



2011 Survey of FDA Scientists

Essay Excerpts

There were three essay questions on the survey which provided the opportunity for scientists to express their concerns and praise in their own words.

Essay #1: As with our previous surveys, we provided an open ended comment question at the end of the survey.

Essay #2: We also asked a question specifically about what the Agency could do to further protect the public's health.

Essay #3: In addition to the traditional open-ended comments, we asked a question directly related to the Agency's Scientific Integrity Policy. At the time the survey was administered the FDA was developing this policy in response to a directive from the President's Office of Science and Technology Policy, and we wanted to see if scientists knew the policy was in development and what they would like to see in it.

Question #16: Question #16 was asked for the first time on this survey, and was designed as a pilot question to get a sense of barriers to decision-making at the Agency. For this reason, we provided possible answers, but also allowed scientists to offer their own suggestions of reasons we might have overlooked.

In an effort to ensure anonymity, center-specific and office-specific results were only presented for those that had more than 50 responses. For this reason, results from the Office of the Commissioner, the Center for Tobacco Products, and the Center for Veterinary Medicine have been combined and presented together.

Acronyms

CBER	Center for Biologics Evaluation and Research
CDRH	Center for Devices and Radiological Health
CDER	Center for Drug Evaluation and Research
CFSAN	Center for Food Safety and Applied Nutrition
CTP	Center for Tobacco Products
CVM	Center for Veterinary Medicine
NCTR	National Center for Toxicological Research
ORA	Office of Regulatory Affairs
OC	Office of the Commissioner

Updated: March 6, 2012



Essay #1: “Do you have any other comments you would like to make?”

Management and Scientist Development Concerns

“There is a serious trend in some disciplines in CDER to overlook the complexity of science as it applies to drug development, to assume that we have complete knowledge of how the human body works and to latch onto simplistic theories and explanations to make safety problems go away. CDER needs leadership that understands that this is happening and that is capable of and willing to take appropriate action to reverse the trend and return the center to scientific integrity.”

– *CDER Scientist*

“In general, the FDA is a wonderful place to work, has a high level of scientific acumen, but leadership can be blind to the real issues.”

– *CDER Scientist*

“Subtle pressure from leadership is very difficult to quantify and regulate, but it exists and is a problem. I am frequently told that senior management 'doesn't want to have to deal with a dispute' and am therefore subtly pressured to make a favorable decision (to industry). I have several times been required to provide a special briefing to management if I believe a product should not be approved - this has never been required when I recommend approval. This adds stress and takes away from already limited time to do my job, and is a subtle form of pressure that always seems to go in the direction of drug approval.”

– *CDER Scientist*

“I think the 'drugs' side of FDA is well-respected and recognized, but not the same for the 'foods'. Much more needs to be spent on food regulation!!”

– *CDER Scientist*

“FDA is a great place to work.”

– *CDRH Scientist*

“In another situation I was aware that there was some public pressure to approve another product (in CBER) but the review team recommended against approval and the product was not initially approved despite a lot of public outcry. Subsequently additional data was submitted, we recommended approval, and the product is now licensed. Overall I have



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

– *CBER Scientist*

“Give those who come to work everyday, those who work in the labs, those who are committed to making things happen in order to provide quality scientific data; give those people the cost of living increases and awards that they deserve.”

– *NCTR Scientist*

“The agency should somehow begin a major program to update technology in all field laboratories. The agency needs to establish a culture of collaboration between field and center scientists.”

– *ORA Scientist*

“The key to agency function is the talent and integrity of its scientific review staff. We have lost many outstanding people because of the policies of some divisions and offices. A mediocre and compliant staff does not serve the public well.”

– *CBER Scientist*

“FDA employees have wield a lot of power in deciding the fate of medical products and the companies who make them. Some training may be necessary to make FDA employees understand that to exercise this power appropriately requires a lot of humility. We don't know everything.”

– *CDRH Scientist*

Influence of Special Interests

“I think that my colleagues across the agency are extremely dedicated (and patriotic in this mission!) to public health and safety through the accurate evaluation of data. I believe we all want to do the right thing for the American public and maintain our own scientific and moral integrity. Much of the time, this is reflected in final decisions, which I feel proud about. But when industry is able to influence the regulators, something has gone terribly wrong.”

– *CDER Scientist*

“No matter how well we do our job, it has to be realized that FDA is just one small part of a broken health care system in a society that embraces a culture of greed. Manufacturers have enormous incentive to selectively withhold evidence or lie outright



about their products. Even when we know a manufacturer is gaming the system, it's extremely difficult to prove malfeasance, so they get away with it, and it becomes the norm. We don't have an integrity issue at FDA, It's pervasive in our society. We are a shining beacon of integrity by comparison.”

– *CDRH Scientist*

“I believe PDUFA and special interest groups have allowed Congress to be lulled into a false sense of security. When things don't 'go their way', a company or its representatives will call and harass office directors to approve their product. In addition, PDUFA is like money laundering. Companies give money to congress to fund regulatory decisions. This is clearly a conflict of interest.”

