

STATEMENT

of

Leonard Berlin, M.D.

To the

U.S. Senate Committee on Health, Education Labor and Pensions

Re: Mammography Quality Standards Act Reauthorization

April 8, 2003

Mr. Chairman, my name is Leonard Berlin. I am a practicing radiologist, a member of the American College of Radiology (ACR), and Chair of the Department of Radiology at Rush North Shore Medical Center in Skokie, Illinois, a suburb of Chicago and also Professor of Radiology at Rush Medical College in Chicago. I am honored to have been asked to testify regarding the reauthorization of the Mammography Quality Standards Act (MQSA) and to specifically address discoverability concerns related to the potential requirement of incorporating interpretive skills self assessment into the Continuing Medical Education (CME) requirements under MQSA.

At the outset let me say that I categorically endorse reauthorizing MQSA, and in fact I believe that MQSA has contributed to the almost 30 percent mortality reduction from breast cancer. I truly believe that the Act has been of great benefit to the public and to the medical community at large, particularly radiologists. I understand that this Committee also favors reauthorizing the Act, but at the same time I am aware that concern has risen that MQSA as currently constructed focuses almost exclusively on the technical aspects of mammography - - namely, equipment, filming, processing, communication of results to patients, and follow up of abnormal or questionable abnormal findings. While the Act as currently constructed does cover certain professional aspects, namely, basic requirements for CME and a requirement that radiologists interpret a certain minimum number of mammograms annually, the Act does not address other professional aspects of mammography such as the accuracy with which radiologists render mammographic interpretations. Considerable attention was drawn to radiologists' consistency and proficiency regarding mammographic diagnoses by newspaper reporter Michael Moss in a series of articles published in the New York Times in June 2002. It is true that there is much variance among radiologists in rendering mammographic interpretations and that some radiologists perform poorly in this regard. Because of such concerns, there has been generated the need to objectively assess and monitor the performance of radiologists when interpreting mammograms, so as to assure the public that all mammograms performed in every part of the nation receives competent relatively uniform radiological evaluation.

I believe that the public does indeed deserve assurance that such an assessment is being carried out and that radiologists who do not meet acceptable mammographic interpretive standards should be withdrawn from the system. There are several ways in which such an assessment can be implemented. In fact, one is almost a reality today. The ACR has developed a self-assessment program which currently is available to every radiologist who interprets mammography. This self-assessment process is optional, and thus some radiologists participate in it, while others elect not to. Whether they do or do not participate in the ACR's process, all radiologists in hospital-based practices and many in private-facility based practices have developed their own performance improvement programs, in accordance with requirements of the Joint Commission for Accreditation of Health Care Organizations. Should the Congress decide to mandate radiologists' participation in a self-assessment program such as that currently offered by the ACR, I have no doubt that the radiologic community will accept and comply with such a mandate, for I do not think that it represents a controversial issue.

However, what could well be a controversial issue is whether the results of such a mandated self-assessment process should be readily available to public scrutiny or discoverable in a legal proceeding. And this leads me to that black threatening cloud that looms on the horizon and has every indication of growing, the quagmire of medical malpractice. For many years I have studied, written and lectured about the adverse impact of medical malpractice litigation on the practice of radiology, specifically as it relates to mammography. Statistics compiled by the Physician Insurers Association of America (PIAA) have shown a rampant increase in lawsuits associated with mammography, such that mammography has now become the most prevalent modality in malpractice lawsuits against radiologists, and that the allegation of an error in the diagnosis of breast cancer has become the most prevalent condition precipitating medical malpractice lawsuits against all physicians. According to the latest figures released by the PIAA, the overall indemnification for all breast cancer malpractice litigation averaged \$438,000 in 2002, a 45% increase in the corresponding figure from 1995.

