Union of Concerned Scientists
Citizens and Scientists for Environmental Solutions

UCS Food and Drug Administration Survey
Selected Excerpts from Essay Responses

In 2006, the Union of Concerned Scientists (UCS) and Public Employees for Environmental Responsibility (PEER) surveyed scientists at the Food and Drug Administration (FDA). The 38-question survey featured one essay question that allowed scientists to provide a written narrative. Out of the 997 survey respondents, 502 (approximately 50 percent) responded to the essay question. Response rates from each FDA Center ranged from 45 percent to 59 percent, with an average of 51 percent.

The following are excerpts from the essays provided, divided into five topic areas: interference with scientific determinations at the FDA, negative effect on public health, chilling effect on scientific candor, FDA scientists face immense pressures, and scientists recommend changes at the agency.

"The integrity of the scientific work produced by FDA could best be improved by…"

I. Interference with Scientific Determinations at FDA

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

Political Influence

Center for Drug Evaluation and Research:

"Preventing political appointees at highest agency levels (OC [Office of the Commissioner], OCC [Office of the Chief Counsel] etc.) from applying pressure on those at center and office levels and/or ensuring that this influence is exposed and known to the public and other stakeholders."

"Less pressure from Congress, FDA management, media to 'approve' drugs, more credit and attention by same groups of review of drugs-whether outcome is approval or non-approval. Less resistance to asking for additional information to permit better informed decision."

"Recognizing that inappropriate pressure on reviewers does occur and is a problem that needs to be addressed."

"Depoliticizing the Commissioner's office. The number of political appointees and related staff has ballooned in the last 5 years."

"Keep political influences out of here."

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"My division/deputy director (in the last 3 weeks) stated to me, "If you don't approve this application, I am going to reassign it to another medical officer."

"Keep the political appointees, the white-house and the congress away from the FDA's decision making process."

"Keeping office of chief counsel out of decisions made by scientific/regulatory staff. OCC's [Office of the Chief Counsel] role should be returned to providing advice in matters of law; they should not be involved in decision-making regarding scientific merit."

"Computer simulations using clearly erroneous models have been used to approve drugs for political reasons."

"We hear rumors of political influence at higher management levels but know nothing for sure. There is little overt pressure on reviewers but nevertheless one goes along to get along."

"The work of FDA is already carried out by serious managers and reviewers with a very high level of integrity. I have observed it for decades and the overall quality of work continues to improve. I, like most of us, are embarrassed by the Plan B action, but feel no interference by the political component in day to day activities. People are free to offer opinions and do not suffer if they disagree with supervisors or other reviewers. There is always room for improvement of analytic and technical skills, but FDA's integrity is not the problem."

"Politicians not interfering in scientific matters. Managers should encourage employees to go on with their judgment, if they feel they are right, even after the discussion by the supervisor."

"Twice in the past month a Division Deputy Director stated during a meeting that they were approving a drug, regardless of the Medical and Statistical review, without ever looking at the data."

"Make all drug approvals provisional for the first 2 years with required follow up on all patients."

Center for Biologics Evaluation and Research:

"Eliminating political interference at the highest levels of the Agency in decisions to approve/disapprove a product. The political views of candidate for advisory committees should not enter into their selection criteria."

"Selection of advisory committee members on scientific grounds without political influence."

"Less micromanaging of scientific review by political appointees within the agency and at HHS [U.S. Department of Health and Human Services]."

"One other issue that should be addressed is that of the Advisory Committee Meetings. I've observed that management and companies have found ways to manipulate this process in favor of approval. These methods are very subtle and would not easily be recognized. Such techniques include: 1. As the Division Director, if I think that one particular person on the committee has a strong opinion because of a particular expertise and if I'm worried that such a person may vote against a drug, I can just choose to schedule the AC meeting at a time when I know that person cannot make it. 2. As a drug company, I can hire, as consultants, just about every single expert on the topic being discussed so that there are no expert consultants available to the FDA. I can also hire Advisory Committee members themselves, thus making them conflicted and unable to participate in the meeting. 3. As a Division Director or Office Director, I can change the content of the Advisory Committee Briefing Document so that potentially damaging, but factual information that the reviewers wanted to include is not included. 4. Finally, as management, I can pressure reviewers to soften their Advisory Committee presentations."

"FDA needs to be allowed to function & do the job (as stated in the FDA mission) without pressure from politicians and military interests."