– *CBER Scientist*

Resources

“We have to do too much with too little.”

– *CBER Scientist*

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

– *CDER Scientist*

“In the 1970's there were ~800 people working on electroinic product radiation control issues. In 1983 that number dropped to ~400 people. Currently CDRH has less than 60 FTE's working on radiological health issues and enforcement and the variety and number of non-medical electronic products continues to grow rapidly.”

– *CDRH Scientist*

“I am concerned about potential decreased funding to the Agency - I believe we serve an important mission in ensuring public health. I also think it is inappropriate for Congress to ask us to take on more responsibility without adequately funding us.”

– *CDER Scientist*

“As with other government agencies, research funding is tight here and is only going to get tighter. As a result, we are encouraged to seek outside funding. However, this process



is made difficult because of burdensome intellectual-property requirements. I believe these should be greatly reduced.”

– *CDRH Scientist*

“I am proud to say I work for the FDA and believe we are doing the best we can given the resources we have been given.”

– *OC/VM/CTP Scientist*

“No matter what you all do with the budget - if you want to eat safe every day - you got to fund FDA.”

– *CFSAN Scientist*

Public Health and Science

“Post-approval monitoring of current pharmaceutical will never be optimized in the U.S. until there is a nationwide electronic data base with the most modern analysis techniques.”

– *NCTR Scientist*

“I think they are doing a good job under impossible circumstances. But they could do a better job. I think congress cares nothing about food safety. That has been shown over and over again.”

– *CFSAN Scientist*

“Please speak up for the FDA reviewers who have no voice regarding the quality of the incoming documents. Please investigate a random sampling of documents regarding regulated devices (e.g., 510(k), PMA, IDE if possible) and compare that to the physician information - many times they seem to be completely different.”

– *CDRH Scientist*

“FDA authority for Post-marketing safety monitoring has improved with FDAAA, however, perhaps the regulations should be a little more strict in terms of sponsor's reporting responsibilities. We continue to receive very incomplete post-marketing reports of serious events that do not have any follow up.”

– *CDER Scientist*

“Give the FDA regulators more teeth in determining if a drug or device should be approved.”



– *NCTR Scientist*

“There has been what feels like a significant change in leadership direction for the better in the past few years. Science is in the fore-front of what we do.”

– *CDRH Scientist*

Other Topics

“I work in the food safety area of ORA. We have a saying 'FDA loves Class 1 samples.' This means FDA labs like to analyze food samples that are 'no action indicated.' I am pretty sure we have been reporting out false negatives. It's like FDA is more concerned about the appearance of doing its job, than actually doing its job.”

– *ORA Scientist*

“At the level where I work most all of my experiences have been positive. Main limitation has been budgetary and outside of the control of those affected by decision making.”

– *NCTR Scientist*

“The process of drug evaluation and approval is poorly understood by the public - journalists need to do a much better job of explaining this process.”

– *CDER Scientist*

“With the appointment of Dr. Hamburg et al under the current Administration I have personally seen a phenomenal improvement in the willingness of the Centers to take the regulated community to task and support actions against those not adhering to the Act.”

– *ORA Scientist*

“The following culture-change strategies have made a big difference in the CDER Reviewer's life: 'Safety First', 'Equal Voice', 21st Century Review, Dispute Resolution and other MaPPs. Office-level and Center-level support of the reviewer's professional development (e.g., attendance to conferences and therapeutic area meetings) will help enhance the quality of reviews.”

– *CDER Scientist*

“When people think of FDA, its not a group of people working to create safe foods and drugs, its an Administration, which is a very dehumanizing concept. We need real people



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on the face of FDA, and they need to get out there and speak and interact with the public at schools, colleges, town hall discussions, where ever.”

- *CFSAN Scientist*

“I realize that many times our hands are tied so we tread lightly. We are doing and injustice to public health by answering to the wrong masters. It seems as though every 4 to 8 years our mission changes. This is disruptive to our true mission. Get back to the basics, and appoint someone who will make changes for the public and no worry about political agendas.”

– *ORA Scientist*



Essay #2: “The FDA could best improve the public’s health by:”

Increased FDA Resources

“The FDA could improve public health by having adequate staffing to review the workload asked of it by congressional mandates, by the sheer amount of data generated by industry and the increasing number of products manufactured.”

– *CBER Scientist*

“The FDA could provide greater support for its researchers in the form of adequate laboratory space and resources. There is also a need to improve its computing resources and support for the development of bioinformatics. Researchers/reviewers are under too great of a work burden.”

– *CBER Scientist*

“Increasing the number of employees that exist for a specific function within the Agency. As it stands we have too many people performing a significant amount work that are driven by PDUFA dates.”

