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“Ordered, Intimidated And Coerced”? CDRH Targeted In Misconduct Probe

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Find out how FDA's device center has until Dec. 1 to respond to a Congressional inquiry into allegations of wrongdoing in its pre-market review process.

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On Nov. 17, the House Committee on Energy and Commerce launched an investigation into whether senior managers at the device center "knowingly corrupted the scientific review process and approved or cleared medical device applications in gross violation" of the law and agency regulations.

The investigation was prompted by an Oct. 14 1letter to Rep. John Dingell (D-Mich.), then chairman of the Committee on Energy and Commerce, from a group of CDRH scientists and physicians alleging serious misconduct at the center.

"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," the group charges in a redacted copy of the October letter released by Dingell that conceals their identities. Hill staffers said the group totals eight individuals.

"This misconduct reaches the highest levels of CDRH management including the Center Director [Dan Schultz] and Director of the Office of Device Evaluation [Donna-Bea Tillman]," the disgruntled staffers allege.

Evidence Of Intimidation "Compelling"

Dingell, along with Rep. Bart Stupak (D-Mich.), chairman of the Subcommittee on Oversight and Investigations, state that they have received "compelling evidence" to support charges that senior managers at CDRH "ordered, intimidated and coerced FDA experts to modify their scientific reviews, conclusions and recommendations in violation of the law."

Documentary evidence includes internal e-mails, reviews, memos and meeting minutes.

The CDRH scientists also claim that device center managers ordered them 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."

CDRH managers "prefer to employ regulation-based 'pseudo-science' rather than science-based regulation," they allege.

"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," the FDAers state.

510(k) Program Deficits Singled Out

While the redacted copy of the letter from the CDRH staffers eschews any mention of specific device types or manufacturers, the petitioners suggest that their concern over use of "invalid" regulatory precedent "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 "represent an unwarranted risk to public health and a silent danger that may only be recognized after many years," the group concludes.

The government scientists specifically recommend "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."

The Governmental Accountability Office has drafted a yet-unreleased report on the 510(k) program that is expected to spur premarket notification reform proposals. And industry stakeholders have speculated that changes to the laws governing the 510(k) process could be included in import safety legislation already circulating in the Energy and Commerce Committee (2"The Gray Sheet" Nov. 17, 2008, p. 7).

CDRH Chief Let Accused Managers Off The Hook?

FDA Commissioner Andrew von Eschenbach previously tasked Assistant Commissioner for Integrity and Accountability William McConagha to investigate the allegations in response to a May 31 letter from the same group of CDRH scientists and physicians.

However, in a Nov. 17 3letter to von Eschenbach, Dingell and Stupak express disappointment that no corrective action has yet been taken, despite an initial assessment by McConagha that the evidence was sufficient to justify disciplinary action.

"We ... understand that Mr. McConagha may have already recommended to you that the seriousness of the charges and credibility of the evidence support removal of certain CDRH managers," the letter continues.

The missive also raises concern that the whistleblowers may have been retaliated against.

"The Committee has learned that physicians and scientists within CDRH who objected to the management practices described above have been subject to reprisals including removal or threatened removal and illegal or inappropriate employee performance evaluations," Dingell and Stupak state.

The whistleblowers blame the CDRH director, who "conducted his own investigation and concluded that we ... need to 'move forward,' thus allowing managers to avoid and evade any accountability."

The scientists also accuse senior staffers with cronyism. "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."

Dingell and Stupak call for "immediate actions" to effect any necessary changes, and request a briefing from McConagha no later than Dec. 1 on what action has been taken or will be taken in response to the allegations.

"These allegations are deeply concerning, and we intend to uncover whether any FDA activity has compromised the health and safety of American consumers," Dingell said.

FDA is not commenting except to say that they will respond directly to the lawmakers on the concerns raised,

according to agency spokesperson Scott McFarland.

Not The First Sign Of CDRH Scientist Revolt

The device center flap is the latest in a series of high-profile cases in which FDA scientists have spoken out against agency decisions in recent years.

Although many of those instances have originated on the drug side of the agency, a substantial matter of CDRH staff dissent was publicized in 2006 relating to the 2005 approval of Cyberonics' PMA for its ***VNS Therapy*** neurostimulation device for treatment-resistant depression.

In that case, a Senate Finance Committee investigation, including review of internal documents and interviews with FDA staff, found that Center Director Schultz approved the product after overruling more than 20 FDA staff members who had concluded that data submitted by the company did not meet reasonable standards for safety and effectiveness (4"The Gray Sheet" Feb. 27, 2006, p. 4).

More generally, a 2006 survey of nearly 1,000 FDA scientists found that only 47% felt that they could openly express concerns within the agency about public health without fear of retaliation, while 36% did not.

In addition, the survey, by the Union of Concerned Scientists, found that 15% of respondents reported being asked "for non-scientific reasons, to inappropriately exclude or alter technical information or my conclusions in a FDA scientific document" (5"The Gray Sheet" July 24, 2006, p. 7).

This is also not the first time Dingell has taken a deep look at FDA's device review process. His investigation of device center activities in the early 1990s culminated in the issuance of a report entitled "Less Than The Sum Of Its Parts," which focused criticism primarily on the device evaluation program, including the 510(k) process in particular, and gave rise to some reforms (6"The Gray Sheet" June 7, 1993, p. 3).

Impact Of Dingell Dethroning Unclear

Three days after Reps. Dingell and Stupak penned the letter to von Eschenbach, Rep. Henry Waxman, D-Calif., unseated Dingell as chair of the Energy and Commerce Committee with the backing of the Democratic caucus.

Waxman's office did not return a call for comment on what priority the CDRH investigation would have under his chairmanship.

But Waxman, if anything, favors even more active government oversight than Dingell in many areas. At the helm of the House Oversight and Government Reform Committee, from which he will now resign as chair, Waxman has been aggressive in investigating the Bush administration's FDA and the medical device industry directly.

The Energy and Commerce post offers Waxman at least the same leverage as he has enjoyed on the investigative front, but more authority to follow through with legislation.

On the flip side, one of the primary reasons cited for Waxman pursing the Energy and Commerce chairmanship is to enact more substantial environmental legislation, so tangible focus on FDA reform could be overshadowed by those efforts.

But even if FDA/CDRH legislation and investigations are slowed by other priorities, there is another means by which the issues raised by the CDRH whistleblowers and now amplified by Congress could be more aggressively pursued: in-house, by a new FDA commissioner named by the Obama administration.

- Jon Dobson

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