"I've been here over 20 years, this is the worst. Science is being ignored or abused. Get politics out of here."

Center for Devices and Radiological Health:

"Not having the Office of General Council controlled by the White House."

"Not allowing influence by Congress and Executive branch on scientific decisions. They are extremely political in nature, and do not serve individuals or public health. Allow FDA to be a scientific agency that is politically and religiously neutral."

"They just take you off the product review entirely if they don't like your opinion."

"Remove ability of management to reverse reviewers' decisions."

"Criteria for FDA appointed positions should explicitly exclude all political considerations."

Center for Food Safety and Nutrition (CFSAN):

"Over the last several years I have noticed a significant increase in the number of decisions that have become politicized (e.g., increasing requests to review even simple regulations and changes, both by Congress and the Commissioner's office and to make apparently politically-motivated changes in language and sometimes to alter bottom line results), and I think the integrity of scientific work could be improved by minimizing the 'politics' of the process."

"Placing scientific integrity above political ideology. Never in my 28+ years as a Ph.D. laboratory scientist at FDA have I seen the agency so politicized as is has been under George W. Bush. Some science and science-based decision making have been bastardized. "

"Asking Professional Societies to recommend experts to serve on review panels. Currently, political appointees or senior FDA managers pick the external panelists, hence raising questions about panel's impartiality…Having 'whistle-blower' system to confidentially review cases when senior scientists feel that they are being pressured to reach a pre-determined conclusion."

"Second, although much is frequently made by upper management about FDA & CFSAN being science based Agency/Center that makes science-based decisions, the science staff feels decisions are sometimes made more on the basis of 'political science' than 'science' alone."

"In the past decade, CFSAN resources increasingly have been used on programs motivated by politics or industry while mission-related activities have been severely curtailed."

Center for Veterinary Medicine:

"FDA leadership/management should let FDA scientists do the jobs they were hired to do instead of penalizing those how refuse to go along with FDA management/leadership's eagerness to cave into political/industry pressures at the expense of public health."

"Removing the political considerations from the process. If decisions are to be science based, there should not be a place for political input. Reaching defensible, scientific conclusions can be difficult enough without managements constant reminders of the politicians, industry members, consumer groups, etc, who may be unhappy with the conclusion. I was hired as a scientist."

"There should be no political appointees in the FDA, anywhere. They sidetrack and derail the science for political ends and goals."

"Removing political appointees, political interest and industry influences from the Agency. We should be totally free and committed to public health safety without political or industry influences."

"Removing politics from the review process and making decisions based solely on science."

National Center for Toxicological Research:

"Removing the excessive political and pharmaceutical industry influence on the agency's decisions, which has increased over the past 6 years would be the most important step."

"Prevent political appointees from making questionable regulatory decisions contrary to the recommendations of the FDA researchers and reviewers."

Office of Regulatory Affairs:

"FDA management will make sure science will take a back seat to politics, more labs will close, and the ability of FDA to remain science based will disappear."

"Prohibit interference with regulatory activities associated with results by political cronies and special interest groups, and insist on more transparent operations."

"By limiting the influence of political appointee's personal opinions when making decisions which involve public health & safety."

"A greater commitment to science, a removal of political influence."

"Keeping the political views & policies of the White House out of the decision making process."

"Reduce management layers. Too many managers. Not enough 'workers.'"

"FDA scientists and investigators are knowledgeable and conscientious and are the first-line contact with regulated industry. We know the facts of the situation, yet managers, centers and compliance constantly second guess and overrule or negate our regulatory recommendations."

"Keeping politics out of science, that is, evaluating scientific data without pressure and influence of management to achieve a 'desired' conclusion, and promoting senior management from within to fill critical decision-making roles as opposed to placing more and more political appointees who are given 'marching orders.'"

"Allow the FDA (a science-based agency) to use science to improve the lives of consumers and to protect the public. Get the politics and special interest groups and FDA-regulated industry(ies) out of the way of attaining/maintaining the FDA's mission statement. We work for the consumer, the US citizen and no one else. Thank you for asking me for my opinion!"

"It feels like politics often have much more of an effect on what's happening in this agency when the only concern should be protecting public health."

"Removing the undue influence of the media and the politics behind the decision-making."

"At the national level, agency decisions are influenced by industry lobbying and political pressure by the current administration."

Industry Influence

Center for Drug Evaluation and Research:
"Forcing Pharmaceutical companies to [present] the best possible product and not to interfere with the decision-making process by calling upper management or asking members of Congress to partake in the assessment/regulatory action process."