– *CDER Scientist*

“With the increased number of pre-market submissions reviewed by my office, I believe that we need more reviewers to keep up with the influx of new devices before they go to market.”

– *CDRH Scientist*

“More field investigators to perform more inspections.”

– *CDRH Scientist*

“FDA does not have the resources it needs to perform the work that is required of it. Particularly in OC, our budgets are continually getting cut and we are unable to keep up with the work mandated by our mission.”

– *OC/VM/CTP Scientist*

“Acquiring the needed permanent personnel resources. We have too many contract employees.”

– *CFSAN Scientist*



“Adding more Field Inspectors to carry out FSMA.”

– *OC/VM/CTP Scientist*

Use of Science and Data

“Approving new drugs that constitute an equal or better, safer and effective therapy than currently approved drugs on the market. Just better than the placebo is not good enough.”

– *CDER Scientist*

“Allowing scientists reviewing devices to use current science, rather than being bound by the 510(k) precedent. This system does not realistically permit review of devices based upon current medical practice and the state of the science. It also does not allow FDA to remove a device from the market when Current science suggests that it may be unsafe or ineffective.”

– *CDRH Scientist*

“Bolstering its scientific base and removing the unnecessary (some recent) layers of bureaucracy.”

– *OC/VM/CTP Scientist*

“Update and streamline various policies and regulations. Adapt to changes in science world and be more proactive in decision making process.”

– *ORA Scientist*

“Maintaining a best practices science/medicine approach to the review of drug products while reducing regulatory hurdles in the review process.”

– *CDER Scientist*

“A use of rigorous science, strong authority over the regulated industry and their drug development program, and independence from the consumer groups.”

– *CDER Scientist*

“A return to using modern interdisciplinary science in making decisions about public health.”

– *CFSAN Scientist*



“Continuing to require adequate proof of the safety and efficacy of the drugs and biologics that are regulated by the FDA. Also, continue to inspect domestic food and drugs in both original form and final production prior to distribution and increase inspections of food and drugs that are imported into the US.”

– *CDER Scientist*

“Establishing standards for submissions by industry. All data should be submitted in a standardized format that may be easily analyzed by the Agency.”

– *CDER Scientist*

“1. Interacting with public health advocates to the same extent as the regulated industry. Currently pharmaceutical manufacturers have close to unlimited access to FDA decision makers. 2. Adopting a public health viewpoint rather than a narrowly legalistic regulatory approach. 3. Focusing as much energy on the quality of decision making as on timeliness (i.e., meeting PDUFA goal dates). 4. Establishing a separate Center for postmarketing regulation of products. This is the model that regulatory agencies elsewhere (EMA, MHRA) use. Having a primary mission of new product approval means that post-marketing safety will always be secondary, yet this is the current FDA model.”

– *CDER Scientist*

“Revamping the 510k process; the use of a predicate device is so outdated. The current process allows clearance of a new device that could be just as inferior as the predicate. Need to evaluate the new product on its own merit.”

– *CDER Scientist*

Post-Market Surveillance

“Improving post-marketing safety funding and hiring more specialists to examine safety once a drug is on the market. Greater support and funding for the Sentinel Initiative and other broad based real time monitoring systems.”

– *CDER Scientist*

“Mandate for, and availability of, better clinical safety data for a drug after its approval.”

– *CDER Scientist*

“1. Greater reliance on the expertise of its professional staff rather than on managers who don't have the expertise to defend scientific decisions and thus tend to go with the easiest and least controversial decision. 2. Post-market data collection on major adverse events



such as cancer and cardiovascular events. We have no idea how drugs and devices really affect these major endpoints.”

– *CDRH Scientist*

“Routinely revoking 510(k) clearance when products turn out to be faulty.”

– *CDRH Scientist*

“Devoting more resources to post-market monitoring and analysis. We currently collect large amounts of data through methods such as annual reports and the MAUDE database but do not have the resources to analyze it and then integrate the resultant information.”

– *CDRH Scientist*

“Conducting or sponsoring more research directed at looking at the safety of drugs presently on the market and those new drugs applying for use. Also, much more post-approval monitoring clinically and a huge improvement in the means to store and analyze such data objectively.”

– *NCTR Scientist*

“Develop a comprehensive database for FDA scientists to analyze post marketing data; more funds to support development of biomarkers for preclinical and clinical diagnosis, monitoring and risk management.”

– *CDRH Scientist*

Politics and Regulatory Authority

“Cutting out the political agenda and taking action against companies that deserve it, whether or not it's on the political agenda.”

– *ORA Scientist*

“Consistent adherence to public good outweighing political issues. Approved products should be shown to be doing more good than harm in people using them, and funding available to assure it.”

– *CDER Scientist*

“FDA needs more resources, needs more transparency and can't let politics interfere with decisions.”

– *CDER Scientist*



“Negotiating PDUFA V to provide more time for pre-marketing assessment by FDA scientists, hiring more reviewers and inspectors when Congress fully funds the Agency, revamp the current negotiation dance we do with the sponsor concerning labeling to give FDA more weight in what goes into labeling.”

