DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

CERTIFICATE

Pursuant to the provisions of Rule 27 of the Federal Rules of Civil Procedure, I hereby certify that Sarah Kotler, Denials and Appeals Officer, Division of Freedom of Information, Office of Public Information and Library Services, Office of Shared Services, Office of the Commissioner, United States Food and Drug Administration, whose affidavit is attached, has custody of official records of the United States Food and Drug Administration.

In witness whereof, I have, pursuant to the provisions of Title 42, United States Code, section 3505, and the authority delegated to me by the Commissioner of Food and Drugs, hereto set my hand and caused the seal of the Department of Health and Human Services to be affixed this 5th day of March, 2010.

Frederick J. Sadler, Director
Division of Freedom of Information

By Direction of the Secretary of
Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

# AFFIDAVIT

Sarah Kotler, being first duly sworn, deposes and says:

1. I am the Denials and Appeals Officer in the Division of Freedom of Information, Office of Public Information and Library Services, Office of Shared Services, Office of the Commissioner, United States Food and Drug Administration.

2. In this capacity, I have custody of official records of the United States Food and Drug Administration.

3. Attached are certified and authentic copies of records of the Food and Drug Administration:

A. Letter from FDA to The Honorable Barrack H. Obama, President of the United States, dated April 2, 2009.

B. Letter from FDA to John D. Podesta, Presidential Transition Team, dated January 7, 2009.

4. Copies of the administrative records are part of the official records of the United States Food and Drug Administration.

Sarah Kotler

County of Montgomery
State of Maryland

Subscribed and sworn to before me this 8th day of March, 2010.

Theola Myo Khin
Notary Public

My commission expires July 7, 2013.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

April 2, 2009

The Honorable Barack H. Obama
President of the United States
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Mr. President:

The purpose of this letter is to draw your attention to the frustration and outrage that FDA physicians and scientists, public advocacy groups, the press, and the American people, have repeatedly expressed over the misdeeds of FDA officials. Recent press reports revealed extensive evidence of serious wrongdoing by Dr. Andrew von Eschenbach, Dr. Frank M. Torti, top FDA attorneys, Center and Office Directors, and many others in prominent positions of authority at FDA. As a result, Dr. Frank M. Torti, Acting Commissioner and the FDA's first Chief Scientist, abruptly left the Agency. But, the many other FDA managers who have failed to protect the American public, who have violated laws, rules, and regulations, who have suppressed or altered scientific or technological findings and conclusions, who have abused their power and authority, and who have engaged in illegal retaliation against those who speak out, have not been held accountable and remain in place.

On Monday, March 30, 2009, Dr. Joshua Sharfstein, newly appointed Principal Deputy Commissioner, assumed the position of Acting Commissioner until Dr. Margaret Hamburg is confirmed. Numerous FDA physicians and scientists are certain that Dr. Hamburg and Dr. Sharfstein will bring the necessary change to FDA to guarantee integrity, accountability, and transparency, to ensure that all future decisions are solely based on science and in accordance with the laws, rules, and regulations. However, sweeping measures are needed to end the systemic corruption and wrongdoing that permeates all levels of FDA and has plagued the Agency far too long.

The latest example of wrongdoing was reported on March 23, 2009 from a Federal District Court Judge who ruled that FDA's decision on the Plan B drug[1] was "arbitrary and capricious because they were not the result of reasoned and good faith agency decision-making." FDA's top leaders at the Center for Drug Evaluation and Research (CDER) testified that they "didn't have a choice, and . . . [weren't] sure that [they] would be allowed to remain [in their positions if they] didn't agree" to ignore the science and the law. To the contrary, they should be removed from their positions of authority precisely because they didn't follow the science and the law. The judge further ruled that there was "unrebutted evidence that the FDA's [decision] stemmed from political pressure rather than permissible health and safety concerns." The "improper political influence" and the many

"departures from its own policies" reveal that such FDA officials are incapable of ensuring integrity and science at FDA.