"Make culture regarding saying 'no' or giving negative results more acceptable – very difficult now with meetings, etc. Management is VERY pharma-friendly."

"FDA's integrity would best be improved by focusing more on ensuring product safety instead of meeting review deadlines. There should be less emphasis on 'helping' industry and more emphasis on overseeing industry and ensuring patients and consumers receive safe and effective medical products at a fair price."

"The FDA is presently being stacked at every management level including the lowest levels based on those who will support the big companies' agenda, and the implications for safety and efficacy will be felt long into the future."

"Submissions are progressively getting worse, even from the largest companies so that we frequently can't even figure out the dose of the drug being used. This appears to be intentional in order to overwhelm us so that we can't find the real problems."

"Stop acting as if industry is highest priority stakeholder and stop planning policies primarily oriented to benefit industry."

"There is a remarkable amount of pressure placed on reviewers to find 'creative' ways to approve problematic drugs. Reviewers who approve drugs consistently get special project-related awards, while those who do an excellent job on a product that doesn't get approved are very clearly ignored. I've never once seen a review team receive an award for a product that wasn't approved. However, this is all done is a very subtle, implied but persistent and clear way which leaves no doubt what is going on, but is very difficult to document."

"The 'workers' - scientists for the most part - want to 'promote and protect' the public health. Doing the 'right thing' for patients does not appear to be the #1 goal…Pro-Pharma attitude needs to be changed."

"Fully funding FDA outside of the PUDFA system."

"Eliminate PDUFA, increase FDA budget…Formal records of all industry contact (espec. 'informal' calls) available to public."

"Less emphasis on adhering to PDUFA [Prescription Drug User Fee Act] timelines and more emphasis on quality of reviews for reviewers."

"The other thing that occurs on a regular basis, as witnessed by many reviewers, is the inappropriate communication between companies and management via undocumented 'back door' channels…On 2 occasions, I've actually seen upper management in their office together with company representatives WITHOUT the presence of project managers or reviewers. Given the pro-approval agenda of certain of those in management, one can only wonder whether or not these NDA's [New Drug Approvals] are sometimes 'pre-approved.'"

"Give reviewers enough time to thoroughly review submissions. PDUFA deadlines keep getting shorter and shorter."

"Eliminating the User Fee arrangement. It is inherently impossible to regulate industry in an unbiased manner when they are paying our salaries and expenses."

"Ending PDUFA funding for review work and the reduced & restrictive time lines."

Center for Biologics Evaluation and Research:

"Allow industry to address scientific concerns rather than expecting management to suppress, delete and eliminate scientific concerns."

"MDUFMA [Medical Devices User Fee Act] mandates are unachievable if public health & science are to be considered."

"Having industry pay our way through fees is a mistake. If fees are charged, they should go to the general FDA fund, not directly to the regulators office fund."

"I never got an email telling me to look out for patient welfare, just industry."

"Getting rid of PDUFA/MDUFMA– direct funding from Congress."

"Full-funding of all review activities without reliance on user fees paid by industry."

Center for Devices and Radiological Health:

"Too frequently, the FDA acts in the best interest of the regulated industry and not in the best interest of public health."

"Stop 'secret' meetings between Managers and industry & subsequent decisions without reviewer participation."

"FDA considers their customer to be the manufacturers. The customer should be the public."

"Management allows a sacrifice of review quality for timelines. Far more interested in the clock than making sure an adequate review is done. User fees have greatly influenced this position."

Center for Veterinary Medicine

"The focus should truly be on protecting public health instead of catering to the interest of industry while pretending to protect public health."

"Science should be brought to the fore-front of the decision making process. Currently science takes a back-seat to profit and industry."

Office of Regulatory Affairs

"Increasing FDA's authority in dietary supplement claims regulation-put the burden of truth on industry rather than the agency to ensure that health claims have a real scientific basis…"

"Repeal P.D.U.F.A. Who do we work for? Answer: American Consumer – not big Pharma."

II. Negative Effect on Public Health

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

Center for Drug Evaluation and Research:

"Safety of drugs is an important issue. FDA should not approve certain drugs without adequate long term safety data. Post marketing safety is important, but drugs should not be approved before adequate long term safety data is gathered. The public should not be guinea pigs just to provide industry with revenue."

"Management's overruling of competent science results in inappropriate drug development."