– *CDER Scientist*

“Having a term for the commissioner that spanned election cycles.”

– *CDER Scientist*

Transparency and Public Relations

“Give priority to safety information currently considered confidential that may have public health impact. Greater ability to enforce transparency in the field of clinical trial results that failed.”

– *CDER Scientist*

“By being more transparent about the specific data used for decision making, especially for post market safety issues.”

– *CDER Scientist*

“Communicating honestly and openly with the public about the many factors that go into it's decision making.”

– *OC/VM/CTP Scientist*

“Increasing the clarity of its communications about regulated product, including labeling as well as public communications. Assuring adequate resources for agency activities and for further strengthening scientific infrastructure and expertise. Increasing the time available and opportunities for FDA staff to engage in outside activities in their professional and scientific areas.”

– *OC/VM/CTP Scientist*

“Finding new ways to share information about medicines with the public. This would take a lot of resources and is a task that has not really been in the Agency's purview, historically.”

– *CDER Scientist*



“Communicating more with the public about the importance and significance of specific food/drug/biologic/device health and safety issues, and about the role the FDA plays in public health beyond the obviousness of food safety.”

– *CDRH Scientist*

“Better communication with the public, including making it easier for FDA scientists to publish technical or commentary articles on controversial topics.”

– *CFSAN Scientist*

“Being fully open with regard to the strengths and limitations of the scientific data/information on each chemical's risk assessment.”

– *CFSAN Scientist*

“Insisting on moving regulations, guidance's, etc, into the public domain for comment -- e.g., insisting that OMB abide by their time commitments and that OMB not involve agencies that have no public health mandate on decisions to publish FDA regulatory documents. This happens frequently with the trade agencies.”

– *OC/VM/CTP Scientist*

“Providing more education to the public safety of medicine and its use, as well as how to maintain safe food through community workshops, flyers and public health announcements.”

– *NCTR Scientist*

Industry Concerns

“Better maintenance of the guidance's to industry; many are over 10 years old. When they are revised, it is typically by non-review staff.”

– *CDER Scientist*

“In recent years, maybe in the last decade, the FDA has shifted its position as regulators, meaning we are here to scrutinize what the industry does, to industry partners, meaning we are here to help you put drugs on the market. It sounds altruistic that we are helping needed treatments be available to the public, but it becomes dangerous when we adopt the position of partners, as allies. There is no other drug regulatory agency, we should not be here to help the drug industry, we should be here to scrutinize and regulate what they do. Our goal should be public health, not industry success. I think that was the goal back



in the days, but since the PDUFAs, when the FDA started to be funded in part by the industry, they became sort of our clients.”

– *CDER Scientist*

“Taking more regulatory actions and following up on bad companies.”

– *ORA Scientist*

“The current work-model relies on applicant's submissions/applications to identify the issues which are reviewed. While this allows efficient use of limited resources, FDA should also identify and investigate public health issues at the level of the review division other than those submitted by Sponsors.”

– *CDER Scientist*

“Fear of upper management to make a decision that may not be popular with industry.”

– *CDRH Scientist*

“Accelerated approval of drugs is tantamount to full approval, because of the difficulty of reversing it. It should be 'conditional' for some (5?) years with adequate safety monitoring before full approval is granted.”

– *CDER Scientist*

“Increasing the quantity and quality of inspections of manufacturing facilities.”

– *CDER Scientist*

“Removing the influence of the industries it regulates and that of politicians and political appointees. FDA and its employees need more resources to perform their job. All FDA employees are overworked, underpaid, unappreciated, and sometimes totally ignored.”

– *CDER Scientist*

Other Topics

“Pushing for and using greater power to take regulatory control of products that are found to be unsafe to the consumer. Creating a system to rank the relative risk of manufacturers and inspecting on a greater frequency and in greater detail those with higher risk. Creating a means to perform rapid inspections of low risk manufacturers.”

– *ORA Scientist*



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“Separating our Imports and Domestic regulatory sectors. Currently all FDA's higher managers are taking from our Import area and using the money/people to accomplish Domestic work which is - in my opinion a much lower risk compared to imports.”

– *ORA Scientist*

“Working with CDC, CMS and AHRQ across HHS to identify high-priority, potentially preventable or treatable health conditions; and adapting a PUBLIC HEALTH-oriented accelerated approval process for the top 10-15. Currently this process is oriented toward 'serious, life threatening' conditions, rather than conditions which cause a lot of harm at the population-level.”

– *CBER Scientist*

“Completely overhauling the advisory committee process. The idea of the committee voting on issues makes no sense; the committees are not constructed in a way that reflects correct balance in a decision-making process. The committee is a collection of expertise. It's role should be similar to peer review: committee members should provide written critiques of industry submissions and FDA responses.”

