



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

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

October 14, 2008

Congress of the United States
House of Representatives
Representative John D. Dingell
2328 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Dingell:

This letter seeks your urgent intervention because serious misconduct by managers of the U.S. Food and Drug Administration (FDA) at the Center for Devices and Radiological Health (CDRH) is interfering with our responsibility to ensure the safety and effectiveness of medical devices for the American public and with FDA's mission to protect and promote the health of all Americans. Managers at CDRH have failed to follow the laws, rules, regulations and Agency Guidance to ensure the safety and effectiveness of medical devices and consequently, they have corrupted the scientific review of medical devices. This misconduct reaches the highest levels of CDRH management including the Center Director and Director of the Office of Device Evaluation (ODE).

██████████ physicians and scientists ██████████ at CDRH have already sought intervention from the FDA Commissioner. The physicians and scientists ██████████ are responsible for ensuring the safety and effectiveness of all ██████████ devices before they are used on the American public. The devices we regulate are crucial and fundamental to medical practice ██████████

██████████ devices constitute a substantial ██████████ cost to the ██████████ American health care system with more than 500 million adult and pediatric ██████████ procedures performed every year in the United States.

It is crucial for FDA to regulate medical devices based on rigorous science. As stated in the November 2007 FDA Science Board Report¹ entitled "FDA Science and Mission at Risk":

¹ Available at http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_00_index.html

“A strong Food and Drug Administration (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 this country, touches the lives, health and wellbeing of all Americans and is integral to the nation’s economy and its security. The FDA’s responsibilities for protecting the health of Americans are far-reaching. ... 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 industries that FDA regulates are among the most successful and innovative in our society, and are among the few that contribute to a positive balance of trade with other countries. 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.”

There is extensive documentary evidence that managers at CDRH have corrupted and interfered with the scientific review of medical devices. The scientific review of medical devices is required to work as follows: FDA clinical and scientific experts (“FDA experts”) review submissions based on the best available scientific information and in accordance with the Food Drug and Cosmetic Act, the Code of Federal Regulations and Agency Guidance documents (when such Guidance documents exist for a particular device or category of devices). FDA experts give their best scientific judgments, opinions and conclusions regarding safety and effectiveness of medical devices and make corresponding regulatory recommendations. These form the scientific and regulatory basis for managers at FDA to make final regulatory decisions (i.e., clearance or approval of medical devices). While managers can disagree with FDA experts, they cannot order, force or otherwise coerce FDA experts to change their scientific judgments, opinions, conclusions or recommendations. In accordance with the law, if managers at FDA disagree with FDA experts, managers must document their disagreements in official Agency records, must scientifically justify any contrary judgments, opinions, conclusions or recommendations and must take personal responsibility for their final regulatory decisions. The review process is well described in long existing Agency Guidance.²

The law requires that qualified experts make safety and effectiveness determinations based on valid scientific evidence. Managers at CDRH with no scientific or medical expertise in [REDACTED] devices, or any clinical experience in the practice of medicine [REDACTED], have ignored serious safety and effectiveness concerns of FDA experts and have ignored scientific regulatory requirements. To avoid accountability, these managers at CDRH have ordered, intimidated and coerced FDA experts to modify their scientific reviews, conclusions and recommendations in violation of the law. Furthermore, these managers have also ordered, intimidated and coerced FDA experts to make safety and effectiveness determinations that are not in accordance with scientific regulatory requirements, to use unsound evaluation methods, and 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

² Available at <http://www.fda.gov/cdrh/g93-1.html>.

managers have knowingly avoided and failed to properly document the basis of their decisions in official Agency records.

Under the banner of regulatory “precedent,” managers at CDRH have demanded that physicians and scientists review regulatory submissions employing methods, and accepting evidence and conclusions, that are not scientifically proven and clinically validated. These demands appear to be based on the misguided notion that because flawed methods, evidence and conclusions were used or accepted in the recent or even the remote past, we must continue to blindly and knowingly accept these flawed methods, evidence and conclusions and continue to use them as the basis for regulatory recommendations. Such invalid regulatory “precedent” goes against current scientific and clinical evidence. Rather than remedy past regulatory or scientific errors after they come to light, and rather than applying the best and latest scientific knowledge and methodology, these managers at CDRH knowingly continue to make the same regulatory and scientific mistakes over and over again. Rather than recall, re-evaluate or otherwise deal with potentially unsafe or ineffective devices that are already on the market, these managers at CDRH continue to approve more devices of the same kind in a non-transparent and non-scientific manner. This is especially true of the 510(k) program but also applies to the PMA program as well as the advice and guidance given to manufacturers before they make regulatory submissions. The practices described above represent an unwarranted risk to public health and a silent danger that may only be recognized after many years.

