agency, National Oceanic and Atmospheric Administration, and U.S. Fish and Wildlife Service. UCS has also surveyed climate scientists at multiple federal agencies across the government. To view complete survey results, excerpts of responses to essay questions, and more detailed survey methodologies, visit www.ucsusa.org/surveys. Not all 2011 questions were asked in the 2006 FDA survey, but where comparison was possible the percent change in response has been included in this report.

Other Recent Reports on the FDA

Department of Health and Human Services (HHS), Office of the Inspector General. 2011. *Review of the Food and Drug Administration's monitoring of imported food recalls*. Washington, DC.

Donaghy, T., F.T. Grifo, M. Halpern, and H. Moline. 2010. *Driving the fox from the henhouse*. Washington, DC: Union of Concerned Scientists.

Government Accountability Office (GAO). 2011. *Food and Drug Administration: Opportunities exist to better address management challenges*. Washington, DC.

Institute of Medicine. 2011. *Medical devices and the public's health: The FDA 5 10(k) clearance process at 35 years*. Washington, DC: National Academies Press.

Institute of Medicine. 2011. *A risk-characterization framework for decision-making at the Food and Drug Administration*. Washington, DC: National Academies Press.

O'Connor, A.B. 2010. Building comparative efficacy and tolerability into the FDA approval process. *Journal of the American Medical Association* 303(10):979–980.

Zuckerman, D.M., P. Brown, and S.E. Nissen. 2011. Medical device recalls and the FDA approval process. *Archives of Internal Medicine* 171(11):1006–1011.

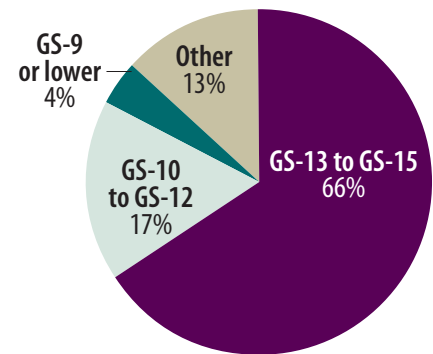
The Union of Concerned Scientists

The Union of Concerned Scientists (UCS) is the leading science-based nonprofit working for a healthy environment and a safer world.

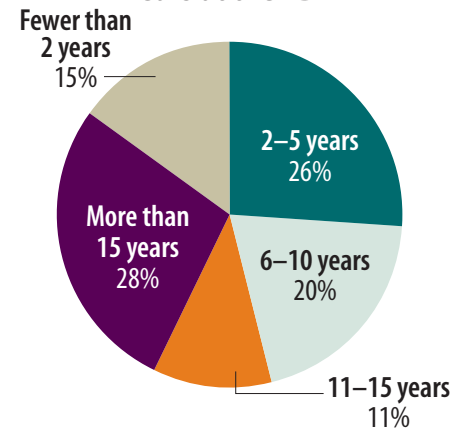
The UCS Scientific Integrity Program

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.

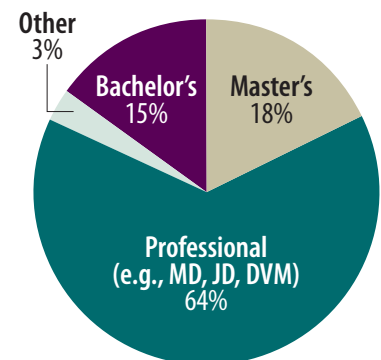
Current Grade Level



Years at the FDA



Highest Level of Education



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