– *CDER Scientist*



Essay #3: “The FDA is currently drafting a Scientific Integrity Policy. What is the most important factor that you believe should be included in that policy?”

Emphasize the Science and Importance of Public Health

“An emphasis that good science/medicine is paramount in the review process with other considerations with respect to the influence of manufacturers, political entities, financial considerations, etc. being nil.”

– *CDER Scientist*

“Base all decisions on good science and don't change conclusions after the author has signed off the report.”

– *CDRH Scientist*

“The FDA should have a clear mandate that its first charge is for the safety of the consumers, and that the pharmaceutical industries interest clearly are not the prime motivation in approving new drugs and monitoring the safety of drugs currently on the market.”

– *NCTR Scientist*

“Decision makers need to put the science first in their decisions. In the science reside the facts. Decisions need to be based on those facts and to as many decimal places as possible. Shun wishful thinking, divine inspiration and opinion. Get the facts and history will show our decisions were correct.”

– *OC/VM/CTP Scientist*

“Scientists should be focus on the continuous improvement of public health and knowledge without compromising basic ethical principles.”

– *OC/VM/CTP Scientist*

“Decisions should be informed by scientific data and should be based on the consensus of expert staff. In addition, there should be a mechanism for registering dissents to a decision, including a rationale for the dissent, prior to a final decision.”

– *CDRH Scientist*



“Decisions and views expressed need to be informed by data and determined rationally. I have seen too many highly opinionated views that use the data selectively and inappropriately.”

– *CDER Scientist*

“FDA rarely makes black or white decisions and reasonable minds can disagree. Staff and management have an obligation to consider all points of view and make unbiased decisions in the best interest of the American public.”

– *CDRH Scientist*

“Honest assessment of the quality of data including potential flaws in collection, coding, comprehensiveness and generalizability to a US population.”

– *CDER Scientist*

“The policy must make clear that managers are responsible for the deficits of their review staffs. In my opinion, the biggest integrity issues relate to FDA employees not executing their work (as opposed to intentionally coming to conclusions at odds with the data). Managers typically ignore the public health threat posed by these employees, as the incentive structure does not reward (and in fact discourages) any other behavior.”

– *CDER Scientist*

“Although the device industry and its representatives and political groups can and should weigh in on how devices are cleared and approved, ultimately, we should have a scientifically and experientially robust review process where needed -- without bending to corporate or political desires b/c they are more concerned about their profit margin than the public's safety.”

– *CDRH Scientist*

“Public health considerations should be paramount.”

– *OC/VM/CTP Scientist*

Political and Administrative Interference with the Science

“To ensure scientific integrity at the agency, managers must not be allowed to interfere with the assessments of reviewing scientists. As it is now, the administrative process requires managers to concur on every piece of work of review scientists and they



frequently insist that reviewers change their scientific/regulatory assessments and conclusions.”

–*CBER Scientist*

“Assure that upper management and political appointees adhere to the same standards as reviewers.”

– *CDER Scientist*

“The FDA managers/ administrators should support the scientists, as opposed to using the scientists to support them.”

– *NCTR Scientist*

“If management makes a decision contrary to the science they should have to write an explanatory memo to the file addressing their decision process AND SIGN THEIR NAMES.”

– *OC/VM/CTP Scientist*

“Upper management must not be able to alter scientific data or reports.”

– *OC/VM/CTP Scientist*

“I don't think any written Integrity Policy means anything as long as managers and supervisors don't manage or supervise, and currently, I have not yet experienced a supervisor or manager that has skills anywhere close to the skills demanded from managers and supervisors in the regulated industry. For the Policy to be meaningful it has to be enforced. I have little hope that that will happen in a meaningful way with the current management.”

– *OC/VM/CTP Scientist*

“This document should contain an oath/statement for managers that states they will not interfere with a scientist's review and/or final recommendation. This statement should be signed and place in the manager's permanent file.”

– *CDRH Scientist*

“Zero-tolerance for efforts by management to suppress, pressure, or coerce scientists into changing their reviews or recommendations.”

– *CDER Scientist*



“FDA should allow/require its scientific subject matter experts to generate policy based on scientific evidence and the consensus of all the experts in the particular scientific area. Decisions on the scientific evidence behind policy generation should NOT be left to managers, up to and including the FDA commissioner, who are not experts in the scientific field or to one manager expert alone.”

– *CDER Scientist*

“Science should trump politics.”

– *CDER Scientist*

“Outside players (Congress, lobbyists, stories from patients) should not carry weight over science/data/fact.”

– *CDER Scientist*

“Total removal of all political influence on scientific decisions. (Unfortunately, easier said than done.)”

– *NCTR Scientist*

“Limit the influence of Presidential/political appointees in the process. They are here to administer this agency, NOT to make our decisions for us.”

– *OC/VM/CTP Scientist*

“Public health decisions should be based on science, not politics, and unpopular information should be evaluated, not quashed.”

