DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD 20850

January 7, 2009

John D. Podesta
Presidential Transition Team
Washington, DC 20270

Dear Mr. Podesta:

We, physicians and scientists of the U.S. Food and Drug Administration (FDA), fully support the agenda of President Obama to "challenge the status quo in Washington and to bring about the kind of change America needs."[1] America urgently needs change at FDA because FDA is fundamentally broken, failing to fulfill its mission, and because re-establishing a proper and effectively functioning FDA is vital to the physical and economic health of the nation. As stated in the November 2007 FDA Science Board Report[2] entitled *FDA Science and Mission at Risk*: "A strong FDA is crucial for the health of our country. The benefits of a robust, progressive Agency are enormous; the risks of a debilitated, under-performing organization are incalculable. The FDA constitutes a critical component of our nation's healthcare delivery and public health system. The FDA, as much as any public or private sector institution in our country, touches the lives, health and well-being of all Americans. ... The FDA is also central to the economic health of the nation, regulating approximately $1 trillion in consumer products or 25 cents of every consumer dollar expended in this country annually. ... The importance of the FDA in the nation's security is similarly profound. ... Thus, the nation is at risk if FDA science is at risk."

The purpose of this letter is to inform you that the scientific review process for medical devices at FDA has been corrupted and distorted by current FDA managers, thereby placing the American people at risk. Through this letter and your action, we hope that future FDA employees will not experience the same frustration and anxiety that we have experienced for more than a year at the hands of FDA managers because we are committed to public integrity and were willing to speak out. Currently, there is an atmosphere at FDA in which the honest employee fears the dishonest employee, and not the other way around. Disturbingly, the atmosphere does not yet exist at FDA where honest employees committed to integrity and the FDA mission can act without fear of reprisal. This letter provides an inside view of the severely broken science, regulation and administration at the Center for Devices and Radiological Health (CDRH) that recently forced FDA physicians and scientists to seek direct intervention from the U.S. Congress.[3] This letter also provides elements of reform that are necessary to begin real change at FDA from the "bottom up."

Since May 2008,[4] the FDA Commissioner has been provided with irrefutable evidence that managers at CDRH have placed the nation at risk by corrupting and distorting the scientific evaluation of medical devices, and by interfering with our responsibility to ensure the safety and effectiveness of medical devices before they are used on the American public. Before a medical device can be cleared or approved by FDA, the law requires[5] that safety and effectiveness is determined based on "valid scientific evidence ... from which it can fairly and responsibly be

concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of the device." Managers at CDRH have ignored the law and ordered physicians and scientists to assess medical devices employing unsound evaluation methods, and to accept non-scientific, nor clinically validated, safety and effectiveness evidence and conclusions, as the basis of device clearance and approval. Managers with incompatible, discordant, and irrelevant scientific and clinical expertise in devices for which they have the full authority to make final regulatory decisions, have ignored serious safety and effectiveness concerns of FDA experts. Managers have ordered, intimidated, and coerced FDA experts to modify scientific evaluations, conclusions and recommendations in violation of the laws, rules and regulations and to accept clinical and technical data that is not scientifically valid nor obtained in accordance with legal requirements, such as obtaining proper informed consent from human subjects. These same managers have knowingly tried to avoid transparency and accountability by failing to properly document the basis of their non-scientific decisions in administrative records. As examples of wrongdoing, the Director of the Office of Device Evaluation (ODE) has gone so far as to:

- Order physicians and scientists to ignore FDA Guidance documents;
- Knowingly allow her subordinates to issue written threats of disciplinary action if physicians and scientists failed to change their scientific opinions and recommendations to conform to those of management;
- Issue illegal internal documents that do not conform to the requirements of Good Guidance Practices,[6] are not publicly available, and, if followed, would circumvent science and legal regulatory requirements;
- Fail to properly document significant decisions in the administrative files;[7]
- Make, and allow, false statements in FDA documents;
- Allow manufacturers to market devices that have never been approved by FDA;
- Remove Black Box warnings recommended by FDA experts;
- Bypass FDA experts and fail to properly label devices; and
- Exclude FDA experts from participating in Panel Meetings[8] because manufacturers "expressed concerns that [FDA experts] are biased."