"There are numerous safety problems with drugs currently on the market that front line reviewers have tried to have addressed or mentioned in the labeling, but who have been overruled for political reasons. Some of these safety issues may outshine Vioxx when they are eventually recognized. Several drugs that have been withdrawn from the market or that have had black box warnings added were predicted by scientists, but we are prohibited from contacting the post-marketing surveillance group."

Center for Devices and Radiological Health:

"Too many defective products are getting on the market because the pre-market review process is flawed."

"Removing awards for employees who agree to overlook safety & effectiveness concerns in order to meet unreasonably short deadlines…Reward those who find safety & effectiveness concerns & work to resolve issues."

"Requiring industry to submit their devices for FDA inspection and operation. If a picture is worth 100 words then having the device is priceless. Inspection of the device prior to market is worth much more than trying to recall a device after it has caused problems or killed people."

"Changing the 30 day time line for original CDE [Center for Drug Evaluation] applications to 45 or 60 days. Thirty days is far too small a period for making decisions regarding significant risk devices. Patients are at risk."

Center for Food Safety and Applied Nutrition (CFSAN):

"How many leaders in CFSAN'S office of the Director have training in NUTRITION? These are the leaders who protect the nutritional quality of the US Food supply."

"With current budget cuts, CFSAN is going to be almost useless. Public beware!!"

"I have seen violations that were not prosecuted because legal staff and/or management knew that the time required to prosecute some violations (such as mercury in fish) would take legal resources away from other violations that would have more immediate and severe health consequences (such as microbial contamination in food)."

Center for Veterinary Medicine:

"Keeping an eye on the push by politicians and industry on FDA to release drugs & biologics quickly. The critical path may not be all that the upper leadership is leading us to believe and thus approved products many be getting to market that are not fully safe or effective."

"Removing White House policy influence/concerns from the scientific decision. This is an impressively fair survey form."

Office of Regulatory Affairs:

"Changing law & policy on dietary supplements. Many are harmful yet FDA ignores these products."

"It is obvious that looking at 1-4% of imported products regulated by FDA is dangerously low and there are not enough field personnel to consistently be thorough in examinations due to the high volume individuals are required to complete daily."

"Consumers no longer trust FDA decisions or personnel as they know we no longer enforce the regulations but rather protect regulated industry/big business to the detriment of the consumers."

"How can we protect the US consumers (taxpayers) if we are not given the appropriate budget to do the job. Our morale is good, just give us the resources to do our job well. Please help."

"Allowing the centers to do a thorough investigation of new drug applications. In my opinion, FDA scientists are pressured to approve new drugs in a short period of time, which in turn leads to adverse reactions. The FDA is doing a disservice to the general public by catering to industry and Congress."

"We are so short staffed there is no way FDA can protect the public. It's just a disaster waiting to happen."

"I believe it takes serious illness of the public and/or deaths in order to get FDA to do anything (Vioxx as an example). The attorneys for FDA seem to find reasons to turn down cases. It seems as if they are protecting industry not the consumer."

III. Chilling Effect on Scientific Candor

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

Center for Drug Evaluation and Research:

"The problem at FDA is not the structure of the organization, but the quality and character of persons in managerial positions. Persons who are 'yes-men', who suppress information, minimize risks to patients and place industry's priorities above those of patients and the public are routinely promoted to positions of authority. There needs to be a better system of a) allowing reviewers the ability to discuss issues IN PUBLIC e.g. in publications without suppression or 'clearance' from upper management b) accountability of upper management to their superiors as well as the public c) a change in culture within the Agency to promote scientific discussion, academic achievement, and internal research results…"

"Allowing staff to publish scientific information without censorship by management."

Center for Devices and Radiological Health:

"Too often, political pressure restricts FDA from providing information to the public."

"Sunshine! We have many restrictions on what we can say and publish that are politically, not legally, based. In the past several years final approval to publish or speak is moving to higher and higher levels; lower management is more and more afraid to make decisions…We have trouble getting permission to say that medical products have safety problems. Staff outrage is pervasive."

"Bullying-I was pressured to recommend to approve a device I thought unsafe."

"The Office that I currently work in is an example. Scientific discourse is strongly discouraged when it may jeopardize an approval, and management is very heavily influenced by industry. When I go to meetings with my upper management, I honestly prepare myself as though I were going to a meeting with an industry representative."

"(1) Appointing a well-respected scientist/clinician as commissioner for a defined term w/o regard to change in presidential administration, & having him/her support healthy scientific culture. (2) Emphasizing need for a culture of open scientific discussion."