– *OC/VM/CTP Scientist*

“Protection of the primary reviewers' review, with no forced editing. Of course, the division as a whole may have a different recommendation, but the primary reviewers' comments should not be altered, and if they are, there should be corrective action.”

– *CDER Scientist*

Whistleblower Protections

“That reviewers continue to be encouraged to state their scientific opinions and allow reviewers to remain current scientifically.”

– *CDER Scientist*



“A policy on bullying. Managers should not be allowed to use aggressive tactics to influence the opinions of reviewers to suit their demands.”

– *CDER Scientist*

“Freedom of speech and to participate in scientific organizations.”

– *CFSAN Scientist*

“That each scientist be allowed and encouraged to speak and write freely of their scientific opinions, while respecting the boundaries of the regulatory science mission of the Agency.”

– *CDRH Scientist*

“Clear protection for scientists and their scientific decisions, whether or not FDA concurs or doesn't concur.”

– *OC/VM/CTP Scientist*

“Freedom to disagree with a position without fear of retaliation.”

– *CDER Scientist*

Reduce Corporate Influence

“Don't accept free lunches from pharmaceutical representatives.”

– *CBER Scientist*

“The decision-makers need to understand the regulations as written; the creation of 'their' interpretation of what something means causes confusion, un-level playing field with industry, and one-sided and possible incorrect/inappropriate science.”

– *CBER Scientist*

“Clear definitions and thresholds conflicts of interest.”

– *OC/VM/CTP Scientist*

“Ensuring that sponsors understand that they FDA should not be harassed into hurrying a product decision in order to please the shareholders. PDUFA timelines should be ratified, stopped or extended if new issues are discovered. Should sponsors not provide all the data they could receive hefty fines from the agency.”

– *CDER Scientist*



“No conflict of interest.”

– *NCTR Scientist*

“Leading with decisions based heavily on the sciences and in the interest of public health instead of the interests of industry.”

– *CFSAN Scientist*

Transparency and Accountability

“A clear and transparent framework for sharing the results of product evaluation with the public, including the airing of differences. Easier agency pathways for overcoming past regulatory decisions (such as bad predicates for 510K devices) that are hard to overcome.”

– *CDRH Scientist*

“My sense is that the integrity of science at FDA is quite sacred. However, much of the activities are opaque because of confidentiality restrictions related to the data - and so the integrity appears possibly threatened because the agency cannot explain certain considerations and actions that are based on that confidential information which cannot be shared with the public. I'm not sure whether, or how this might be addressed, as the data does not belong to the agency, but sponsors.”

– *OC/VM/CTP Scientist*

“I would suggest that any research authorized by FDA require a statement about how the information was obtained and from whom it was obtained. If individuals from interested parties were consulted, the statement needs to include the nature of the interaction and the efforts engaged to preserve objectivity. Additionally, I think it's appropriate to ask the researchers if they have any strong beliefs about the research they are performing, as this will go to objectivity.”

– *CFSAN Scientist*

“That people will be held responsible for poor decision making and that all individuals, including medical officers, will be held to the same standards of conduct.”

– *CDER Scientist*

“Accountability and transparency of decision making.”

– *NCTR Scientist*



“Part of integrity is adequate training of staff. The transparency policy has resulted in documents being release to the public without any training or notification of staff. How does that represent integrity of management to employees?”

– *CDRH Scientist*

“Recognition that FDA employs a large number of medical and scientific professionals and there will be differences in interpretation of data. Sometimes there is a need for center management to make difficult decisions (i.e. don't let the perfect be the enemy of the good).”

– *CBER Scientist*

Other Recommendations

“It’s nice to write a policy, but how will it be executed? Who will oversee that it is being adhered to and how will this be accomplished? These questions need to be answered in advance, otherwise the act of writing a policy is just a gesture that amounts to a wasted effort.”

–*CBER Scientist*

“Actually implementing and paying attention to whatever policy is written, rather than shoving it aside and ignoring the subject - which is the fate of all our policies.”

– *CBER Scientist*

“If FDA truly wants its decisions to be based in science, FDA needs to stop looking at how decisions were made in the past and what precedents were set that FDA believes it is now bound by. FDA also needs to focus more on the risks and problems with devices rather than the availability of the treatment options.”

– *CDRH Scientist*

“Having clear criteria on how scientific evidence will be reviewed to avoid manipulation of which studies (and how) are used to support policy development.”

– *CFSAN Scientist*

“An opportunity to independently appeal first line supervisory decisions. That is, if my boss disagrees with my decision, I would like to appeal it to someone else other than their boss - an independent, objective, entity.”

– *CDRH Scientist*



“Since Agency decisions need to be driven by the science supporting those decisions, it is of critical importance that the science utilized be of the highest quality and beyond reproach. It should be made clear and with great emphasis that the quality and integrity of the science submitted to and/or generated by the Agency is inviolable and attempts to submit and/or produce anything less will not be tolerated.”