For seven months, Dr. von Eschenbach and his Assistant Commissioner for Accountability and Integrity (Mr. Bill McConagha) have conducted a sham investigation resulting in absolutely nothing: no one was held accountable, no appropriate or effective actions have been taken, and the same managers who engaged in the wrongdoing remain in place and have been rewarded and promoted. Dr. von Eschenbach and Mr. McConagha failed to take appropriate or effective actions while the physicians and scientists who had the courage and patriotism to speak out, and who refused to comply with FDA management wrongdoing, have suffered severe and ongoing retaliation.[9] The failure of Dr. von Eschenbach and Mr. McConagha to take appropriate or effective actions has made them complicit in the wrongdoing,[10] has harmed the reputations and lives of individual employees, and has unnecessarily placed the American public at risk.

In October 2008, the U.S. Congress was provided with the same evidence of wrongdoing that was given to the Commissioner. After Congress examined the evidence, the U.S. House of Representatives Committee on Energy and Commerce sent a letter to the FDA Commissioner dated November 17, 2008,[11] stating that they had "received compelling evidence of serious wrongdoing ... and well-documented allegations ... from a large group of scientists and physicians ... who report misconduct within CDRH that represents an unwarranted risk to public health and a silent danger that may only be recognized after many years ... and that physicians and scientists

within CDRH who objected [to the misconduct]... have been subject to reprisals."

Unfortunately, the preceding facts are only the latest examples of shocking managerial corruption, wrongdoing and retaliation at CDRH. Back in February 2002, a biomedical engineer at CDRH reported serious managerial misconduct to the current Director of ODE and ultimately filed an EEOC lawsuit in September 2004. After six long stressful years of hardship and litigation, a Judge issued a forty-two page *Decision and Findings of Fact*[12] concluding that: "the Agency promoted a hostile working environment ... permeated with derogatory comments and adverse employment actions" ... the Agency "failed to exercise any reasonable care to prevent and correct promptly the harassing behavior" ... the actions toward the engineer were "unconscionable" and "occurred openly within the FDA, unchecked, for over four years" ... that "FDA managers were aware and failed to take appropriate or effective corrective actions; but rather, demonstrated a systemic disregard for federal regulations as well as the FDA's own policies." The Judge further concluded: "supervisors [including the current Director of ODE] knew or should have known of the hostile work environment, but neither the supervisors nor the Agency did anything to correct the situation or prevent further discrimination" ... and "failed to exercise any reasonable care to prevent or correct the hostility of [managers] towards the Complainant." Shockingly, the current Director of ODE herself testified in court that she was aware of the "hostile work environment" but "did not want to get involved," thereby corroborating her complicity in the corruption and retaliation against this employee. These independent facts confirm the longstanding pandemic corruption that cries out for new leadership at FDA from the bottom up.

We are confident that new leadership from the bottom up will be a top priority of Mr. Daschle as the new Secretary of the Department of Health and Human Services (HHS). As Mr. Daschle has recognized,[13] the integrity of the FDA scientific review and decision-making process, where scientific experts make evaluations and recommendations, must be evidence-based and independent, insulated from improper influences. As a matter of fact, Mr. Daschle points to the 1998 FDA approval of mammography computer-aided detection (CAD) devices[14] as an example of a breakdown of the independent scientific review and decision-making process. These CAD devices were supposed to improve breast cancer detection on mammograms. As Mr. Daschle recognized, post-approval scientific publications revealed that actual clinical performance of these CAD devices did not improve breast cancer detection[15] and they were associated with increased patient recalls and unnecessary breast biopsies.[16] We note that the Agency knowingly approved these devices in 1998 even though there was no clinical evidence of improved cancer detection and, furthermore, the device was never tested in accordance with its intended use— one of the principal required elements for device approval.[17] Astoundingly, the approval was based on pseudo-science that consisted of unsubstantiated estimates of potential benefit using flawed testing. Use of these devices is a major public health issue as approximately 40 million mammograms are performed every year in the U.S.[18] Furthermore, as a failure of FDA post-approval monitoring, the FDA never carried out any post-marketing assessment or re-evaluation of the clinical performance of these devices, ignoring accumulating clinical evidence provided by independent research publications revealing that these devices were ineffective and potentially harmful when used in clinical practice.

