



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 drug¹ 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 Podesta⁴: “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 Times⁶ 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, approved⁸ 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 directly⁹ 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 email¹¹ 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 Journal¹³ and FDA documents¹⁴ 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 letter¹⁷ 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 Times²¹, 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. Tillman²⁴ “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. Schultz²⁵], the company removed the product from the market²⁶ 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.

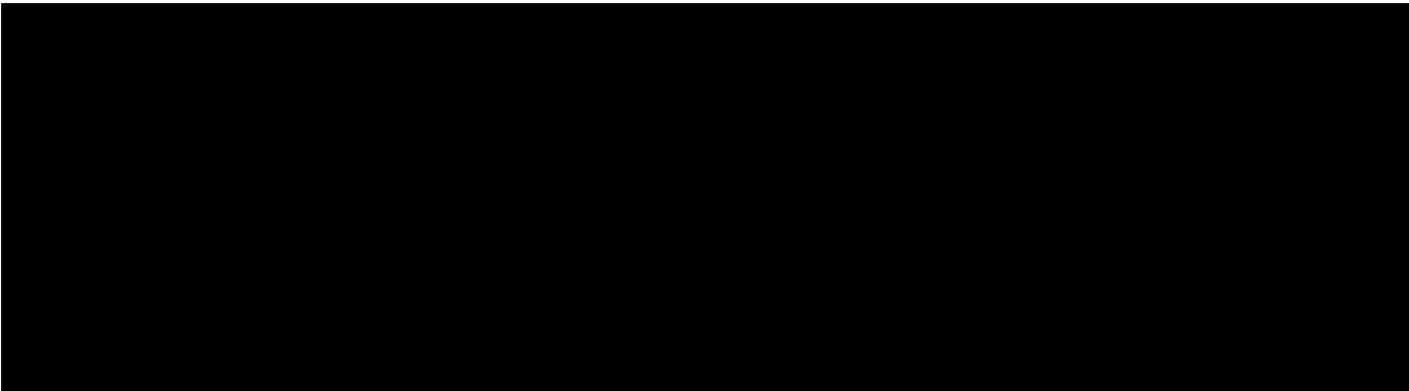
FDA must carry out its work in a transparent manner based on sound science in order to improve the lives of all Americans, reduce health care costs, and expand health care access. Much work remains to be done at FDA and all pending matters need to be addressed. The wrongdoing revealed in the Wall Street 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

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.ucsus.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