On October 14, 2008, FDA physicians and scientists wrote to members of the House Energy and Commerce Committee reporting that top FDA officials at the Center for Devices and Radiological Health (CDRH) had distorted the scientific review of medical devices and then retaliated against those who brought this to light.[2] Congressman John Dingell (then Chairman) and Congressman Bart Stupak (Chairman, Subcommittee on Oversight and Investigations) wrote to then FDA Commissioner Dr. Andrew C. von Eschenbach (since resigned), stating that there were "well-documented allegations that senior managers within CDRH" had "acted in violation of the law … [and that] sweeping measures may be necessary to address the distortion of science alleged by so many CDRH scientists."[3]

On January 7, 2009, FDA physicians and scientists wrote to Mr. John Podesta[4]: "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. … 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."[5]

On January 13, 2009, the NY Times[6] reported that FDA officials allowed "improper political influence"[7] to guide official FDA actions. The Director of the Office of Device Evaluation, Dr. Donna-Bea Tillman, approved[8] a medical device used for the detection of breast cancer despite the fact that all of the FDA experts involved recommended against approval of the device three times. Dr. Tillman's decision to overrule the FDA experts "followed a phone call from a Connecticut congressman [Christopher Shays]."

On January 26, 2009, FDA physicians and scientists wrote to you directly[9] seeking your help and recommending that "you remove and hold accountable all managers who have ordered, participated in, fostered or tolerated the well-documented corruption, wrongdoing and retaliation at the Agency." That letter was prompted by concerns that FDA officials were planning to investigate physicians and scientists in retaliation for the January 13, 2009 story in the NY Times. These concerns were well-founded.

On March 13, 2009, one week after another episode detailing wrongdoing and improper political influence involving top FDA officials was published in the Wall Street Journal,[10] Acting Commissioner Dr. Frank M. Torti and FDA attorneys sprung into action. Their solution— send an FDA-wide email[11] admonishing FDA employees that they "must comply with … obligations to keep certain information … confidential … [including] e-mail to and from employees within FDA [that document the] deliberative process" and threatening that "violation … can result in disciplinary sanctions and/or individual criminal liability."

These threats did not escape the scrutiny of Senator Chuck Grassley,[12] Ranking Member of the U.S. Senate Committee on Finance. In a letter to Dr. Torti on March 24, 2009, Senator Grassley wrote: "Your memorandum … appears to run contrary to many statutes protecting executive branch communications with members of Congress. … I am concerned with the timing of your memorandum, given some recent high profile matters concerning your Agency and the release of information that has shown failures in FDA's regulatory mission. [This] could be viewed … as an effort to chill and/or prevent FDA employees from exercising their rights under whistleblower protection laws. … Whistleblowers are some of the most patriotic people I know—men and women who labor, often anonymously, to let Congress and the American people know when the Government isn't working so we can fix it."

The Wall Street Journal[13] and FDA documents[14] revealed efforts by top FDA officials (including Dr. von Eschenbach, Dr. Torti, Mr. William McConagha, and other FDA attorneys) to cover-up their attempts to improperly influence, obstruct, impede and distort the due and proper administration of the FDA scientific regulatory process involving a knee implant device. According to the Columbia University Journalism Review,[15] "the [Wall Street] Journal describes a process in this case that's, well, corrupt. I don't know what else you'd call it. It even has a smoking gun."[16] An advisory committee of outside experts, convened to provide advice on the safety and effectiveness of the knee implant, was misled and manipulated by Dr. Daniel Schultz (Director of CDRH) as well as top FDA attorneys. Dr. Schultz was accused of "stacking the committee to get the decision the company wanted," and of falsely stating in an official document that the conclusions reached by the advisory committee were "clear" and "unanimous"—to the contrary, they were not. A letter[17] from Senator Grassley to Dr. Torti dated March 6, 2009 indicated that Dr. Schultz and top FDA attorneys had concealed the fact that two of the authors of a major publication presented to the advisory committee in support of the knee implant device, had affiliations with the device manufacturer ("the first author of the article is [the manufacturer's] Vice President of Scientific Affairs," Senator Grassley noted). Dr. Jay Mabrey, Chief of orthopedic surgery at Baylor University Medical Center in Dallas and Chairman of the advisory committee, should be commended for his integrity and willingness to speak out once he became aware of what had transpired. Dr. Larry Kessler, former Director of the Office of Science and Engineering Laboratories at FDA, who had direct knowledge of the advisory committee meeting and process, characterized the process as "show[ing] the FDA at its worst."

