

March 31, 2003

VIA ELECTRONIC MAIL

Dr. Charles Finder  
Center for Devices and Radiological Health (HFZ-240)  
Food and Drug Administration  
1350 Piccard Dr.  
Rockville, MD 20850

Subject: Radiologists who Interpret Mammograms

Dear Dr. Finder:

My name is Kathy McKinney-Tovar and I am a 44-year-old woman. In November 2000 I was diagnosed with breast cancer after being misdiagnosed for two years. I would like to share the events that led to my diagnosis because they are pertinent to the agenda of the April 28, 2003 meeting of the National Mammography Quality Assurance Advisory Committee. I appreciate you sharing my letter with the committee, as I am unable to personally attend the meeting.

My story begins with my first mammogram which was made in 1998; I turned 40 that year. Radiologist A interpreted my 1998 and 1999 mammograms. A second radiologist, Radiologist B, also appears to have reviewed my 1999 mammogram as his name is on the report. In both years the radiologist(s) made observations about microcalcifications in the left breast and considered them to be benign and recommended no follow up other than routine, annual screening. A benign cluster of macrocalcifications was also noted in the upper, outer, left breast, in the 1998 report. The 1999 report refers to the same feature as a loose grouping of small, benign microcalcifications and states that the calcifications are stable. Any radiologist who reads mammograms should know there is a huge difference in the significance of macro versus microcalcifications. In 2000 my mammogram was made at a different mammography clinic because my insurance had changed. The new radiologist, Radiologist C, indicated that there was a dominant mass with associated microcalcifications in the upper, outer quadrant of my left breast and that the lesion was now more easily recognized than on the two previous mammograms, especially the 1998 films where no discrete mass was identifiable, although some of the calcifications were clearly present. He wrote that a small component of the nodule was evident in 1999. His findings led to a biopsy and my breast cancer diagnosis. From my story you can see that the problem in detection was not with the quality of the films but with the interpretive skills of Radiologists A and B.

After my first mammogram I discovered a pea-sized lump in the upper, outer quadrant of my left breast where Radiologists A and B had noted a cluster of calcifications. I saw a surgeon who examined the lump and told me it was a benign cyst and ordered no further

follow up or evaluation because I had recently had a mammogram. After the second mammogram I returned to the surgeon again because the lump had grown. He assured me that it was benign and once again recommended no further follow up or evaluation. Although he passed away before I was diagnosed, I believe that he relied on the mammography reports of Radiologists A and B who misread my films when he concluded there was nothing suspicious about my lump. On June 24, 2002, the *Archives of Internal Medicine* published an article<sup>1</sup> stating that surgeons who relied on benign mammography reports when deciding not to biopsy a mass were responsible for 30 percent of physician-caused delayed diagnoses. You can see from this article and my own experience that the problem of having a misread mammogram becomes an even bigger issue when surgeons rely on mammography reports when forming their opinion about whether or not a biopsy is warranted.

By the time I was finally diagnosed my cancer was Stage IIB, not an early catch. If my cancer had been caught two years earlier, when the evidence appeared on my first mammogram, it would have been caught at Stage 1 or possibly Stage 0 when the treatment may have been limited to a lumpectomy and my chance of being cured would have exceeded 90 percent. As it was, I followed the suggestions of my doctors who recommended the following treatments in an effort to save my life: mastectomy, chemotherapy, radiation therapy, Tamoxifen, and Lupron. I hope and pray that I won't die of breast cancer because of my delayed diagnosis and that there will be no long-term side effects of the treatments that will injure my health or cause my death.

Prior to my diagnosis, I, like all women I know, assumed that if I went for an annual mammogram and promptly reported breast lumps or other abnormalities, I could rest assured that breast cancer would be diagnosed in the earliest stages when the survival rate is very high. I now know that I was wrong. People in the medical profession have told me that a misdiagnosed breast cancer is all too common a story.

Because breast cancer is so frequently misdiagnosed, I began to question the value of mammography. I researched the issue and learned that mammograms are very difficult films to interpret, but they are still the best screening tool we have. I also learned that the biggest obstacle to getting an accurate reading is the skill of the radiologist. *The New York Times* ran an article<sup>2</sup> on June 27, 2002 regarding that fact. The article reported that while the best radiologists will miss as many as 10 percent of the cancers, some radiologists are missing as many as 40 percent!

While researching the issue, I learned that the skills of radiologists reviewing mammograms could be improved if the following actions are taken:

1. Test radiologists at regular intervals to ensure that they are qualified to read mammograms. Require additional training for any radiologist who does not pass

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<sup>1</sup> Goodson, William, et al. Causes of physician delay in the diagnosis of breast cancer. *Archives of Internal Medicine*. 2002;162:1343-1348.

<sup>2</sup> Moss, Michael. Spotting breast cancer: Doctors are weak link. *The New York Times*. June 27, 2002.

- the skills test and prohibit those who cannot pass the test from reading mammograms. Look at the training that Swedish radiologists receive because they have the highest breast cancer detection rates in the world.
2. Devise a tracking system that will keep accurate record of how many cancers a radiologist misses and provide concrete feedback to radiologists who misinterpret a mammogram so they can learn from their mistakes. Any radiologist who is found to miss more than a "reasonable" number of cancers should be prohibited from continuing to read mammograms.
  3. Require that mammographers read enough mammograms on a yearly basis to remain as accurate as humanly possible. Studies suggest that 2,500 is the minimum number of mammograms that need to be read annually. Under current mammography regulations, physicians must review only 960 mammograms every two years, a number that studies have shown to be too low to be effective. Look to Canada and other countries that require their radiologists read at least 2,500 films a year to learn how they provide mammograms to women living in poor and rural areas.
  4. For each radiologist, maintain records of the percentage of cancers they have missed and the number of mammograms they read annually. These records should be made available to all women who wish to have access to that information before scheduling a mammogram.

I urge the committee to implement the improvements listed above to the Mammography Quality Standards Act to ensure that only qualified radiologists are allowed to interpret mammograms. Don't let your mother, sister, daughter or wife be misdiagnosed by a radiologist who isn't qualified to interpret mammograms.

Sincerely yours,

Kathy McKinney-Tovar  
Vallejo, California