Voices of Scientists at the FDA

2011 Survey of scientists at the FDA

Survey Methodology

March 7, 2012
Scientific Integrity Program
Union of Concerned Scientists
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I. Survey Design and Administration

Background
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 conducts research to illuminate political interference in the work of federal scientists and restore scientific integrity in federal policy-making.

This survey is the seventh in a series designed to assess the level of political interference at federal agencies. Since 2006, UCS has conducted mail and email surveys of scientists employed by various federal agencies, including the Food and Drug Administration (FDA), US Department of Agriculture, Environmental Protection Agency, National Oceanic and Atmospheric Administration, and the US Fish and Wildlife Service.

In 2006, UCS first surveyed scientists at the FDA to examine the state of science at the Agency. Five years later, this survey asked many of the same questions to see if, and how, things have changed. This report describes the project staff, the procedures followed for project development and data collection, and the final survey outcomes.

Project Staff
This survey was developed, administered, and analyzed by UCS Scientific Integrity staff.

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Project Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jennifer Freeman</td>
<td>Consultant</td>
<td>Sample Collection</td>
</tr>
<tr>
<td>Francesca Grifo</td>
<td>Program Director</td>
<td>Question Development, Data Analysis</td>
</tr>
<tr>
<td>Heidi Moline</td>
<td>Associate Analyst</td>
<td>Project Management, Survey Programming, Data Coordinator, Statistical Analysis</td>
</tr>
<tr>
<td>Bhavana Venkataram</td>
<td>Intern</td>
<td>Data Entry</td>
</tr>
</tbody>
</table>

Sample Design
This project was intended reach every possible scientist at the FDA, and thus should be considered a population survey. Though selecting a random sample would have been appropriate, we found it both practical and possible to attempt to survey all scientists. While it is assumed some scientists were inadvertently excluded from the survey by means of our selection criteria, efforts were made to include every Agency scientist.

The FDA's organization consists of the Office of the Commissioner and four directorates overseeing the core functions of the agency: Medical Products and Tobacco, Foods, Global Regulatory Operations and Policy, and Operations. Scientists from the following FDA centers and offices were included in the survey:

- Center for Biologics Evaluation and Research (CBER)
- Center for Devices and Radiological Health (CDRH)
- Center for Drug Evaluation and Research (CDER)
- Center for Food Safety and Applied Nutrition (CFSAN)
- Center for Tobacco Products (CTP)
To create the FDA scientist database, UCS staff referenced agency websites and identified eligible individuals through job titles and descriptions. Email addresses, first names, and titles were collected for each possible individual. Individuals were considered eligible if their job title or job description contained the following keywords:

- chemist
- biologist
- pharmacologist
- epidemiologist
- physicist
- microbiologist
- health scientist
- biomedical engineer
- veterinary
- dental officer
- bioimaging
- nutritionist
- environmental
- toxicologist
- biotechnology
- geneticist
- public health
- dietician
- optometrist
- researcher
- nurse
- molecular
- dentist
- entomologist
- staff fellow
- mathematical statistician
- scientific advisor
- animal scientist
- pharmacist

With these keyword searches, there were 7231 individuals identified as potential scientists and included in the original FDA database compiled by UCS staff. To ensure that the percentage of participants by center in our selection accurately reflected the size and composition of the centers and offices, we compared our sample composition to the distribution of Full Time Employees (FTEs) within the Agency.

### Survey Participants vs. FTEs (by Center)

<table>
<thead>
<tr>
<th>Center</th>
<th>CBEP</th>
<th>CDER</th>
<th>CDRH</th>
<th>CFSAN</th>
<th>CTP</th>
<th>CVM</th>
<th>NCTR</th>
<th>OC</th>
<th>ORA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survey Participants</td>
<td>638</td>
<td>2153</td>
<td>908</td>
<td>563</td>
<td>66</td>
<td>386</td>
<td>227</td>
<td>320</td>
<td>1970</td>
</tr>
<tr>
<td>FTEs</td>
<td>946</td>
<td>2889</td>
<td>1203</td>
<td>877</td>
<td>194</td>
<td>436</td>
<td>217</td>
<td>859</td>
<td>3895</td>
</tr>
</tbody>
</table>

### Survey Design

The questionnaire was developed in collaboration with multiple UCS staff. The definition of “scientist” or “scientific work” from an eligibility perspective was intentionally vague, as it was assumed that participants contacted for the study might interpret the survey’s application to themselves differently.

