

## **Appendix D**

Excerpts from Anonymous Letters to POGO

In the summer and fall of 2008, POGO received anonymous letters from writers who indicated that they were scientists working within CDRH, and who described managerial interference with the review decisions by scientists. In these letters, writers indicated that they believed that unsafe devices had been approved. In addition, almost all the writers described an atmosphere in which threats of retaliation were common. Most seemed fearful that they might be identified as authors.

Below are excerpts from some of these letters.

### **Letter 1**

The nature of this letter is extremely sensitive. Anonymity is requested. Other colleagues have been encouraged to write to you, and I hope that you honor their request of anonymity too.

There are many instances in which the FDA senior management allowed companies a pass to misrepresent or doctored data: especially in the earlier phases of medical device testing—nonclinical laboratory testing. I believe about 30 percent of the premarket approvals (PMA) and 80 percent of the premarket notifications (510(k)) contain flawed data or misrepresentations.

CDRH retaliates repeatedly against its employees. They have coerced middle managers and first level supervisors to devalue (discredit) scientific assessments and threaten employees with insubordination if they object to their demands. Senior management has overruled [redacted] to approve flawed data over the objections of their scientists.

The morale inside the CDRH is critically low among employees. Subject matter experts have been exiled to other offices and centers.

To reiterate, please honor the request of anonymity of those who have contacted you. They should not have to sacrifice their livelihood to do so.... FDA senior management is betting that you will not. I believe you will, because it is in your best interest to protect your sources.

### **Letter 2**

Each day scientists are threatened and harassed by their management to approve or accept the results from unsafe and ineffective devices without verification. Staffers have no choice but to comply with their requests or faced the threat of insubordination.

### **Letter 3**

I am writing to you on the condition of anonymity.... There is a concerted effort by some managers to conceal, if necessary, manipulate records to mask compliance issues. I am not interested in being a public whistleblower.

In reality, we have no protections against retaliation. The retaliation is expressed in our midyear and end of year personnel evaluations.

There is mandatory indoctrination of employees to overlook fraud and omissions in applications. Also incentives (bonuses, outstanding appraisals, and public recognition) reinforce this behavior.

Many scientists would attest to the conditions in CDRH if they were allowed to speak freely.

By intimidating its employees in this manner, CDRH has almost certainly broken federal labor laws and reneged on its promise to produce safe and effective devices for human use. In my opinion, the medical device industry and the insurance industry have contributed heavily to politicians and management in CDRH—who have authority over the actions of their employees—to recommend the approval of less reliable and unsafe products for use in the marketplace and in the human clinical trials.

#### **Letter 4**

I write to you as a [redacted] in FDA Center for Devices and Radiological Health. I must remain anonymous in this effort. Our whistleblowers laws and policies are ineffective.

On behalf of other managers, supervisors, and scientists in [units in CDRH], I urge you to take immediate action to notify Congress and other outside, independent groups that can raise public awareness about unsafe and unreliable medical devices, radiological products, and combination products that enter the market every day.

The information that I am disclosing to you could jeopardize the livelihood of some managers. CDRH senior management retaliates repeatedly against its employees, lower and middle management if there is the possibility of delay to the premarket clearance process. Some managers are forced to retaliate against employees to push approvals.

#### **Letter 5**

Regrettably, I must remain anonymous, due to my position as a scientist in [a unit in CDRH].

Numerous regulatory catastrophes have arisen internally, from the proliferation of misleading and misrepresented claims of safety in preclinical testing to revelations of improprieties among senior officials. I know at least 10 device manufacturers who submitted false data or withheld key data were awarded product approval in the past two years.

#### **Letter 6**

Many staffers in [units within CDRH] are continued to be silenced—harassed and threatened with bad evaluations, reprimands, and terminations—during the course of their reviews of medical device submissions.

## **Letter 7**

Please do not contact us. Anonymity is requested.

Irresponsible management, supervisors, and team leaders have put corporate interests above public safety and undermine the health and lives of American citizens. The world does not know about the government's ineptitude in the review of medical and radiological devices.

The Center is not even monitoring reports of lethal effects found in the nonclinical laboratory studies supporting the devices that it approves for marketing. Many scientists are told to ignore the problems or resolve differences with manufacturers. There is no enforcement.