The Major Cause of Breast Cancer Almost Everyone Ignores

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By Dr. Mercola

The U.S. Food and Drug Administration (FDA) secretly monitored the personal e-mail of nine whistleblowers—its own scientists and doctors—over the course of two years.

The monitored employees had warned Congress that the agency was approving medical devices that posed unacceptable risks to patients.

Six of the monitored scientists and doctors recently filed a lawsuit against the FDA, charging that the agency violated their constitutional rights to privacy by monitoring lawful activity in personal email accounts, and using that information to harass and ultimately relieve some of them of their positions.

According to the Washington Post[1]:

> *"All had worked in an office responsible for reviewing devices for cancer screening and other purposes.*
>
> *Copies of the e-mails show that, starting in January 2009, the FDA intercepted communications with congressional staffers and draft versions of whistleblower complaints complete with editing notes in the margins.*
>
> *The agency also took electronic snapshots of the computer desktops of the FDA employees and reviewed documents they saved on the hard drives of their government computers."*

The FDA has declined to comment on the allegations, stating it does not comment on cases involved with litigation.

However, according to internal FDA documents obtained by the plaintiffs under the Freedom of Information Act, the agency had asked the Department of Health and Human Services' (DHHS) inspector general to conduct an investigation back in May 2010, stating suspicions that the plaintiffs had improperly disclosed confidential business information about the devices.

The HHS inspector general's office found no evidence of criminal conduct, stating the doctors and scientists had legal right to share their concerns with Congress and journalists.

Hence no investigation was launched. But the FDA was not satisfied.

On June 28 that same year, Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health wrote that, *"We have obtained new information confirming the existence of information disclosures that undermine the integrity and mission of the FDA and, we believe, may be prohibited by law,"* and again requested action be taken against the employees in question. (Shuren is also the official who oversees mercury dental fillings, which they have been fraudulently referring to as 'silver fillings.' Shuren had promised to make an announcement about dental amalgam by the end of 2011. But with just six minutes left in the work year, at 4:54 pm on Friday, December 30, the FDA conceded that no announcement was forthcoming – not in 2011, and maybe not at all.)

After consulting with general prosecutors, the inspector general declined the second request for an investigation as well. Now the question is whether the agency monitored their employees within legal limits, and whether the purpose of the extensive monitoring was reasonable.

Senator Charles Grassley doesn't seem to think so, stating that:

> *"The FDA has a huge responsibility to protect public health and safety. It's hard to see how managers apparently thought it was a good use of time to shadow agency scientists and monitor their e-mail accounts for legally protected communications with Congress."*

Story at-a-glance

- The FDA secretly monitored the personal e-mail of a group of agency whistleblowers for two years. All of the monitored employees worked in the office responsible for reviewing medical devices, including those for cancer screenings and were expressing concerns over several devices. Some of the employees were harassed and/or terminated, and six of them are now suing the agency
- There's a lot of compelling evidence that the dangers of mammography are being covered up, and that a Congressional hearing is well overdue
- While roughly 15 percent of women in their 40's detect breast cancer through mammography, many other women experience false positives, anxiety, and unnecessary biopsies as a result of the test, according to the data. In fact, a full decade ago, a Danish study published in The Lancet concluded that previous research showing a benefit of mammograms was flawed and that *widespread mammogram screening is unjustified*.
- According to the Cochrane Collaboration, for every 2,000 women getting mammography screening over the course of 10 years, just ONE woman will have her life prolonged. Meanwhile, 10 healthy women, who would not have been diagnosed with cancer had it not been for the mammography screening, will be misdiagnosed as having breast cancer, and will be treated unnecessarily

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Although its roots go way further back, the current saga began in 2007, when the plaintiffs, all of whom worked for the FDA's Office of Device Evaluation, claim they began making internal complaints about a dozen radiological devices about to be approved despite lack of proof of effectiveness. The doctors and scientists were concerned that millions of patients would be put at risk.
According to the featured article:

- Three devices risked missing signs of breast cancer
- One device risked falsely diagnosing osteoporosis
- One ultrasound device could malfunction while monitoring pregnant women in labor
- Several colon cancer screening devices employed such heavy doses of radiation that they risked *causing* cancer in otherwise healthy people

They also recommended against approval of a computer-aided imaging device for breast cancer screening a total of three times. But after the third rejection, a senior manager, Donna-Bea Tillman, suddenly approved the device in 2008. This and much more was detailed in a 2009 letter from an unknown number of FDA employees to President Obama's transition team.[2,3] In that letter (in which all the signatures were blacked out due to fear of retaliation from the FDA), the authors clearly spell out the need for a complete overhaul of the agency due to deep-rooted systemic corruption at the highest levels.

They write:

> *"On January 7, 2009, FDA physicians and scientists wrote to Mr. John Podesta: 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."*

Remarkably, just two months later, Acting Commissioner Dr. Frank M. Torti and FDA attorneys sent an email to all FDA employees stating they "must comply with … obligations to keep certain information … confidential … [including] e-mail to and from employees within FDA [that document the] deliberative process." Furthermore, employees were told that "violation … can result in disciplinary sanctions and/or individual criminal liability."

A few days later, on March 24, 2009, Senator Grassley sent a letter to Dr. Torti stating that:

> *"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."*

Congressional Hearing on Mammography Cover-Up is Overdue

Folks, this is a major story, and it's about to get much bigger... There's loads of powerful and damning information out there that can, and will, be used to call for a congressional hearing on the mammography cover-up. Decades ago, in 1974, the National Cancer Institute (NCI) was warned by professor Malcolm C. Pike at the University of Southern California School of Medicine that a number of specialists had concluded that "giving a women under age 50 a mammogram on a routine basis is close to unethical."

And in the 1990's, Dr. Samuel Epstein started warning people about the dangers of mammography, stating:

> *"The premenopausal breast is highly sensitive to radiation, each 1 rad exposure increasing breast cancer risk by about 1 percent, with a cumulative 10 percent increased risk for each breast over a decade's screening... The high sensitivity of the breast, especially in young women, to radiation-induced cancer was known by 1970. Nevertheless, the establishment then screened some 300,000 women with X-ray dosages so high as to increase breast cancer risk by up to 20 percent in women aged 40 to 50 who were mammogramed annually."*

Since then, concerned FDA doctors and scientists have issued a number of written warnings in the form of letters to various authorities, such as the October 2008 letter to Representative Dingell, notifying him of corruption within the FDA, which sparked a House Energy and Commerce Committee investigation into **Center for Devices and Radiological Health** (**CDRH**) activities. [4]

A second letter, sent in January 2009 to HHS Secretary-Designate Tom Daschle, Baltimore City Health Department Chief Joshua Sharfstein, and nine members of Congress, delved into more detail. According to Medical Devices Today[5]:

> *"In the case of an April 2008 approval of a computer-aided detection device for mammography, the scientists specifically charge (by title, but not by name) ODE Director Donna-Bea Tillman "and her subordinates" with 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."*
>
> *The letter also includes a bullet-pointed list of nine "examples of wrongdoing" by the ODE Director, including ordering physicians and scientists to ignore FDA guidance documents and allowing manufacturers to market unapproved devices."*

In October that same year (2009), the US Preventative Task Force revised its recommendations on mammograms,[6] stating that women in their 40's should no longer get routine mammograms for early detection of breast cancer. Instead, the panel recommended waiting until the age of 50, and only doing one mammogram every other year, instead of yearly. They also suggested women between 40 to 49 should talk to their doctor about the risks and benefits of the test, and then decide if they want to be screened. The Canadian task force followed suit in November last year.[7]

Many cancer organizations were outraged and have shunned the task forces' new directive; completely ignoring the data supporting their decision... The main reason behind the changed guidelines? The inherent dangers and short-comings of mammographic screening...