– *NCTR Scientist*

“A Scientific Integrity board made up of both management and non-management personnel with the authority to meaningfully discipline any FDA staff proven to have violated the Policy.”

– *OC/VM/CTP Scientist*

“There should be clear communication of certain negative consequences to all those who violate integrity of data and truth in all scientific and commercial endeavors.”

– *CDER Scientist*

“[The] policy should be set up such that reporting of all results is advantageous over selecting just some results to report, which can be misleading. The policy should include more than just threatening companies with BIMO inspection.”

– *CDRH Scientist*

“The scientist at FDA should be allowed to attend basic scientific conferences like ASCB, etc. where new scientific advances are presented and discussed.”

– *CDRH Scientist*

“This is crap. Scientific integrity is well understood and there is no need for this statement.”

– *OC/VM/CTP Scientist*

“That the mechanisms of who decides what gets studied are included and REPORTED. Shining a light on who decides what we look at and why is more important than edits to technical documents.”

– *CFSAN Scientist*



Comments from Question #16: “In your opinion, what are the greatest barriers to timely Agency decision?”

FDA Resources are Inadequate

“If protecting and promoting public health is a national need at the fundamental level for the growth and welfare of all citizens and thereby the country, US Congress should appropriate the needed budget for FDA's operations 100% from tax revenues. Why does the FDA need to go to Congress (Senators and Representatives stated to be influenced by lobbyists) every 5 years for PDUFA negotiations? Get FDA 100% public funds; demand higher transparency, accountability and scientific/professional merit-based career growth based on pre-established and well communicated standards/criteria. That can be better than what we have now.”

– *CDER Scientist*

“Most decisions are timely. More personnel/resources could speed things up.”

– *OC/VM/CTP Scientist*

“Understaffed in my Center for the complexity of the issues.”

– *CDRH Scientist*

“The volume of regulatory submissions is increasing faster than my division’s capacity.”

– *CDER Scientist*

“Many reviewers are overwhelmed by the workload. Thus it becomes difficult to take the time to immerse yourself in complex issues and bring it to conclusion. We are always focused on crises situations.”

– *CDER Scientist*

“Often insufficient resources may impact timeliness of decisions. With too few qualified people to do reviews, our scientists are over-loaded. Additional resources to hire more staff would alleviate this problem.”

– *CBER Scientist*



“In my premarket review division, each reviewer is expected to complete an average of 1.7 FTE's worth of work per person, but there is no center or office management intent or resources to appropriately fund sufficient numbers of reviewers or first line supervisors to conduct the work we are expected to do.”

– *CDRH Scientist*

“FDA has been without resources and beholden to industry for so long that the position of submissiveness to industry and fear of moving forward.”

– *ORA Scientist*

“PDUFA timelines and 21st review processes continue to shorten the amount of time that scientists have to truly evaluate the safety and efficacy of drug products. The dosage forms, scientific methods, conditions treated, and safety profiles of the drugs we review are continually increasing in complexity and potential issues but we are confined by the short timelines to make decisions. Faster is not always better. The Agency needs more reviewers if we are expected to meet these deadlines and still promote the public health. I am also discouraged by the reliance on post-marketing safety evaluation to catch any safety signals we miss pre-marketing or to finish studies we think are critical in order to approve a new product.”

– *CDER Scientist*

Special Interest Influence

“I think the greatest barrier is poor submission quality by industry. High quality submission are reviewed in a timely fashion by the FDA.”

– *CDER Scientist*

“Incoming documents from regulated industry have been dropping significantly in scientific quality. Regulated industry approaches premarket clearance (510k) or approval (PMA) from a different angle (i.e. self-interest) than does FDA (i.e. public health). Both FDA and regulated industry need to find a better way to increase the scientific and regulatory character of the incoming documents to speed new devices to be market.”

– *CDRH Scientist*

“Congress.”

– *CBER Scientist*

“Lack of quality submissions from the sponsor.”



– *OC/VM/CTP Scientist*

“Barriers to timely decisions usually have to do with a Sponsor submitting poor data and then arguing with us about whether it's good enough to support approval or support a particular decision about the drug product when we believe otherwise.”

– *CDER Scientist*

“Influence of "embedded" political friends of the past administration with civil service status.”

– *ORA Scientist*

“Industry stakeholders strongly influence Agency Office management on data assessment/review functions, timelines, and decision making aspects of the drug applications. This in turns determines what Agency scientists can and cannot do.”

- *CDER Scientist*

“The greatest barrier to timely decisions depends upon the decision. For premarket applications, the greatest barrier to making a decision is the reluctance of industry to provide data. When it comes to rules and guidance, the biggest problem is the layers of bureaucracy and the need to navigate the existing laws.”

– *CDRH Scientist*

“Uncertainty as to what to submit.”

– *CDRH Scientist*

“Since we don't have a risk model, companies reinvent what needs to be submitted every time to meet "substantial equivalence" determinations.”