The culture of wrongdoing and cover-up is nothing new but is part of a longstanding pattern of behavior. For example, in July 2005,[18] Dr. Daniel Schultz "approved a medical device against the unanimous opinion of his scientific staff,"[19] overruling "more than twenty FDA scientists, medical officers and management staff."[20] According to the New York Times[21], the decision represented the first time in the agency's history that a director "approved a device in the face of unanimous opposition from staff scientists and administrators beneath him." As described in a Senate Finance Committee report following an investigation led by Senator Grassley,[22] Dr. Schultz never revealed to the public that the FDA scientists, medical officers, and all other staff involved, completely disagreed with his decision. The report also stated that "what remains the same in FDA's approval of a device or a drug is the requirement that data supporting a sponsor's application for approval be scientifically sound. Otherwise health care providers and insurers as well as patients may question the integrity and reliability of the FDA's assessment of the safety and effectiveness of an approved product."– We completely agree.

Amazingly, just 3 weeks ago, on March 6, 2009, it was reported by the consumer advocacy organization *Public Citizen* that Dr. Tillman "approved a [medical] device that has failed to demonstrate any clinical benefit" and that showed "trends toward higher risks of death."[23] According to *Public Citizen*: The March 6, 2009 approval by Dr. Tillman[24] "bears an eerie resemblance to another device, Intergel, an anti-scarring device intended for pelvic surgeries that also demonstrated reduced scarring without clinically validated outcomes. … Less than two years after Intergel was approved [by Dr. Schultz[25]], the company removed the product from the market[26] due to reports of post-operative pain, foreign body reactions and tissue scarring requiring repeat surgery, including three deaths among women who received it. This history should have given the FDA pause before once again approving a similar device with a questionable safety record."[27]

But now, things may finally change at FDA and meeting the expectations of the public may become a reality. On March 14, 2009, an FDA-wide e-mail was sent from the Acting Secretary of HHS: "Dr. Margaret "Peggy" Hamburg will be nominated by the President to serve as the next Commissioner and Dr. Joshua "Josh" Sharfstein will serve as the Principal Deputy Commissioner of the FDA. … The FDA is the premier agency of its kind in the world, and President Obama wants to revitalize the agency and empower it to make the best possible decisions for the American people based on the best science available. Dr. Hamburg and Dr. Sharfstein will work hard to support scientific integrity at FDA, strengthening the ability of the agency's professionals to do their work on behalf of the American people. They are the perfect people to translate the President's vision for the FDA into reality."

We share your vision and we urge that you provide all necessary support to enable your new leadership to bring change to FDA without delay as part of your planned healthcare reform. As stated in a recent NY Times editorial, you must "send a clear signal to the bureaucracy that the days of neglect are over. Officials [must] make clear that the … practice of distorting science and weakening regulation to favor industry also is over."[28] – We completely agree.