The survey was designed to be delivered by email and administered online. In an email invitation, participants were informed of the opportunity to participate and provided a unique link to take the survey. Because we tried to include as many Agency scientists as possible, we
provided an opt-out link on the survey invitation for individuals who felt they were not “scientists.”

In developing the survey, UCS staff communicated with senior FDA officials about the survey and its purposes. The director of each FDA center that was surveyed was provided with an advanced copy of the survey and encouraged to provide feedback.

II. Survey Implementation and Procedures

Survey Development and Programing
The survey was developed and administered with the survey software, NoviSurvey. UCS purchased a one-year access to NoviSurvey system in June 2011, following a period of pilot testing the software. The online survey was programmed in June of 2011 by UCS staff. The survey was tested by UCS staff and revisions were implemented as needed.

The survey could be completed in Internet Explorer or Mozilla Firefox browsers. Upon release of the survey, some participants reported some difficulty with the survey in Apple Safari. This difficulty was reported to NoviSurvey and was reported to be a limitation of the software.

The layout of the survey was designed in NoviSurvey. It was designed to promote ease of use, limit scrolling, and maximize survey completion and comprehension. The UCS logo was at the top of each page. Most questions were offered in a multiple choice format; however some were available in a matrix format, with multiple questions in a single table.

Site Security and Identity Protection
Data submitted through the online survey was stored on a secure server at the UCS Washington, DC offices. Access to the raw data on the survey development site required digital authenticated authorization and was available only to the survey administrator. Participants could not forward the link to other individuals, as access to the survey was directly linked to each individual's email address.

Each email address acted as a unique username, and could only complete the survey once, though the survey could be paused and later completed. For these purposes, email addresses of respondents were temporarily recorded by the survey platform. When the survey closed, these data were deleted by the data manager to de-identify the data.

To protect the identity of individuals in smaller centers, center-specific data was reported in aggregate for those those centers or offices with fewer than 50 responses.

Data Collection Procedure
The survey was sent to 7231 FDA email addresses and was open for one month. After accounting for bounce backs and self-identified non-scientists, the final sample included 7043 FDA employees. Each participant was emailed an invitation to participate in the survey from the email address of Francesca Grifo, Director of the UCS Scientific Integrity Program. The email explained the purpose and procedures, and underscored the confidential and voluntary nature of
the survey. In addition to an overview of the survey, it included a link to the survey website, a link for non-scientists to opt-out of the survey, and a link to previous UCS surveys. Contact information was provided for UCS staff, and recipients were encouraged to contact project staff if they had questions or felt they had been contacted in error.

<table>
<thead>
<tr>
<th>Contact Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Type</td>
</tr>
<tr>
<td>Email Invitation</td>
</tr>
<tr>
<td>Email Reminder</td>
</tr>
<tr>
<td>Email Reminder</td>
</tr>
<tr>
<td>Survey Closed</td>
</tr>
</tbody>
</table>

The first invitation was sent to participants on July 19, 2011. Following this invitation, 79 emails bounced back to the survey coordinator as “undeliverable.” One week later, a reminder email was sent to individuals who had not responded. A second reminder email was sent after an additional week. The survey was closed August 17, 2011, with an open operating time of approximately one month.

Throughout the data collection period, respondents were allowed to access their survey as often as they wished until their surveys were completed. Because the unique username allowed for retrieval of partially completed surveys, the email addresses of respondents were temporarily recorded by the survey platform. When the survey closed, these data were deleted by the data manager to de-identify the data. To ensure that each individual completed the survey only once, email addresses of respondents were temporarily recorded by the survey software. The email addresses associated with partially completed surveys were deleted at the close of the survey.