FDA managers continue to fail to apply even the most fundamental scientific and legal requirements for the approval of these, and so many other, devices. These failures constitute a clear and silent danger to the American public. Since 2006, FDA physicians and scientists have recommended five times not to approve mammography CAD devices without valid scientific and clinical evidence of safety and effectiveness. Manufacturers of these devices have repeatedly

failed to provide valid scientific and clinical evidence demonstrating safety and effectiveness of these devices in accordance with the intended use as required by the law. These matters were the subject of a Radiological Devices Panel meeting in March 2008[19] at which independent outside experts ratified all of the scientific, clinical, and regulatory points of the FDA experts required for proper assessment of the safety and effectiveness of these devices. Despite this, in April of 2008, the Director of ODE ignored the recommendations of all of the experts and approved these devices without any scientific, clinical or legal justification. Although unknown to Mr. Daschle and the American public, the Director of ODE and her subordinates committed the most outrageous misconduct by ordering, coercing, and intimidating FDA physicians and scientists to recommend approval, and then retaliating when the physicians and scientists refused to go along. This, and similar management actions with other devices, compelled us to write the FDA Commissioner in May 2008 and, because he utterly failed to take appropriate or effective actions, we later informed the U.S. Congress in October 2008.

We, physicians and scientists at FDA, seek your immediate attention for change and reform at FDA. To bring real change and reform to FDA, it is absolutely necessary that Congress pass, and the President[20] sign, new legislation providing the strongest possible protections for all government employees,[21] especially physicians and scientists, who speak out about wrongdoing and corruption that interferes with their mission and responsibility to the American public. We desperately need honesty without fear of retaliation for our evaluations and recommendations on medical devices, as well as accountability and transparency, to become the law and thus the foundation of the FDA mission and workplace. We totally agree with the following statement of President Obama:[22] "Often the best source of information about waste, fraud, and abuse in government is an existing government employee committed to public integrity and willing to speak out. Such acts of courage and patriotism, which can sometimes save lives and often save taxpayer dollars, should be encouraged rather than stifled. We need to empower federal employees as watchdogs of wrongdoing and partners in performance. Barack Obama will strengthen whistleblower laws to protect federal workers who expose waste, fraud, and abuse of authority in government. Obama will ensure that ... whistleblowers have full access to courts and due process."

As President Obama has emphasized, he intends to govern the nation and to bring about change from the bottom up. We believe that, as applied to FDA, this means a complete restructuring of the evaluation and approval process such that it is driven by science and carried out by clinical and scientific experts in their corresponding areas of expertise who are charged with review of regulatory submissions in accordance with the laws, rules and regulations. It is necessary that FDA expert physicians and scientists approve final regulatory determinations of safety and effectiveness, rather than multiple layers of managers who are not qualified experts and who often ignore scientific evidence and the law. President Obama has also emphasized the need for complete transparency in government. His Transparency Policy[23] should be mandatory for all FDA regulatory decisions and associated documentation. The long-standing FDA practice of secret meetings and secret communications between FDA managers and regulated industry must be strictly prohibited. Complete transparency in the regulatory decision-making process would serve as a deterrent to wrongdoing and an incentive for excellence.

FDA also requires major renovation of the organizational structure of the various Centers and Offices to restore internal checks and balances that proactively prevent corruption and manipulation of facts, science, and data. At present, FDA is plagued by a heavy-layered top-down organizational structure that concentrates far too much power in isolated Offices run by entrenched managers where cronyism is paramount. We recommend that the Office of Device Evaluation be

dismantled and split into multiple Offices, each headed by a physician or scientist with strong leadership credentials and extensive clinical and technical expertise in the specific devices they regulate. These leadership positions should be rotated on a regular basis. Furthermore, the current system of employee performance evaluation must be eliminated because it is used as an instrument of extortion by management and to terrorize employees who would otherwise serve as "watchdogs of wrongdoing and partners in performance."[24] The performance of FDA physicians and scientists must be based on an independent peer review process where extramural experts review the quality of the scientific content of their regulatory work.

We strongly support the sentiments expressed in a recent letter from Congressman Bart Stupak[25] urging complete change in FDA's current leadership. At CDRH, such change can be implemented immediately by removing and punishing all managers who have participated in, fostered or tolerated the well-documented corruption and wrongdoing. All improper management actions, including improper adverse personnel actions, and clearance/approval of medical devices that were not made in accordance with the laws, rules and regulations, must be reversed. Such swift and decisive action of transparency and accountability will send a strong message FDA-wide that wrongdoing will no longer be tolerated. In order to have a truly fresh start, we recommend that the new Commissioner request resignations from management positions by all current managers within CDRH, and use a competitive merit-based process to re-fill all management positions.