Part of the reason for the high number of lawsuits associated with mammography is the public's perception of mammography's accuracy. Many believe that mammography is infallible, that it is a matter of simply looking at black and white shadows on an X-ray film, of going through a simple mathematical calculation, and that thus all radiologists should arrive at the same interpretation. Alas, such is not the case. Shadows on mammograms are far more often varying shades of gray, normal glandular and connective tissues in the breast often obscure suspicious abnormalities, and many suspicious abnormalities often masquerade as normal structures. As a result, many breast cancers, perhaps 15% to 20% as estimated by some researchers, are not visualized on mammograms. But the problem is far more complex than that. If we take a batch of mammograms that today reveal a breast cancer, or a batch of chest X-rays that today reveal lung cancer, and then look at a corresponding X-ray film taken perhaps one year earlier on the same patient that had been interpreted as normal, we will find that upon retrospective review the beginnings of these cancers can be detected

on those previous X-ray films. This is why it is so crucial for radiologists to be able to compare prior mammograms to the current study. Many such studies have been done and have been published in the scientific literature and they are referenced in some of the articles that I have written that are appended to this report. Suffice it to say that research studies performed at some of the most prestigious medical institutions in the United States reveal that as many as 90% of lung cancers, and 70% of breast cancers, can at least partially be observed on previous studies read as normal. Does this mean that the radiologist who initially read those films as normal is negligent or guilty of malpractice? No, it does not. What these studies do mean is that in hindsight, after a diagnosis of cancer is clearly visualized, the diagnosis of a cancer on a previous study that was non-apparent initially now becomes somewhat clear. But hindsight bias or so called "Monday morning quarterbacking" is not an indication of negligence nor a measure of poor performance. An Illinois Appellate Court (Warren vs. Burris, 10-23-01) said it more meaningfully: "In hindsight, almost everything is foreseeable, but that is not the test we should employ."

Because the public perceives - - or rather, misperceives - - that mammography should be 100% accurate, women and/or their families frequently resort to malpractice litigation if breast cancer is diagnosed subsequent to having had a mammogram that had been interpreted as normal. And, because the public perceives - - or rather, misperceives - - that early diagnosis of cancer virtually guarantees a cure and that a delay in the diagnosis of cancer is tantamount to a death knell, even when there is reliable and objective expert testimony that a delay had no ill-effect, juries are nevertheless all too ready and willing to award great compensation to the patient. Although, as noted before, the average indemnification in breast cancer approaches \$500,000, awards of \$3 Million or \$5 Million or even \$12 Million are not unusual.

The degree to which public perception influences the outcome of a malpractice lawsuit involving breast cancer is exemplified by a case in Chicago in which a radiologist was accused of missing a cancer on a mammogram, causing a 14-month delay in diagnosis. Once the tumor had been found, a lumpectomy was performed and there was no evidence that the cancer had spread to the surrounding lymph nodes. The patient filed a malpractice lawsuit against the radiologist but it was nearly four years before the case was finally scheduled for a jury trial. At the time the patient was completely free of disease and every indication was that she was cured. Nevertheless, just before trial was to begin, the radiologist's defense attorney wrote a letter to the radiologist's insurance company that stated, in part:

Even though our consulting oncologist in this case is prepared to testify that the 14-month delay in diagnosis had no effect whatsoever in either the treatment or the prognosis of the patient, I recommend that the case be settled because given the perception that women can be cured of breast cancer only through early detection by screening mammography, I believe it will be very hard to convince a jury to rule in favor of the radiologist.

The case was settled for \$350,000.

The specter of malpractice litigation exerts an enormous adverse impact on radiologists who perform mammography. Being found liable for allegedly misinterpreting a mammogram not only significantly increases the malpractice insurance premium paid by the radiologist, but indeed may even make obtaining such insurance impossible. Being found liable in such malpractice litigation also can make a radiologist ineligible to contract with a managed care organization, and at times can lead to severance of medical hospital staff credentialing. The end result is that more and more radiologists are refusing to perform mammography, and fewer and fewer radiology residents completing their formal training are opting to take additional fellowship training in mammography. In turn, mammography facilities are closing.