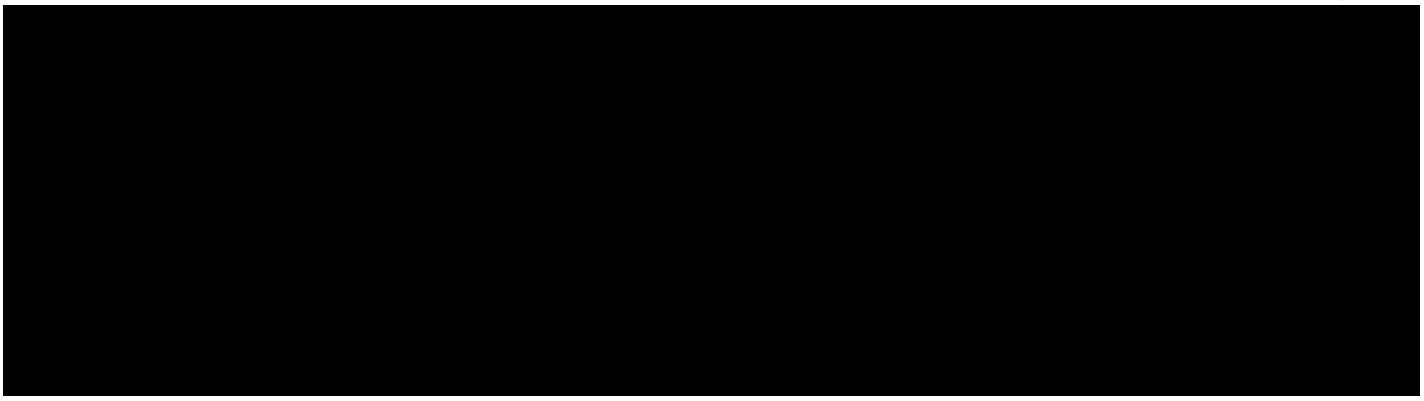
FDA must carry out its work in a transparent manner based on sound science in order to improve the lives of all Americans, reduce health care costs, and expand health care access. Much work remains to be done at FDA and all pending matters need to be addressed. The wrongdoing revealed in the Wall Street Journal involves top FDA officials and requires immediate investigation. Astoundingly, since May 2008,[29] Dr. von Eschenbach, Dr. Torti, Mr. McConagha, and numerous top FDA officials, have been well-aware of other serious wrongdoing, and failed to take any actions, while the physicians and scientists who spoke out and refused to comply have suffered retaliation.

The clearance/approval of medical devices that were not made in accordance with the laws, rules and regulations, need to be re-visited. Furthermore, those FDA employees who have engaged in wrongdoing, who have violated laws, rules, and regulations, who have abused their power and authority, and/or who have engaged in retaliation, should be dealt with swiftly. Immediate and decisive disciplinary action will send a strong message FDA-wide that wrongdoing will no longer be tolerated and those who engage in wrongdoing will be held accountable. Some wrongdoing may be beyond the scope of FDA's jurisdiction and may need referral to the U.S. Attorney General.

All FDA employees who are committed to public integrity, who follow the laws, rules and regulations, who use science to promote public safety and health, and who have the courage and

patriotism to speak out, must be protected and must have their professional lives restored. We ask that you accept nothing less.

Sincerely,



cc: Kathleen Sebelius, HHS Secretary-Designate
Dr. Howard Koh, HHS Asst. Secretary of Health-Designate
Dr. Margaret Hamburg, FDA Commissioner-Designate
Dr. Joshua Sharfstein, Principal Deputy Commissioner of the FDA
Senator Chuck Grassley, Ranking Member, Senate Committee on Finance
Senator Max Baucus, Chairman, Senate Committee on Finance
Senator Edward Kennedy, Chairman, Senate HELP Committee
Senator Michael Enzi, Ranking Member, Senate HELP Committee
Senator Claire McCaskill, Government Affairs Committee
Senator Barbara Mikulski, Senate HELP Committee
Congressman John Dingell, Chairman Emeritus, House Energy and Commerce Committee
Congressman Henry Waxman, Chairman, House Energy and Commerce Committee
Congressman Bart Stupak, Chairman, Subcommittee on Oversight and Investigations
Congressman Joe Barton, Ranking Member, House Energy and Commerce Committee
Congressman Greg Walden, Ranking Member, Subcommittee on Oversight and Investigations
Congressman Edolphus Towns, Chairman, Committee on Oversight and Government Reform
Congressman Darrell Issa, Ranking Member, Committee on Oversight and Government Reform
Congressman Chris van Hollen, Committee on Oversight and Government Reform