UCS staff received 3 calls from individuals with questions about the survey. Sixty-three scientists sent emails refusing to participate in the survey and requested to be removed from the reminder list. An additional 109 individuals clicked on the opt-out link because they were not scientists.

**III. Survey Process Outcomes and Response Rates**

The final data are itemized in Table 4 below. Upon sending out the survey to an initial sample of 7231 email addresses, 188 individuals were classified as ineligible, 79 email addresses bounced back and were found to be inactive accounts; an additional 109 scientists selected an opt-out option because they were not scientists. This resulted in a final eligible sample of 7043.

There was no response from 5983 individuals. Sixty-three individuals sent an email back to Dr. Grifo refusing to participate in the survey. Partial surveys were completed by 173 employees. Completed surveys, defined as completed through required questions (essay questions were not required), were received from 824 employees. The total number of surveys included in the response data is 997.
When adjusted for emails that were no longer active and for non-scientists, the total response rate was 14.2%. The range of the response rate by center and office varied, with the highest response rate from NCTR (23.7%) and the lowest from CMV (8.1%).

### Final Dispositions and Response Rates

<table>
<thead>
<tr>
<th></th>
<th>CBER</th>
<th>CDER</th>
<th>CDRH</th>
<th>CFSAN</th>
<th>CTP</th>
<th>CVM</th>
<th>NCTR</th>
<th>OC</th>
<th>ORA</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial Sample</strong></td>
<td>638</td>
<td>2153</td>
<td>908</td>
<td>563</td>
<td>66</td>
<td>386</td>
<td>227</td>
<td>320</td>
<td>1970</td>
<td>7231</td>
</tr>
<tr>
<td>Non-scientists/Bounce back</td>
<td>10</td>
<td>71</td>
<td>19</td>
<td>11</td>
<td>0</td>
<td>14</td>
<td>8</td>
<td>18</td>
<td>37</td>
<td>188</td>
</tr>
<tr>
<td><strong>Final Sample</strong></td>
<td>628</td>
<td>2082</td>
<td>889</td>
<td>552</td>
<td>66</td>
<td>372</td>
<td>219</td>
<td>302</td>
<td>1933</td>
<td>7043</td>
</tr>
<tr>
<td>Refusals</td>
<td>12</td>
<td>22</td>
<td>6</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>15</td>
<td>63</td>
</tr>
<tr>
<td>Non-Response</td>
<td>532</td>
<td>1756</td>
<td>731</td>
<td>454</td>
<td>55</td>
<td>342</td>
<td>167</td>
<td>256</td>
<td>1753</td>
<td>5983</td>
</tr>
<tr>
<td><strong>Respondents</strong></td>
<td>96</td>
<td>326</td>
<td>158</td>
<td>98</td>
<td>11</td>
<td>30</td>
<td>52</td>
<td>46</td>
<td>180</td>
<td>997</td>
</tr>
<tr>
<td>Partial Surveys</td>
<td>16</td>
<td>55</td>
<td>15</td>
<td>14</td>
<td>3</td>
<td>8</td>
<td>12</td>
<td>12</td>
<td>28</td>
<td>173</td>
</tr>
<tr>
<td>Complete Surveys</td>
<td>80</td>
<td>271</td>
<td>143</td>
<td>84</td>
<td>8</td>
<td>22</td>
<td>40</td>
<td>34</td>
<td>152</td>
<td>824</td>
</tr>
<tr>
<td><strong>Response Rate</strong></td>
<td>15.3%</td>
<td>15.7%</td>
<td>17.8%</td>
<td>17.8%</td>
<td>16.7%</td>
<td>8.1%</td>
<td>23.7%</td>
<td>15.2%</td>
<td>9.3%</td>
<td>14.2%</td>
</tr>
</tbody>
</table>
APENDIX A: FDA Organization
APENDIX B: Survey Invitation email

July 19, 2011

Dear FDA Scientist,

The Union of Concerned Scientists (UCS) is conducting a web survey of nearly 7500 scientists working in the seven Centers and two Offices at the U.S. Food and Drug Administration (FDA). With your help, we hope to better understand the role of science and government oversight in protecting public health. This survey is a follow-up to a 2006 FDA survey and is part of a broad effort to examine how public agencies conduct and use science in decision-making in order to better serve the American public.