– *CDRH Scientist*

“Poor quality pre-market applications and lack of cooperation from manufacturers.”

– *CDRH Scientist*

“The greatest barriers of all is possible conflict of interest (politics vs. science) for decision makers at any level.”

– *ORA Scientist*



“The FDA scientists can only recommend approval status, which ultimately will be decided by a committee that will include industry representatives and not FDA reviewers.”

– *NCTR Scientist*

“There is a lot of concern about potential political fallout for decisions and industry is very good about not only taking their case to the media, but also enlisting their political allies to intervene in deciding making processes.”

– *ORA Scientist*

“Political meddling in the regulatory process can cripple enforcement actions. Political appointees need to be as dedicated to the Agency mission as the career public employees. Too many of them seem to just look at an upper level FDA position as a stepping stone to a fat check from a consulting firm.”

– *ORA Scientist*

Barriers in the Review Process

“One of the greatest barriers to timely Agency's decision, in addition to above, is also due to limited knowledge and training on upcoming new scientific disciplines and, materials and technologies, seen in products submitted to Agency for reviews resulting in inappropriate decision, or reluctance of leadership to make appropriate decision.”

– *CDRH Scientist*

“EXTREMELY inefficient. Late on reviews and reviewers do not follow the time clock. Products are held up simply because reviews are not completed without any scientific justification. Reviewers are also too adverse to risk.”

– *OC/VM/CTP Scientist*

“Inefficient review processes as well as review of incomplete and poorly assembled applications.”

– *CDER Scientist*

“The internal decision, management and information collection pathways and support systems are chaotic because of a lack of clear scientific and informatics strategic goals and plans. Documentation of how decisions are made are sparse. The result being that decision making must rediscover past historical information on related decisions continually.”



– *CDER Scientist*

“Old policies and antiquated attitudes developed years ago and their influence on the older decision makers in the agency.”

– *ORA Scientist*

“In my (limited) experience regulatory decisions and efficiency are hindered by a report writing and evidence collection process that are overly burdened with a requirement for excess detail and documentation. The issues are more legal than scientific, stemming from a limit on the powers granted to the Agency by Congress. I understand that other consumer protection agencies have greater powers to act immediately when investigations and scientific analysis indicate that products are unsafe to the consumer.”

– *ORA Scientist*

“The process of review of position statements and actions is so burdensome that it all but stops putting out new or revised decisions and actions.”

– *CDRH Scientist*

“I have worked for the agency for many years. It's strength is in the honesty, dedication, and expertise of its professional people. The biggest hindrance are the laws that Congress passes, direct to consumer ads, political appointees running the legal department, too big to manage effectively, too large a Commissioners Office with too many political, although well-meaning professionals. Management could be better.”

– *CDER Scientist*

“The increasing complexity of the review process and the greater demands to meet quality control standards increasingly impacts negatively on the timeliness of the review process and quality of the reviews.”

– *CBER Scientist*

“Medical products of all kinds are increasingly complex. Though some FDA centers have made progress in developing systems to tackle the complexity- CDRH resources to tackle this complexity are woefully inadequate. As a result, the center staff from burnout and turnover is high. Yet, it takes years to become a expert scientific reviewer of the complex applications. In addition, because CDRH does its work through regulatory processes- which are difficult to change, it lacks adequate flexibility to tackle some thorny problems.



Current leadership is working very hard to change that but faces tremendous headwind from the regulated industry.”

– *CDRH Scientist*

Other Topics

“People often seem to overlook some of the basic inefficiencies that lead to delays. For instance, CDRH still requires paper submissions. Even a basic electronic process could take 10%-20% off the typical review time. Upon receipt, it may take 2-3 days of paper shuffling before the document gets to the review decision. Official letters to the company can also take 3-4 days, given that a secretary must type the correspondent's address onto a boilerplate letter and then document center may take a couple of days to send/fax the letter to the company. Reviewers also waste time printing records (emails, memos, etc...) only for these items to be scanned into a database; uploading an electronic copy to the database would save time and paper. Considering that CDRH is suppose to review files in 90 days, the number of days spent "paper shuffling" add-up, and take away from the time scientists have to review a file.”

– *CDRH Scientist*

“We regulate products in the scenario of emerging science and cannot always be right, and disagreement is expected. Timely decisions still need to be made, however and the uncertainties disclosed.”

– *CDER Scientist*

“Turf wars between offices.”

– *CDRH Scientist*

“Compliance Officers are much too slow to take action and much too reluctant to take action. Also, there is no follow-up for seriously filthy food firms. My District won't allow an OAI classification for filth in food manufacturing firms.”

– *ORA Scientist*

“FDA management should not be making any decisions at all. FDA management is not loyal to the American Consumers they swore to protect. They are only loyal to themselves and not the FDA employees either. Washington is broken!”

– *ORA Scientist*