"The best scientists in every review area are consistently harassed, intimidated, and not allowed input into scientific policy."

Center for Food Safety and Applied Nutrition:

"Fostering an environment where scientific disagreements are acknowledged as being a necessary part of the scientific process."

Office of Regulatory Affairs:

"Allow more free communication between working scientists and policy makers-insist on a dialogue."

"…the freedom to publish findings regardless of political sensitivity."

"Assure typical lab analysts and workers that their future and job security does not depend on compromising scientific accuracy. This issue is a big one, and difficult. Many lab workers are fearful in this respect, feel intimidated by it."

"Not ostracize scientists or black ball them because their foresight sees a problem with a drug, device, food, biologics, etc. that possess a potential hazard to health now or in the future."

"Labs need leaders who are not afraid of scientific principles, and who are willing to support those principles any way they can."

"Bad news is strongly discouraged from flowing up. The lower level people know the problems but each level is scared to send bad news to the person over them. You just say what your supervisor wants to hear and life is easier that way."

IV. FDA Scientists Face Immense Pressures.

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

Pressures on Scientists

Center for Drug Evaluation and Research:

"There should be a process whereby non-scientific, non-supportable positions by managers with minimal scientific training or background in pharmaceutical development can be challenged & overturned. There should not be a binding arbitrary 'yes' or 'no' by managerial leadership that is not supported by the scientific staff. This is not a papacy."

"The culture at FDA is to approve drugs. To not approve a drug takes more time for the reviewer to try to gather enough information to mount a strong, defensible argument against approval. As it is with many reviewers working long hours just to keep up with incoming applications, it is easier to ignore what could be a potential problem in an application than to spend even more time & effort to fight against the strong current towards approval."

"Giving their scientists time to educate/refresh their knowledge. Letting scientists attend more training/conferences."

"(1) Increasing scientific/clinical review manpower & retaining experience reviewers who now leave due to combination of (1) high work load due to inadequate level of staffing and (2) incommensurate compensation (i.e. pay is lower then competing opportunities in industry, academics, practice or other Federal Agencies such as NIH). Difficult to recruit experienced physicians, especially specialists."

"There is a remarkable amount of pressure placed on reviewers to find 'creative' ways to approve problematic drugs. Reviewers who approve drugs consistently get special project-related awards, while those who do an excellent job on a product that doesn't get approved are very clearly ignored. I've never once seen a review team receive an award for a product that wasn't approved. However, this is all done is a very subtle, implied but persistent and clear way which leaves no doubt what is going on, but is very difficult to document… The problem with the FDA is not that the whole agency operates in an inappropriate way. The problem is that when there are individuals who do behave inappropriately who reach upper management positions, there's no mechanism at all to address this."

"In the end, I really firmly believe that nothing will likely ever come of this survey. Only a catastrophe or scandal can force a meaningful change in a place like the FDA. But I applaud your efforts, and it is comforting to know that there is someone out there who cares about these issues."

"Rewarding scientists for good science and not for arriving at the most convenient results, or for completing drug reviews quickly. Management should never tell scientists what conclusions would be acceptable. Officially, the agency does not put such pressures on its scientists, and yet it has happened to me. A less experienced FDAer would probably feel that they have no choice but to go along with what the boss wants, especially if they need a promotion."

"Separating scientists from expectation that they will recommend approval."

Center for Biologics and Research (CBER):

"First class scientists are leaving the FDA, and recruiting new ones will be very difficult. For the record, soon I'll be leaving for a much better position at NIH."

"Guard and support young scientists it CBER to be independently successful – this is future of CBER (young scientists leaving because no future at CBER – no funds)."

"Base regulatory decisions on scientific analysis and the judgment of subject matter experts. Thank you for taking an interest in these issues and doing a survey."

"Actually supporting science-not just lip service!"

"Integrity of scientists not the question… Retention difficult – lack of support & training for young scientists"

"We select and promote TERRIBLE leadership, who are not qualified as either scientists or managers (and/or we do not attract good candidates). As a direct result, we have no effective advocates, lousy resources, declining respect and morale, and are losing the few good people we do have in droves. Most distressingly, there is no remaining support for, or interest in, SCIENCE."

Center for Devices and Radiological Health:

"Allowing FDA to base their decisions on science instead on the fear of industry appeal, mgmt disapproval, potential law suits."