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[1] See http://www.nyed.uscourts.gov/pub/rulings/cv/2005/05cv366mofinal.pdf at page 41
[2] See http://energycommerce.house.gov/Press_110/110-ltr-101408.CDRHscientists.pdf
[3] See http://energycommerce.house.gov/Press_110/110-ltr-111708.vonEschenbach.CDRH.pdf
[4] See http://www.thegraysheet.com/nr/FDC/SupportingDocs/gray/2009/011209_Lettr2transitionteam.pdf
[5] See http://www.thegraysheet.com/nr/FDC/SupportingDocs/gray/2009/011209_Lettr2transitionteam.pdf
[6] See http://www.nytimes.com/2009/01/13/health/policy/13fda.html
[7] See http://www.nyed.uscourts.gov/pub/rulings/cv/2005/05cv366mofinal.pdf at page 41.
[8] See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/PMA.cfm?ID=12320
[9] See http://www.nytimes.com/2009/01/28/us/28fda.html?ref=health
[10] See http://online.wsj.com/article/SB123629954783946701.html
[11] See http://invivoblog.blogspot.com/2009/03/fda-commish-to-employees-keep-quiet-or.html
[12] See http://grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=19930
[13] See http://online.wsj.com/article/SB123629954783946701.html

[14] See http://online.wsj.com/public/resources/documents/WSJ_regenLetter_090303.pdf; http://online.wsj.com/public/resources/documents/WSJ_510K_090303.pdf; and http://online.wsj.com/public/resources/documents/WSJ_regenLetter2_090303.pdf
[15] See http://www.cjr.org/the_audit/wsj_exposes_corruption_at_the.php
[16] See http://online.wsj.com/public/resources/documents/WSJ_regenLetter_090303.pdf; The FDA officials on the e-mails include:

- Dr. Frank Torti, Acting FDA Commissioner
- Susan Winckler, Chief of Staff to Dr. Frank Torti
- William McConagha, Assistant Commissioner for Accountability and Integrity
- Jeffrey Senger, Deputy Chief Counsel, Office of the Commissioner
- Ann Wion, Deputy Chief Counsel, Office of the Commissioner
- Beverly Chernaik, FDA Attorney in the Office of the Commissioner
- Matthew Warren, Regulatory Counsel in Office of the Commissioner
- Dr. Daniel Schultz, Director of the Center for Devices and Radiological Health (CDRH)
- Dr. Donna-Bea Tillman, Director of the Office of Device Evaluation (ODE)
- Kate Cook, Associate Director for Regulations and Policy at CDRH
- Les Weinstein, CDRH Ombudsman
- Catherine Norcio, Policy Advisor to Dr. Daniel Schultz

[17] See http://grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=19632
[18] See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/PMA.cfm?ID=7798
[19] See http://www.nytimes.com/2006/02/17/politics/17fda.html?_r=1&ex=1164344400&en=3ecd97edf816da86&ei=5070; and http://www.ucsusa.org/scientific_integrity/abuses_of_science/nerve-stimulator html
[20] See http://finance.senate.gov/press/Gpress/02_2006%20report.pdf
[21] See http://www.nytimes.com/2006/02/17/politics/17fda html
[22] See http://finance.senate.gov/press/Gpress/02_2006%20report.pdf
[23] See http://www.citizen.org/pressroom/release.cfm?ID=2842
[24] See http://www.accessdata.fda.gov/cdrh_docs/pdf7/P070005a.pdf
[25] See http://www.fda.gov/cdrh/pdf/P990015a.pdf
[26] See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/printer.cfm?id=130
[27] See http://www.citizen.org/pressroom/release.cfm?ID=2842
[28] See http://www.nytimes.com/2009/01/27/opinion/27tue3.html?scp=1&sq=editorial%20devices%20fda&st=cse
[29] See http://www.thegraysheet.com/nr/FDC/SupportingDocs/gray/2009/011209_Lettr2transitionteam.pdf

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.