The survey is an opportunity for the voice of FDA scientists to be a part of policy debates that may impact your work. Please complete the survey on your personal time, no later than Friday, July 29. It should take about 10 minutes.

To complete the survey, please click on the following link: Survey of FDA Scientists

If your job duties DO NOT involve science, click the following link to decline this survey: My job does not involve science. (Note: Scientific work may include but is not limited to, basic research, laboratory testing, data collection, risk assessment, veterinary medicine, economic analysis, science policy, and other topics)

UCS maintains strict security procedures to ensure the anonymity of survey respondents. IP addresses will not be collected. Any connection between your personal information and your survey responses will be kept completely confidential and will be destroyed within 24 hours of completion of the survey.

Your participation in this project is voluntary. You may end the survey at any point and you may decline to answer any questions. If you choose to, you will be able to stop the survey and resume later, however the survey may only be completed once.

Your participation is extremely important since a high response rate is essential to high quality data. Results in aggregate form will be made available online (see below) and may also be provided to executive branch officials, Congress, members of academia, and the media.

To view the results of this survey or previous UCS surveys, see www.ucsusa.org/surveys. If you have questions about the results or goals of this survey, please contact me at (202) 331-5446 or fgrifo@ucsusa.org.

Thank you in advance for your important and highly valued contribution to this research!

Sincerely,

Francesca Grifo
Senior Scientist & Director
Union of Concerned Scientists
APENDIX C: Survey

FDA Survey of Scientists ---- Final Template

Thank you for taking the time to complete this survey!

UCS maintains strict security procedures to ensure the anonymity of survey respondents. You may end the survey at any point and you may decline to answer any questions. IP addresses will not be collected. Any connection between your personal information and your survey responses will be kept completely confidential and will be destroyed within 24 hours of completion of the survey. To ensure confidentiality, Centers that have fewer than 50 respondents will not be included in stratified results.

Scientists from the following FDA Centers and Offices have been asked to complete this survey:

- Center for Biologics Evaluation and Research
- Center for Devices and Radiological health
- Center for Drug Evaluation and Research
- Center for Food Safety and Applied Nutrition
- Center for Tobacco Products
- Center for Veterinary Medicine
- National Center for Toxicological Research
- Office of the Commissioner

If you have any questions regarding this survey, contact:

Dr. Francesca Grifo
Senior Scientists & Director
Scientific Integrity Program
Union of Concerned Scientists
(202) 331-5446
fgrifo@ucsusa.org
Mission

1. Overall, the FDA has sufficient resources to effectively perform its mission of "protecting the public health... and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health." [Excerpt from full FDA mission statement]
   ○ Strongly Agree
   ○ Agree
   ○ Don't Know
   ○ Disagree
   ○ Strongly Disagree

2. The Center/Office where I work has the resources it needs to meet its role in fulfilling the mission of FDA.
   ○ Strongly Agree
   ○ Agree
   ○ Don't Know
   ○ Disagree
   ○ Strongly Disagree

3. The FDA is acting effectively to protect public health.
   ○ Strongly Agree
   ○ Agree
   ○ Don't Know
   ○ Disagree
   ○ Strongly Disagree

4. The FDA is moving in the right direction.
   ○ Strongly Agree
   ○ Agree
   ○ Don't Know
   ○ Disagree
   ○ Strongly Disagree
FDA Survey of Scientists ---- Final Template

Management

5. I respect the integrity and professionalism of the leadership at my Center/Office.
   - Strongly Agree
   - Agree
   - Don't Know
   - Disagree
   - Strongly Disagree

6. I respect the integrity and professionalism of overall FDA leadership.
   - Strongly Agree
   - Agree
   - Don't Know
   - Disagree
   - Strongly Disagree