To illustrate the effect that the medical malpractice quagmire is having on radiologists who interpret mammograms and to put it on a more personal level, let me quote from several unsolicited letters that I have received from radiologists around the nation who perform mammography:

Dear Dr. Berlin:

I am a private practice radiologist in Wisconsin. I practice at a small hospital in a Western Suburb of Milwaukee in a six-member group. The hospital that I practice at is in a fairly affluent region and the average patient is very educated. I do worry about the malpractice issues regarding mammography. I consider myself an above-average mammographer and I believe I have made a positive impact on many lives by providing quality breast imaging and diagnosis. However, I do not have a fellowship in mammography and practice general radiology. Because of the current atmosphere of litigation and our patients' unrealistic expectations, if I were given the choice to stop "manning" our women's center, I would seriously consider it.

Signed,

Christopher Canitz, MD

Dear Dr. Berlin:

I currently interpret over 5,000 mammograms annually. My junior partners and I are running scared. Excessive and unreasonable caution results in numerous unnecessary biopsies ... One recent lawsuit takes the cake. A junior partner was sued by a woman who developed an interim breast cancer. We all agree the screening mammogram was negative eight months prior to discovery of the cancer, except of course the plaintiff's so-called expert-witness. But the truth is irrelevant. The patient developed liver and brain metastases during the discovery process and the insurance company settled for \$800,000. Settlement in the State of Florida is at the sole discretion of the malpractice carrier and is not

subject to approval or permission by the insured physician. Our malpractice premium rose to \$50,000 per man and the junior partner is moving to New Mexico. Even perfect professional performance provides no protection in Florida!

Signed,

Charlie Fisher, MD, Tampa FL.

Dear Dr. Berlin:

It has unfortunately occurred to me of late that in a short time we won't have to worry about mammography any more because breast imaging simply will be something done only at a handful of centers. The current statistics are grim. As of now, well over 600 facilities have closed their doors on mammography, and the current rate of closings is 20 per month, and that does not appear to be declining. Just this morning, one of the fellows that I trained said her facility in Tempe, AZ was closing. It is truly a mess. I talked with a man who is the head of a private practice in Carmel, CA and he said they simply shut down all breast imaging for the usual reasons: nobody in his practice wanted to do it (emotionally draining with a high "burnout" factor), all related to the malpractice problems. The Boca Raton, FL breast center recently topped \$5 million in settlements over breast malpractice cases.

Signed,

Peter Dempsey, Houston, TX.

I cite these letters not to focus on the medical malpractice problem in general, for that is a subject with which I know Congress is dealing at another level on another day. The purpose of my emphasizing the adverse impact of malpractice on radiologists who do mammography is what may happen if the results of any self-assessment process undertaken by radiologists are made public or discoverable in legal proceedings. The malpractice litigation problem will be exacerbated, and as a result, many more radiologists will simply refuse to undergo self-assessment exercises and participate in performance improvement activities. Therefore, I urge that if self-assessment is made mandatory as part of the MQSA reauthorization, that the results remain privileged. A California Appellate Court (Clarke vs. Hoek, 1985) spoke to this issue far more eloquently than I:

There is a strong public interest in supporting, encouraging and protecting effective peer review programs and activities. The quality of ...medical care depends heavily upon members' frankness in evaluating their associates' medical skills and their objectivity. The fear of potential malpractice liability would not only discourage participation by medical professionals in volunteer review committees, but would stifle candor and impair objectivity in staff evaluations...[California law] expresses a legislative judgment that the public

interest in medical staff candor extends beyond damage immunity and requires a degree of confidentiality...External access to peer investigations conducted by staff committees stifles candor and inhibits objectivity. It evinces a legislative judgment that the quality of ...medical practice will be elevated by armoring staff inquiries with a measure of confidentiality.

Let me summarize. Radiologists are in short supply. Breast imagers are in even shorter supply. The combination of low reimbursement with the high probability of being sued for a missed diagnosis is clearly not the best tool for recruiting young radiologists to participate in the field of mammography. Seven hundred mammography facilities have closed nationwide in the past two years. This downward trend will continue and waiting times will continue to increase for women seeking timely mammography services unless Congress acts responsibly with regard to mammography self-assessment. It is my belief that, given the current litigious climate, it is imperative that any self-assessment requirement recommended by this Committee and enacted by Congress be deemed non-discoverable.

With deep humility and respect, I thank you for the opportunity to testify on this important matter to women's health. I would be happy to answer any questions members of the Committee may have.