Center for Food Safety and Applied Nutrition (CFSAN):

"Many reviewers are very dedicated, intelligent, responsible scientists who truly care about protecting public health. These reviewers are usually put down by management. This is very sad."

"Peer review of upper management. Why must only the scientific/research staff face peer review scrutiny?"

"The Center should treat the science staff with more respect and integrity and reward these doing good science. The staff, for the most part, have the greatest (and increasing) workloads (especially review scientists) and are doing work of greater difficulty and required expertise than others and this effort is appreciated and recognized the least."

"Mandating spending on political and industry motivated programs not only has severely curtailed mission-relevant programs required by statute; it also has degraded integrity of programs that eventually do get funded… many CFSAN employees now feel that honesty and scientific objectivity have been compromised and that demonstrating scientific objectivity could cost them their jobs."

National Center for Toxicological Research:
"More of a commitment by FDA management and the political establishment towards reversing the decline in the FDA science base…Morale is at the lowest point I've seen in 2+ years at FDA; I am glad I will be eligible for retirement soon."

Office of Regulatory Affairs:
"In my opinion, it is already too late to worry about the integrity of FDA's scientific work. There are many other problems that will destroy the agency's credibility first. It is fact that FDA cannot even cover all the employees' salaries with their budget. This is leading to further lab consolidation/lab closures which will further dilute the FDA's scientific knowledge base."

"When a manager thinks he can consolidate labs, thus losing experienced analysts with 20+ years FDA experience, and then think they can replace that person, one for one, with a new hire and not have any drop in production or quality is ridiculous."

"Part of the science integrity issue is management being influenced by industry (applicants) and the other is Commission Corps people being placed in mgt. positions w/out qualifications."

"Management needs to actually have RESPECT for the scientists talents and abilities, as well as ideas and suggestions."

"We use or are mandated to use ancient scientific methods and it's almost impossible to update."

"With the management in Rockville, MD, our ability in this field to enforce laws & regulations have been hampered. I feel ineffective in carrying out my duties to protect the consumers."

"Reduce the influence of power-gaming leadership. Often, the agenda of leaders is their own control above all other issues, even above scientific accuracy and principle. The attitude causes demeaning control practices over scientists."

"Scientists are becoming ineffective because of the imposition of an overwhelming amount of inappropriate QA and other tasks not directly related to the primary mission of screening for violative and dangerous products. Scientists need to focus on the science and not rush to produce attractive sample statistics."

"Administrators and supervisors, who are often less qualified academically and scientifically, determine whether the Scientist is allowed to pursue research, and/or to publish findings in peer-reviewed journals."

"I work with some very wonderful, hard working colleagues who are all frustrated by the poor leadership in our own office (as well as the agency as a whole) and the lack of action taken against firms who continually violate the FD&C Act. Morale has declined so much in the last three years in our office that experienced people that would have continued working after reaching retirement age are now counting the days until they can leave. The incompetence I see in management is unbelievable. I know of people in my office who are very upset and disgusted with problems in our office and the agency. But they were afraid to fill this out."

Resources and Funding

Center for Drug Evaluation and Research:

"Provide more resources so that the best and brightest minds can be recruited & retained."

"Congress doesn't pay & PDUFA doesn't pay enough."

"More/better funding for hiring and training. More review staff, esp." for safety evaluation."

"The FDA is under funded and relie[s] heavily on user fees to support its review practice. I think that this represents a conflict of interest. Congress and the American public does not adequately support the FDA in order for it to do the appropriate science that could ultimately speed the review process."

"Most important: Get rid of PDUFA and increase Federal base budget. Currently, we are dependant upon user fees and this is a huge conflict of interest. 'The fox is guarding the henhouse.'"

Center for Biologics Evaluation and Research (CBER):

"Scientific research by FDA employees must be supported, and at a much higher level of funding. Work being done by FDA scientists is work important to public health that would never be done by academia (NIH & universities) or by industry."

"FDA is being starved for operating expenses and laboratory resources, while deadlines grow ever shorter."

"At CBER, the FDA budget funds less than 20% of the lab cost of our research. The scientists have to go out and fund their own research. Other FDA centers are worse off in funding. This level of science is atrocious and will lead to unsafe products."

"In recent years, FDA's budget for intramural research has decreased to the point where FDA's research scientists are forced to identify external sources of funding – in some cases via CRADAs [FDA's Cooperative Research and Development Agreement] w/industry. These are reviewed for conflict of interest. However, increased use of these mechanisms increase opportunities for either potential or perceived conflict-of-interest situations. We should receive sufficient funds from FDA to avoid this potential problem - it's currently a slippery slope."