7. FDA leadership stands behind agency employees or managers who make decisions that may be controversial.
   - Strongly Agree
   - Agree
   - Don't Know
   - Disagree
   - Strongly Disagree

8. My direct supervisor stands behind scientists who put forth positions that may be controversial.
   - Strongly Agree
   - Agree
   - Don't Know
   - Disagree
   - Strongly Disagree

9. The FDA offers opportunity for advancement based on scientific expertise, not just on administrative and supervisory expertise.
   - Strongly Agree
   - Agree
   - Don't Know
   - Disagree
   - Strongly Disagree
FDA Survey of Scientists ---- Final Template

Management

5. I respect the integrity and professionalism of the leadership at my Center/Office.
   - Strongly Agree
   - Agree
   - Don't Know
   - Disagree
   - Strongly Disagree

6. I respect the integrity and professionalism of overall FDA leadership.
   - Strongly Agree
   - Agree
   - Don't Know
   - Disagree
   - Strongly Disagree

7. FDA leadership stands behind agency employees or managers who make decisions that may be controversial.
   - Strongly Agree
   - Agree
   - Don't Know
   - Disagree
   - Strongly Disagree

8. My direct supervisor stands behind scientists who put forth positions that may be controversial.
   - Strongly Agree
   - Agree
   - Don't Know
   - Disagree
   - Strongly Disagree

9. The FDA offers opportunity for advancement based on scientific expertise, not just on administrative and supervisory expertise.
   - Strongly Agree
   - Agree
   - Don't Know
   - Disagree
   - Strongly Disagree
FDA Survey of Scientists ---- Final Template

Professionalism & Candor

10. I am provided appropriate time and resources to keep up with advances in my profession.
   - [ ] Strongly Agree
   - [ ] Agree
   - [ ] Don't Know
   - [ ] Disagree
   - [ ] Strongly Disagree

11. Currently, I can openly express any concerns about the mission-driven work of my agency without fear of retaliation.
    - [ ] Strongly Agree
    - [ ] Agree
    - [ ] Don't Know
    - [ ] Disagree
    - [ ] Strongly Disagree

12. Currently, I am allowed to publish work in peer-reviewed scientific journals regardless of the level of controversy of the topic.
    - [ ] Strongly Agree
    - [ ] Agree
    - [ ] Don't Know
    - [ ] Disagree
    - [ ] Strongly Disagree

13. Currently, I am allowed to speak to the public and the news media about my scientific research findings, regardless of the level of controversy of the topic.
    - [ ] Strongly Agree
    - [ ] Agree
    - [ ] Don't Know
    - [ ] Disagree
    - [ ] Strongly Disagree
FDA Survey of Scientists ---- Final Template

Direction

14. FDA leadership is as committed to product safety as it is to bringing products to the market.
   ○ Strongly Agree
   ○ Agree
   ○ Don't Know
   ○ Disagree
   ○ Strongly Disagree

15. The current level of independence and authority of FDA post-market product safety systems sufficiently serves the public.
   ○ Strongly Agree
   ○ Agree
   ○ Don't Know
   ○ Disagree
   ○ Strongly Disagree

16. In your opinion, what are the greatest barriers to timely Agency decisions? (Select up to 3)
   ○ Reluctance of leadership to make a decision
   ○ Uncertainty or disagreement with the science
   ○ Influence of industry stakeholders
   ○ Influence of other agencies or the Administration
   ○ Inefficient decision-making process within the Agency
   ○ Potential discrepancy with existing rules or regulations
   ○ Uncertainty of Agency jurisdiction
   ○ Complexity of the issue
   ○ Other

Comments?
Science

17. The FDA collects the scientific and monitoring information needed to effectively meet its mission.
   - Always
   - Frequently
   - Occasionally
   - Seldom
   - Never
   - Don't Know

18. FDA scientific documents and reports make use of the best judgment of its scientific staff.
   - Always
   - Frequently
   - Occasionally
   - Seldom
   - Never
   - Don't Know

19. FDA determinations and actions are consistent with the scientific findings contained in agency documents and reports.
   - Always
   - Frequently
   - Occasionally
   - Seldom
   - Never
   - Don't Know

20. Expert advice from scientific advisory committees is heeded and incorporated into regulatory decisions.
   - Always
   - Frequently
   - Occasionally
   - Seldom
   - Never
   - Don't Know
FDA Survey of Scientists ---- Final Template

Outside Influence

21. In making policy or regulatory decisions that impact public health, many factors may be considered by Agency decision makers. On the scale below, please indicate how much weight you think each of the following factors has in the FDA's final decisions.