The FDA mission is not limited to pre-market evaluation of safety and effectiveness. FDA is also responsible for the total product life cycle including actual clinical performance.[26] FDA must not engage in a fire-fighting regulatory posture after medical products are introduced into clinical practice and used on patients.[27] FDA must pursue a culture of proactive regulatory science and remain vigilant in monitoring clinical performance of devices. For FDA to fully accomplish its post-marketing responsibilities there must be complete coordination between FDA and all HHS health-related agencies and institutes.[28] This will provide FDA with the necessary critical scientific capability and capacity[29] to achieve its post-marketing oversight. In turn, FDA will be able to provide the American public and all health care decision makers with objective and scientifically rigorous assessments that synthesize available evidence on diagnosis, treatment and prevention of disease. Ultimately, this will result in a lower health care burden on our society.

In a time of transition, with the country facing an economic crisis with potential devastating consequences to the American people, we strongly believe that change and reform at FDA must be a top priority because FDA is central to the physical and economic health of the nation and because it can play a central role in reducing the future healthcare burden and avoiding public health catastrophes.[30] We sincerely hope that, together, we can establish a culture of science, honesty, transparency and integrity at FDA to serve as the genesis of reform for the entire American health care system.

Sincerely,

Cc: Senator Tom Daschle, HHS Secretary-Designate
Dr. Joshua Sharfstein, HHS Transition Team
Congressman John Dingell
Congressman Henry Waxman
Congressman Bart Stupak
Congressman Chris Van Hollen
Senator Edward Kennedy
Senator Michael Enzi
Senator Barbara Mikulski
Senator Max Baucus
Senator Chuck Grassley

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[1] See http://change.gov/agenda/
[2] See http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_00_index.html
[3] See http://energycommerce.house.gov/images/stories/Documents/PDF/Newsroom/110-ltr-101408.CDRHscientists.pdf; http://energycommerce.house.gov/images/stories/Documents/PDF/Newsroom/110-ltr-111708.vonEschenbach.CDRH.pdf
[4] See letter to Dr. Andrew von Eschenbach dated May 30, 2008; See also documentary evidence provided to Dr. von Eschenbach and Mr. Bill McConagha beginning in June 2008.
[5] See 21 CFR 860.7.
[6] See 21 CFR 10.115.
[7] See 21 CFR 10.70.
[8] See http://www.citizen.org/publications/release.cfm?ID=7620
[9] See letter to Mr. Bill McConagha dated October 20, 2008.
[10] See letter to Dr. Andrew von Eschenbach dated September 29, 2008.
[11] See http://energycommerce.house.gov/images/stories/Documents/PDF/Newsroom/110-ltr-111708.vonEschenbach.CDRH.pdf
[12] EEOC No. 531-2006-00114X.
[13] See e.g., pages 116-128 and 169-180 of *CRITICAL—WHAT WE CAN DO AOBUT THE HEALTH-CARE CRISIS*, by Senator Tom Daschle, Thomas Dunne Books, New York, 2008.
[14] Id. at page 121.
[15] See http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4349b1-01%20FDA%20Radiological%20Devices%20Panel%20Meeting%20Introd.pdf at pages 52-56.
[16] See Id. at pages 42 and 52-56.
[17] See 21 CFR 860.7.
[18] See http://www.fda.gov/CDRH/MAMMOGRAPHY/scorecard-statistics.html
[19] See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/details.cfm?mtg=694
[20] See http://www.whistleblowers.org/index.php?option=com_content&task=view&id=695&Itemid=100
[21] See the December 2008 Report from the Union of Concerned Scientists, *Federal Science and the Public Good – Securing the Integrity of Science in Policymaking*, available at http://www.ucsusa.org/assets/documents/scientific_integrity/Federal-Science-and-the-Public-Good-12-08-Update.pdf.
[22] See http://change.gov/agenda/ethics_agenda/
[23] See http://change.gov/page/-/open%20government/yourseatatthetable/SeatAtTheTable_memo.pdf
[24] See http://change.gov/agenda/ethics_agenda/
[25] See http://online.wsj.com/public/resources/documents/stupak-letter-to-obama-20081205.pdf
[26] See http://www.fda.gov/cdrh/strategic/tplc.html
[27] See page 4, Section 1.2.1 at http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf
[28] See http://www.hhs.gov/about/orgchart/
[29] See page 44. Section 3.2.4 at http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf
[30] See, e.g. National Center for Health Statistics, Health, United States, 2007, with Chartbook on Trends in the Health of Americans, available at http://www.cdc.gov/nchs/data/hus/hus07.pdf ; and 2008 World Cancer Report, available at http://www.iarc.fr/en/Publications/PDFs-online/World-Cancer-Report

Note: We can provide all documents referenced in footnotes upon your request.