When physicians and scientists have objected to the management practices described above, managers at CDRH have engaged in reprisals and ignored these critical concerns. FDA physicians and scientists therefore contacted the Office of the Commissioner:

- On May 31, 2008, [REDACTED] FDA physicians and scientists [REDACTED] wrote to the FDA Commissioner, Dr. Andrew von Eschenbach (See attached letter).
- The Commissioner immediately asked Mr. William McConagha, the Assistant Commissioner for Integrity and Accountability, to begin a full investigation.
- Since early June 2008, FDA physicians and scientists have met with Mr. McConagha numerous times and have facilitated his investigation by providing written documentary evidence including internal emails, reviews, memos, meeting minutes, etc.
- Mr. McConagha has characterized the documentary evidence as “compelling,” “convincing” and “sufficient” to justify curative and disciplinary actions. As a result, the Commissioner met with the CDRH Director in August.
- On September 3, 2008, [REDACTED] FDA physicians and scientists [REDACTED] met with the Director of CDRH in the presence of representatives from the Commissioner’s Office. At the request of Mr. McConagha, the FDA physicians and scientists presented the issues and documentary evidence to the Director of CDRH (See attached presentation).

- The Director of CDRH then conducted his own investigation and concluded that we, FDA physicians and scientists, need to “move forward,” thus allowing managers to avoid and evade any accountability and without taking any curative or disciplinary actions whatsoever. The Director of CDRH has further aggravated the situation by knowingly allowing a continuation of management reprisals. These reprisals now include removal and threatened removal of physicians and scientists [REDACTED] [REDACTED] [REDACTED] as well as illegal and improper employee performance evaluations.
- On September 29, 2008, [REDACTED] FDA physicians and scientists wrote a second letter to Dr. von Eschenbach (see attached letter).

To date, despite involvement by the Commissioners Office, there has been enormous internal resistance from entrenched managers at CDRH including the Center Director and the Director of ODE. These managers seem far more concerned about ensuring their current positions and protecting and promoting their own careers and those of their cronies, than they are about ensuring the safety and effectiveness of medical devices and protecting and promoting the health of all Americans. CDRH managers prefer to employ regulation-based “pseudo-science” rather than science-based regulation.

It is evident that managers at CDRH have deviated from FDA’s mission to identify and address underlying problems with medical devices before they cause irreparable harm, and this deviation has placed the American people at risk. Given the large number of [REDACTED] [REDACTED] submissions to the FDA, the complexity of the scientific and medical issues involved and the importance of [REDACTED] devices to the practice of medicine, we believe that proper regulation of [REDACTED] devices requires the establishment of a new and separate Office at FDA [REDACTED]. This Office must be staffed by expert physicians and scientists at all levels including management and must provide vision and leadership by being proactive rather than reactive, by incorporating the latest scientific and technological evidence into device evaluation, compliance and post-market surveillance, and by making all regulatory decisions in a transparent manner based on sound scientific and clinical principles. At the same time, there is a need for new legislation that modernizes the regulatory structure of the 510(k) program so that complex medical devices are not allowed onto the market without a comprehensive (or in some cases, any) clinical evaluation of their safety and effectiveness. This is especially true for [REDACTED] devices due to their markedly increased use in clinical practice and because [REDACTED] devices employ highly complex hardware and software, undergo rapid technological changes and touch the lives of so many patients on a daily basis. The current framework for medical device adverse event reporting does not work for many [REDACTED] devices [REDACTED] as the adverse effects of [REDACTED] devices are rarely detected immediately, are not transparent on an individual patient basis, and can only be prevented by a rigorous pre-market evaluation process.

FDA leaders need to re-establish the trust of the American people. Congress needs to ensure that FDA physicians and scientists can do their jobs by being allowed to follow the laws, rules and regulations without fear of reprisal, by applying the best and latest scientific knowledge and methodologies, by having an updated modern regulatory structure, and by allocating sufficient financial and other resources to FDA.¹ Finally, FDA leaders and Congress must restore compliance with the law, must hold accountable those managers at FDA that fail to carry out the

FDA mission to protect and promote the health of all Americans, and must protect FDA physicians and scientists so that they can protect the American public.

As the Branch of government responsible for oversight of the FDA, we urgently seek your intervention and help.

[REDACTED]

[REDACTED]

[REDACTED]