<table>
<thead>
<tr>
<th></th>
<th>No Weight</th>
<th>Little Weight</th>
<th>Some Weight</th>
<th>A Lot of Weight</th>
<th>Don't Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Political Interests</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consumer Interests</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Business Interests</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

22. In your opinion, how appropriate is the level of consideration of these factors at the FDA?

<table>
<thead>
<tr>
<th></th>
<th>Too Low</th>
<th>About Right</th>
<th>Too High</th>
<th>Don't Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Political Interests</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consumer Interests</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Business Interests</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
FDA Survey of Scientists ---- Final Template

Outside Influence

23. In the past year, how often have you experienced instances where:

<table>
<thead>
<tr>
<th></th>
<th>Frequently</th>
<th>Occasionally</th>
<th>Seldom</th>
<th>Never</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public health has been harmed by businesses withholding safety information from the agency?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corporate interests have forced the withdrawal or significant modification of a FDA policy or action designed to protect consumers or public health?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-governmental interests (such as advocacy groups) have forced the withdrawal or significant modification of a FDA policy or action designed to protect consumers or public health?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Members of Congress have forced the withdrawal or significant modification of a FDA policy or action designed to protect consumers or public health?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FDA decision makers made requests to inappropriately exclude or alter technical information or conclusions in a FDA scientific document?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selective or incomplete use of data was used to justify a specific regulatory outcome?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Changes or edits were made during review that altered the meaning of scientific findings without providing a meaningful opportunity to correct them?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
FDA Survey of Scientists —— Final Template

Outside Influence
Several forms of political interference in science are listed below. Some of these were addressed in the questions you have just completed. Please refer to the list below when answering the following question.

- Inappropriate influence in scientific decisions by political appointees from your or other agencies
- Inappropriate influence by commercial, non-governmental, or advocacy interests
- Direction to provide incomplete, inaccurate, or misleading information to the public
- Direction to exclude or alter technical information in an agency scientific document
- Selective or incomplete use of data to justify specific regulatory outcomes
- Pressure to ignore impacts of a regulation on specific populations
- Changes or edits during review that change the meaning of scientific findings
- Disappearance or unusual delay in the release of scientific information
- New or unusual administrative requirements that impair scientific work
- Statements by agency officials that misrepresent scientists' findings
- Requests to consider data or use methods that are not scientifically credible or appropriate

24. How many activities or situations like those listed above have you personally experienced during the past year?
- None
- 1-5
- 6-10
- 11-20
- More than 20
- Not Applicable

25. How many activities or situations like those listed above have you heard about during the past year?
- None
- 1-5
- 6-10
- 11-20
- More than 20
- Not Applicable

26. If you compare the past two years to the 5-year period before it, would you say activities or situations like those listed above are occurring:
- Less often than before
- About the same as before
- More often than before
- Unsure
- Not applicable
Center-Specific Questions

27. Have you ever been pressured to approve or recommend approval for an NDA despite reservations about the safety, efficacy, or quality of the drug?
   - Yes
   - No
   - Not Applicable

28. How confident are you that CDER’s final decisions adequately assess the safety of a drug?
   - Very Confident
   - Somewhat Confident
   - Not Confident
   - Not at all Confident
   - Don’t Know

29. How confident are you that FDA adequately monitors the safety of prescription drugs once they are on the market?
   - Very Confident
   - Somewhat Confident
   - Not Confident
   - Not at all Confident
   - Don’t Know
FDA Survey of Scientists ---- Final Template