Could More Women Be Harmed than Helped with Mammography?

While roughly 15 percent of women in their 40's detect breast cancer through mammography, many other women experience false positives, anxiety, and unnecessary biopsies as a result of the test, according to the data. In fact, a full decade ago, a Danish study published in *The Lancet* concluded that previous research showing a benefit of mammograms was flawed and that *widespread mammogram screening is unjustified*.

That mammograms are still recommended *at all* speaks volumes about the state of modern medicine...

Mammograms expose your body to radiation that can be 1,000 times greater than that from a chest x-ray, which poses risks of cancer. Mammography also compresses your breasts tightly (and often painfully), which could lead to a lethal spread of cancerous cells, should they exist.

In April 2011, the prestigious Cochrane Collaboration chimed in, saying mammography screening may cause more harm than good[8]. For their informative leaflet, please see the following link. Even more provocative is the new book, *Mammography Screening: Truth, Lies and Controversy* by *Peter C. Gøtzsche, Professor of* Clinical Research Design and Analysis Director at The Nordic Cochrane Centre, and Chief Physician. The very first paragraph of the book's ad reads[9]:

> *"The most effective way to decrease women's risk of becoming a breast cancer patient is to avoid attending screening."*

Now, that's a bold statement! And it's backed up by facts. According to the Cochrane Collaboration, for every 2,000 women invited for screening over the course of 10 years, just ONE woman will have her life prolonged. Meanwhile, 10 healthy women, who would not have been diagnosed with cancer had it not been for the mammography screening, will be misdiagnosed as having breast cancer, and will be treated unnecessarily. Additionally, more than 200 women will experience significant psychological distress for many months due to false positives.

Did You Know? There are No Guidelines for Lumpectomies...

These sad and shocking statistics are worsened further by reports such as this one, published in the *New York Times* on January 31,[10] revealing that oncologists (cancer surgeons) perform lumpectomies without any guidelines whatsoever, despite the fact that it's the most commonly performed breast cancer surgery there is. According to the cited study, about half of all women undergoing a second lumpectomy may not have needed it. On the other hand, some who did not get repeat surgery may have benefited from it.

According to *The New York Times*:

> *"Rates of repeat surgery can vary widely by doctor, from zero percent to 70 percent, according to the study. The additional operations are done when pathology reports on tumor specimens suggest that the first operation may have left behind some cancer cells. But surgeons differ when it comes to interpreting those reports.*
>
> *... Such uncertainty about a cancer operation that has been in use for 30 years is "a shame," said Dr. Laurence E. McCahill, the first author of the study and a surgeon and assistant director of the Lacks Cancer Center in Grand Rapids, Mich.*
>
> *... [Another] major reason for the variation in repeat operations after lumpectomy is that there is no consensus among surgeons about how big a rim or "margin" of healthy tissue should be taken out when a cancer is removed. Surgeons try to cut cleanly around a tumor and remove enough of a margin to ensure that they excised all the cancer."*

Indeed, you'd think they'd have it nailed down a bit better by now, but it just goes to show that a lot of what the general public assumes is science-based medicine is anything but. Interestingly, a study by the Norwegian Institute of Public Health indicates that spontaneous remission of breast cancer is not quite as miraculous as we might think. In fact, it's actually quite common. According to their findings, more than one in five invasive cancers detected in the study by mammography vanished without ever being treated![11, 12]

All in all, there's convincing evidence that mammography is not all it's cracked up to be, and the FDA is not doing its stated job to protect your health. Instead, they're busy catering to industry and skirting the boundaries of the law to protect their own and their client's behinds; their client, of course, being the drug or medical company—the ones they're supposed to be regulating and keeping honest...

It's going to take a lot to change the course of this agency at this point, but indeed it must be done. Or the entire notion of a safety and efficacy standard for drugs and medical devices of all kinds will be moot.

REFERENCES: Main Sources: Washington Post, January 29, 2012 and New York Times, January 31, 2012