"Sufficient resources to maintain scientific research to support review of novel biologic products."

"Providing adequate resources to do the mission related work both research and regulation."

"FDA needs the resources (funding, competitive hiring practices, additional reviewers) to maintain and retrieve its reputation as the regulatory "Gold Standard.""

"Increase funding for the scientific work done at/by the FDA. If the funding decreases are not reversed, the agency will not be effective in recognizing, preventing or mitigating future public health disasters. Increasing public funding of FDA scientific work is a very, very inexpensive insurance that the decisions are made based upon science rather than perception or per-conception."

Center for Devices and Radiological Health:

"More lab money – doing good research on $3-5K per year is unrealistic."

"Increase the budget of FDA, esp. for lab research."

Center for Safety and Applied Nutrition (CFSAN):

"Increasing resources to permit FDA to maintain itself as a premier regulator of foods, drugs and cosmetics."

"All of the Centers have been chronically under-staffed for years, and also under-funded… The latest budget cuts to the CFSAN drastically threatens the scientific expertise of the Center by cutting programs and research projects. Maintaining a strong science base is dependent on a solid budget that can support research programs and attract and encourage scientific experts to stay employed with the Center."

"It should be of great concern to you and the public that large budget cuts are expected in FY 07…The worst legacy of this terrible Administration (in my opinion) may be the systematic dismantling of the agency by budget cuts."

"We need more money. We need new equipment. We should be using the latest analysis techniques & modern technology instead of relying on conventional methods. We should be collecting & analyzing a much larger percentage of import & domestic food samples/products."

"The Office of the Center Director has grown massively with very highly paid management/advisory positions in the last several years at CFSAN while the lower 'actual worker' level science positions are shrinking with staff not being replaced (after retirements and job moves/changes etc.)"

"FDA does not have sufficient resources to enforce regulations and policies under the purview of CFSAN. FDA does not have the resources to do the job that the American people expect it to do."

Center for Veterinary Medicine:

"Making sure each Center has enough funds available to obtain 'state of the art' equipment and supplies required to conduct good quality research. We also need funds to ensure personnel can be replaced or added in order to adequately manage the workload."

National Center for Toxicological Research:

"The major problem at FDA is insufficient resources (money) to conduct the needed high quality research. Under the current budget, research at FDA will almost cease to exist. Without research scientists the Agency will not have the scientific expertise to make science-based regulatory decisions."

"Next year (2007) the funding will be at such a level that we may no longer be able to conduct research."

"More funding. Our research budget has been reduced by > 80% over the last two years. These funding cuts have stifled laboratory research."

Office of Regulatory Affairs:

"Adequate money to buy supplies and materials to perform the best science possible."

"Provide FDA with sufficient funding to effectively complete mission, including funding for Presidential mandates."

"Increased funding for better maintenance of equipment and ability to purchase needed supplies and consumables."

"We are the oldest Public Health Agency in the nation and yet our resources are far less than CDC [Centers for Disease Control and Prevention] & USDA [U.S. Department of Agriculture]. FDA can't lead when we don't have adequate resources."

"Bigger budget. $162,000 to run a lab is entirely laughable."

"Providing the money and resources needed to replace old instrumentation, and purchase items needed/identified for an analysis. Also more training is needed to keep up the latest technologies. Very few opportunities are offered to lab personnel. FDA is doing the best job they can with the limited resources provided."

"Providing supplies and equipment needed to perform the necessary work."
"More funding is needed for better equipment, supplies and the hiring of laboratory aides."

"Our operating budget in the field lab has been dramatically cut over the past 5 years leading to the elimination of necessary consumer protection programs. We do not have the resources to fully evaluate the safety and efficiency of products on the market or in development."

"In our district, we do not even have the equipment to do our jobs properly and we are short-handed, both in support staff and investigators. This is the biggest reason I hear for not being allowed to do the inspections that are needed…"

"Increasing funding so we could operate without seeking outside funding."

V. Scientists Recommend Changes at the Agency

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

Center for Drug Evaluation and Research:
"Establishing a scientific integrity program for education of managers & new reviewers"

"More resources to better serve the public and allow time for more state-of-the-are training for its employees including good managerial and decision making training."