Demographics

30. My current position at FDA is:
   ○ Management
   ○ Non-management

31. What is your current grade level?
   

32. What is the highest level of education you have completed?
   

33. How long have you been working at FDA?
   ○ Less than 2 years
   ○ 2-5 years
   ○ 6-10 years
   ○ 11-15 years
   ○ more than 15 years

34. Have you ever worked for regulated industry or a group representing them?
   ○ Yes
   ○ No

35. How many years did you work for a regulated industry or a group representing them?
   ○ Less than 2 years
   ○ 2-5 years
   ○ 6-10 years
   ○ 11-15 years
   ○ More than 15 years
FDA Survey of Scientists ---- Final Template

Comments
Comments are limited to 2000 characters. If you need more space, please use the additional comment box at the end of the page.

36. The FDA could best improve the public's health by:

37. The FDA is currently drafting a Scientific Integrity Policy. What is the most important factor that you believe should be included in that policy?

38. Do you have any other comments you would like to make?

39. Additional comment space.
APENDIX D: Center-Specific Survey Questions

CBER

Survey of FDA Scientists: Center for Biologics Evaluation and Research

CBER Questions

27. Have you ever been pressured to approve or recommend approval for a product despite reservations about the safety, efficacy, or quality of the product?
   ○ Yes
   ○ No
   ○ Not Applicable

28. How confident are you that CBER's final decisions adequately assess the safety of a product?
   ○ Very Confident
   ○ Somewhat Confident
   ○ Not Confident
   ○ Not at all Confident
   ○ Don't Know

29. How confident are you that FDA adequately monitors the safety of biological products once they are on the market?
   ○ Very Confident
   ○ Somewhat Confident
   ○ Not Confident
   ○ Not at all Confident
   ○ Don't Know
CDER

Survey of FDA Scientists: Center for Drug Evaluation and Research

CDER Questions

27. Have you ever been pressured to approve or recommend approval for a New Drug Application (NDA) despite reservations about the safety, efficacy, or quality of the drug?
   ○ Yes
   ○ No
   ○ Not Applicable

28. How confident are you that CDER’s final decisions adequately assess the safety of a drug?
   ○ Very Confident
   ○ Somewhat Confident
   ○ Not Confident
   ○ Not at all Confident
   ○ Don’t Know

29. How confident are you that FDA adequately monitors the safety of prescription drugs once they are on the market?
   ○ Very Confident
   ○ Somewhat Confident
   ○ Not Confident
   ○ Not at all Confident
   ○ Don’t Know
CDRH

Survey of FDA Scientists: Center for Devices and Radiological Health

CDRH Questions

27. Have you ever been pressured to approve or recommend approval for a device or product despite reservations about the safety, efficacy, or quality of the product?
   - Yes
   - No
   - Not Applicable

28. How confident are you that the decisions about substantial equivalence made by leadership are based on valid scientific and clinical evidence?
   - Very Confident
   - Somewhat Confident
   - Not Confident
   - Not at all Confident
   - Don’t Know

29. How confident are you that the decisions about device safety and effectiveness made by leadership are based on valid scientific and clinical evidence?
   - Very Confident
   - Somewhat Confident
   - Not Confident
   - Not at all Confident
   - Don’t Know

30. Overall, how confident are you that CDRH’s final decisions adequately assess the safety of a device or product?
   - Very Confident
   - Somewhat Confident
   - Not Confident
   - Not at all Confident
   - Don’t Know

31. How confident are you that FDA adequately monitors the safety of devices or radiologic products once they are on the market?
   - Very Confident
   - Somewhat Confident
   - Not Confident
   - Not at all Confident
   - Don’t Know
Survey of FDA Scientists: Center for Food Safety and Applied Nutrition

CFSAN Questions

27. The FDA has adequate resources to fully implement the Food Safety Modernization Act.
   - Strongly Agree
   - Agree
   - Don't Know
   - Disagree
   - Strongly Disagree

28. How confident are you that the FDA adequately protects the consumer from foodborne illness associated with the following foods?

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