"Congress is also largely responsible for the present situation by not giving us adequate regulatory authority to obtain data. For example it was appropriate not to publicly discuss the issue of suicides in teenagers with antidepressants as we didn't have sufficient data. The companies knew this and dragged their feet for years either not providing the requested information, or providing misleading or wrong information. The companies involved only provided the appropriate data when the issue became public. We also have no penalties for when companies intentionally lie or mislead us, e.g. seizures in animals are reported as severe muscle cramps, and healthy animals with supposedly no signs of adverse drug effects are euthanized."

"Limiting direct consumer advertising for 2-5 yrs after drug approval. Reevaluate a new drug in 2 yrs after approval."

"The public and FDA's role to serve the public would be best served by improving post marketing safety evaluation, data gathering and review. What does the office of Drug Safety do anyway?"

"FDA should be much freer to share, clinical trial and adverse event information with the public."

"Stronger Leadership, independent of/resistant to pressure from Industry, Lobbying groups/Congress."

"A better reporting system for post-marketing adverse events."

"We need a full time, permanent commissioner, who is not a political appointee. We have not had one in years."

"FDA employees that leave or retire from FDA must not be allowed to be employed by the regulated industry for at least five years."

"Separate safety from OND [Office of New Drugs] and have an independent safety review division or agency, which does not depend on PDUFA."

"(1) Changes in the laws that favor drug companies. (2) Complete separation of science/politics in the Agency. (3) Appointment of a strong, non-political, permanent commissioner."

"The management should cultivate a culture of openness to dissent and allow admission and review of FDA errors. The management should make safety of products a primary concern and should be able to enforce and set time limits for industry compliance with regulatory action! The policy makers should request legislation for the addition of consumer-friendly efficacy information to product information. The management should encourage publication of drug safety information."

"Stronger Office of Drug Safety. We are a consulting entity whose decisions can be dismissed."

"Separating pre- and post-approval activities with separate centers, each with its own regulatory authority and responsibility. The physician to a pregnant woman is her Obstetrician. Once the baby is delivered, a pediatrician takes over the care and responsibility for the baby – not the Obstetrician."

Center for Biologics Evaluation and Research:

"We also need strong post-market surveillance & a strong compliance officer, willing to take appropriate actions when public health is jeopardized."

"All safety data should not be considered to be confidential. Articles for publication of clinical trial results should include the original study protocol."

Center for Devices and Radiological Health:

"More rigorous expectation by industry to design and implement blinded, randomized, statistically sound clinical trials of medical devices. I don't know why industry's first and continuing position is to design the weakest study possible. Some promising therapies have failed due only to ineffective study design. FDA doesn't have authority to expect and enforce a better level of study design."

"Encouraging FDA scientists to freely conduct research not just related to current submissions and products, but also to forward-looking technologies and methods that have the potential to improve public health."

"Provide support for expanded post-market oversight & product evaluation."

"Revamping notion of 'substantial equivalence' from 510(K)…two devices can be 'substantially equivalent' but both be ineffective. Equivalence tells us little about accuracy and therefore little about effectiveness."

Center for Veterinary Medicine:

"In our center is would be important to develop new regulations in the pre-approval process so we can give the field and industry a better sense on how to conduct studies in order that their applications would be a better quality."

"Adverse event reporting should be mandatory, not optional. Existing drugs should be reviewed every 10 years, and applicable new science applied. This would require that sponsors do more testing in many cases. Sponsors of new antimicrobials should be required to provide benchmark resistance rates daring the pre-approval process."

National Center for Toxicological Research:

"Increasing the independence of agency decisions & regulations in the interest of public health."

"Creating by example and fiat a culture of integrity in all of its management. What starts at the top filters to the bench."

Office of Regulatory Affairs:

"Give FDA recall & seizure authority…give FDA authority to seize & discard illegal imports upon arrival @ port."

"Changing the laws by Congress to give FDA more authority to seize."

"Enforcing existing regulations."

"Giving FDA the authority it needs to carry out Regulatory Action against violative firms!"

"Strengthening the FD&C act to permit FDA to effectively regulate."

"Being able to levy fines against all regulated industry with repeat offenses/violations."

"If FDA did not have to rely on other agencies to enforce the law. FDA depends on US customs (CBP) for immediate action on violative products. In the eyes of other agencies it makes FDA look weak."

"Stronger and independent post-market review of approved drugs and services. Independent in that it is FDA, but a separate group not involved in approval process."

"Better laws that don't protect/shelter industry."

"Post-approval long term monitoring of clinical trials."